SCHEDULING STATUS: S2

PROPRIETARY NAME (AND DOSAGE FORM):

IBUMAX COLD AND FLU (Film-coated tablets)

COMPOSITION:
Each film-coated tablet contains 200 mg ibuprofen and 30 mg pseudoephedrine hydrochloride.
Inactive ingredients include colloidal silicon dioxide, croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, Opadry yellow, and sodium lauryl sulphate.
Contains lactose.

PHARMACOLOGICAL CLASSIFICATION:
A 5.8 Preparations for the common cold, including nasal decongestants.

PHARMACOLOGICAL ACTION:
Pharmacodynamics:
Ibuprofen is a non-steroidal anti-inflammatory compound with analgesic, antipyretic and anti-inflammatory properties.
Pseudoephedrine hydrochloride is a direct- and indirect-acting sympathomimetic agent. It is a vasoconstrictor and has nasal decongestant properties.

Pharmacokinetics:
Ibuprofen:
Absorption:
Ibuprofen is well absorbed. Bioavailability following oral administration of the racemate is more than 80 %.

Distribution:
Following oral administration of a single 800 mg dose of the racemate, time to the peak serum concentration of 61,1 ± 5,5 µg/mℓ is 1,6 ± 0,3 hours. Ibuprofen is bound avidly to plasma proteins (more than 99 %) with a volume of distribution of 0,15 ± 0,02 ℓ/kg.

Metabolism:
Ibuprofen undergoes hepatic metabolism and 90 % of an administered dose is metabolised to hydroxylate or carboxylate derivates. The half-life is approximately 2 hours.

Elimination:
The metabolites are renally excreted with less than 1 % of administered ibuprofen appearing unchanged in the urine.

Pseudoephedrine:
Absorption:
Bioavailability following oral administration of pseudoephedrine is almost 100 %.

Distribution:
Pseudoephedrine is not bound to plasma proteins and has a volume of distribution of 2,64 – 3,51 ℓ/kg. Time to peak serum concentration following administration of a 60 mg immediate-release tablet is 1,4 – 2 hours.

Metabolism:
Pseudoephedrine has a half-life of approximately 4,3 – 8 hours.

Elimination:
Approximately 43 – 96 % of an administered dose is excreted in the urine. At a high urine pH (> 7,0), pseudoephedrine is extensively reabsorbed; $t_{1/2}$ increases and clearance decreases.

INDICATIONS:
IBUMAX COLD AND FLU tablets are indicated for the relief of cold and flu symptoms, including nasal congestion, headache, fever and sore throat.

CONTRAINDICATIONS:
IBUMAX COLD AND FLU tablets are contraindicated in:
- Patients with hypersensitivity to ibuprofen and pseudoephedrine, or to any of the other ingredients of **IBUMAX COLD AND FLU**.
- Heart failure.
- Patients taking monoamine oxidase inhibitors (MAOIs) or within 14 days of termination of MAOI treatment.
- Patients with hypersensitivity to NSAIDs, including patients in whom attacks of asthma, angioedema, urticaria, or rhinitis have been precipitated by aspirin.
- Pregnant or lactating women (see **"PREGNANCY AND LACTATION"**) or in children under the age of 12 years.
- Patients with active or history of recurrent ulcer / haemorrhage / perforations.
- Patients with a history of gastrointestinal bleeding, ulceration or perforation (PUBs) related to previous NSAIDs, including **IBUMAX COLD AND FLU**.

WARNINGS AND SPECIAL PRECAUTIONS:
Patients who are currently taking monoamine oxidase inhibitors (see **"CONTRAINDICATIONS"**) or other medicines for psychiatric or emotional conditions, depression, or hypertension should not take **IBUMAX COLD AND FLU** tablets without consulting their doctor or pharmacist.

IBUMAX COLD AND FLU tablets should not be given to patients with hyperthyroidism, phaeochromocytoma, prostatic enlargement, cardiovascular disease such as ischaemic heart disease, dysrhythmia or tachycardia, occlusive vascular disorders including arteriosclerosis, hypertension or aneurysms, diabetes mellitus or closed-angle glaucoma.
In patients with angina pectoris, anginal pain may be precipitated.

In view of **IBUMAX COLD AND FLU**'s inherent potential to cause fluid retention and oedema, heart failure may be precipitated in some compromised patients. Caution is required in patients with a history of hypertension and/or heart failure.
IBUMAX COLD AND FLU tablets should be used with caution in patients receiving digoxin, guanidine, or tricyclic antidepressants or in patients undergoing anaesthesia with halogenated anaesthetics (see **"INTERACTIONS"**).

The elderly have an increased frequency of adverse reactions to NSAIDs, including **IBUMAX COLD AND FLU**, especially gastrointestinal bleeding, ulceration and perforation (PUBs), which may be fatal.

The risk of gastrointestinal bleeding or perforation (PUBs) is higher with increasing doses of **IBUMAX COLD AND FLU**, in patients with a history of ulcers, and the elderly.

When gastrointestinal bleeding or ulceration occurs in patients receiving **IBUMAX COLD AND FLU**, treatment with **IBUMAX COLD AND FLU** should be stopped.

IBUMAX COLD AND FLU should be given with caution to patients with a history of gastrointestinal disease (e.g. ulcerative colitis, Crohn's disease, hiatus hernia, gastro-oesophageal reflux disease, angiodysplasia) as the condition may be exacerbated.

Serious skin reactions, some of them fatal, including exfoliative dermatitis, Stevens-Johnson syndrome, and toxic epidermal necrolysis have been reported. **IBUMAX COLD AND FLU** should be discontinued at the first sign of skin rash, mucosal lesions, or any other sign of hypersensitivity.

IBUMAX COLD AND FLU contains lactose. Its use is not recommended in patients with galactose intolerance, the Lapp lactase deficiency or glucose or galactose malabsorption syndrome.

Effects on the ability to drive and use machinery:
IBUMAX COLD AND FLU may exert a mild to moderate influence on a patient's ability to drive or operate machinery. **IBUMAX COLD AND FLU** may cause dizziness, double or blurred vision, changes in colour perception or other visual disturbances. Patients should be advised to refrain from driving a car and operating machinery until they know how **IBUMAX COLD AND FLU** affects them.

INTERACTIONS:
Ibuprofen:
- NSAIDs: use of two or more NSAIDs together, including aspirin, should be avoided as it could result in an increase in side-effects.
- Corticosteroids: there is an increased risk of gastrointestinal ulceration or bleeding when ibuprofen, such as contained in **IBUMAX COLD AND FLU**, is used together with corticosteroids.
- Anticoagulants (warfarin): ibuprofen may enhance the effects of anticoagulants, such as warfarin, and phenylbutazone.
- Lithium, methotrexate, and digoxin: ibuprofen may cause an increase in plasma concentrations of these medicines.
- Antiplatelet agents, such as clopidogrel, and selective serotonin reuptake inhibitors (SSRIs): there is an increased risk of gastrointestinal bleeding when ibuprofen is administered together with these agents.
- The serotonin norepinephrine reuptake inhibitor (SNRI) venlafaxine, sibutramine, bisphosphonates, erlotinib, pentoxyfilline: the risk of gastrointestinal bleeding is increased when ibuprofen is used together with these medicines.
- Zidovudine: there may be an increased risk of haematotoxicity if zidovudine is used with ibuprofen.
- Ritonavir: ritonavir may increase the plasma concentration of ibuprofen.

Pseudoephedrine:
- Because of the potential for pseudoephedrine to cause a hypertensive crisis in patients receiving MAOIs, including the reversible inhibitors of monoamine oxidase type-A (RIMA), the use of **IBUMAX COLD AND FLU** together with phenelzine or with moclobemide is contraindicated (see **"CONTRAINDICATIONS"**).
- An increased risk of dysrhythmias may occur if pseudoephedrine is given to patients receiving digoxin, quinidine or tricyclic antidepressants and there is an increased risk of vasoconstrictor or pressor effects in patients receiving ergot alkaloids or oxytocin.
- Aluminium hydroxide mixture may increase the absorption rate of pseudoephedrine, while kaolin decreases the absorption rate.

General:
Reversal of the action of antihypertensive agents may occur and special care is therefore advisable in patients receiving concomitant antihypertensive therapy.

Interactions with alpha- and beta-receptor blocking medicines may be complex.

Interactions are possible with reserpine, tricyclic antidepressants, digoxin and alpha-methyldopa (see above).

IBUMAX COLD AND FLU tablets should be used with caution in patients receiving digoxin, guanidine, or tricyclic antidepressants or in patients undergoing anaesthesia with halogenated anaesthetics (see **"WARNINGS AND SPECIAL PRECAUTIONS"**).

PREGNANCY AND LACTATION:
IBUMAX COLD AND FLU should not be used by pregnant or lactating women (see **"CONTRAINDICATIONS"**).

Use of non-steroidal anti-inflammatory drugs (NSAIDs), such as **IBUMAX COLD AND FLU**, during the third trimester of pregnancy may result in premature closure of the foetal ductus arteriosus *in utero*, and possibly, in persistent pulmonary hypertension of the new-born. The onset of labour may be delayed and its duration increased.

DOSAGE AND DIRECTIONS FOR USE:
Adults and children over 12 years:
Always take the lowest possible dose for the shortest possible duration of treatment.
Take one to two tablets every 4 to 6 hours. Do not take more than 6 tablets in any 24-hour period. Always take **IBUMAX COLD AND FLU** with food or milk.
Advise patients to consult their doctor if symptoms persist beyond 3 days.

SIDE-EFFECTS:
IBUPROFEN:
Infections and infestations:
Frequency unknown: Urinary tract infection.

Immune system disorders:
Less frequent: Anaphylaxis or anaphylactoid reactions, angiitis (vasculitis) (see **"Vascular disorders"**), angioedema, bronchospastic allergic reactions, hepatotoxicity and aseptic meningitis due to hypersensitivity reactions (see **"Nervous system disorders"** and **"Hepatobiliary disorders"**), allergic rhinitis, serum sickness-like reaction, systemic lupus erythematosus-like syndrome.
Frequency unknown: Hypersensitivity reactions including fever, asthma, rashes (see **"Skin and subcutaneous tissue disorders"**), laryngeal oedema due to an allergic reaction, Loeffler syndrome (eosinophilic pneumonitis).

Blood and lymphatic system disorders:
Less frequent: Agranulocytosis (granulocytopenia), anaemia, aplastic anaemia (pancytopenia), eosinophilia, haemolytic anaemia, leukopenia (neutropenia), thrombocytopenia with or without purpura.
Frequency unknown: Pure white-cell aplasia, bone marrow depression, disseminated intravascular coagulation, ecchymosis / bruising, hypocoagulability, petechiae.

Metabolism and nutrition disorders:
Less frequent: Fluid retention / oedema, hyperkalaemia, decreased appetite or loss of appetite.
Frequency unknown: Hyponatraemia, continuing thirst, unexplained weight loss.

Psychiatric disorders:
Less frequent: Hallucinations, depression, nervousness or irritability.
Frequency unknown: Disorientation, feeling of depersonalisation, psychotic reaction, anxiety.

Nervous system disorders:
Frequent: Dizziness.
Less frequent: Confusion, aseptic meningitis (see **"Immune system disorders"**), peripheral neuropathy, drowsiness, trouble in sleeping.
Frequency unknown: Convulsions, dysarthria, headache (including severe headaches especially in the morning), forgetfulness, migraine, syncope, trembling or twitching, unusual weakness with no other signs or symptoms.

Eye disorders:
Less frequent: Toxic amblyopia, visual disturbances such as blurred or double vision, conjunctivitis, dry, irritated or swollen eyes, scotomata.
Frequency unknown: Changes in visual colour perception, corneal opacity, retinal or macular disturbances, corneal deposits, eye pain, palpebral oedema, retinal haemorrhage, photophobia.

Ear and labyrinth disorders:
Less frequent: Decreased hearing or any change in hearing, tinnitus (ringing or buzzing in ears).
Frequency unknown: Vertigo / light-headedness.

Cardiac disorders:
Less frequent: Dysrhythmias, congestive heart failure or exacerbation thereof, tachycardia.
Frequency unknown: Angina pectoris or exacerbation of chest pain, pericarditis.

Vascular disorders:
Less frequent: Increased blood pressure (may reach hypertensive levels), flushing or hot flushes.

Respiratory, thoracic and mediastinal disorders:
Less frequent: Shortness of breath or troubled breathing, unexplained nosebleeds.
Frequency unknown: Bronchospasm in patients with asthma, haemoptysis, pulmonary oedema.

Gastrointestinal disorders:
Frequent: Mild to moderate abdominal cramps, pain or discomfort, mild to moderate epigastric pain or discomfort, heartburn, nausea.
Less frequent: Gastrointestinal bleeding or haemorrhage, gastrointestinal perforation, gastrointestinal ulceration, including oesophageal, gastric or peptic ulceration, multiple gastrointestinal ulcerations, and perforation of pre-existing sigmoid lesions, e.g. diverticula, carcinoma, gastritis, gingival ulceration, aphthous stomatitis, pancreatitis, bloated feeling or gas, constipation, diarrhoea, indigestion, vomiting, irritation, dryness or soreness of the mouth.
Frequency unknown: Peptic ulcer, dyspepsia, colitis or exacerbation thereof, enterocolitis, regional enteritis or exacerbation thereof, abdominal distension, dysphagia, oesophagitis, gastroenteritis, glossitis, swelling of the lips and tongue, bitter taste or other taste change.

Hepatobiliary disorders:
Less frequent: Toxic hepatitis or jaundice.
Frequency unknown: Hepatitis, liver failure, cholestatic hepatitis or jaundice, raised liver transaminase values in patients with chronic hepatitis C infection. Hepatotoxicity due to hypersensitivity reactions (see **"Immune system disorders"**).

Skin and subcutaneous tissue disorders:
Less frequent: Bullous eruptions / blisters, hives, and itching due to an allergic reaction (see **"Immune system disorders"**), erythema multiforme, Stevens-Johnson syndrome (often associated with hepatotoxicity), toxic epidermal necrolysis, photosensitive or photo-allergic dermatologic reaction.
Frequency unknown: Bullous leukocytoclastic vasculitis, eczema, exfoliative dermatitis, desquamation, erythema or other skin discolouration, erythema nodosum, photosensitivity reactions resembling porphyria cutanea tarda and epidermolysis bullosa, loosening or splitting of fingernails or other nail disorder, increased sweating.

Musculoskeletal, connective tissue and bone disorders:
Frequency unknown: Muscle cramps or pain, muscle weakness.

Renal and urinary disorders:
Less frequent: Renal impairment or failure, renal papillary or tubular necrosis, haematuria, cystitis, polyuria.
Frequency unknown: Nephrotoxicity such as interstitial nephritis, nephrotic syndrome, cystitis, glomerulitis or glomerulonephritis, nephrosis, oliguria / anuria, increase in serum creatinine concentration, acute flank pain, reversible renal dysfunction, bladder pain, crystalluria, renal calculi, or uretheral obstruction, urethritis, dysuria, frequent urge to urinate, incontinence, proteinuria, strong-smelling urine.

Reproductive system and breast disorders:
Less frequent: Unexplained, unexpected, and/or unusual heavy menstrual bleeding.

General disorders:
Frequency unknown: Chest pain, fever with or without chills, lymphadenopathy, general feeling of discomfort or illness.

PSEUDOEPHEDRINE:
Metabolism and nutrition disorders:
Frequency unknown: Altered metabolism, including disturbances of glucose metabolism.

Psychiatric disorders:
Frequent: Anxiety, restlessness.
Less frequent: Hallucinations, particularly in children.

Nervous system disorders:
Frequent: Insomnia.
Less frequent: Convulsions.

Cardiac disorders:
Frequent: Tachycardia.

Respiratory, thoracic and mediastinal disorders:
Frequency unknown: Dyspnoea.

Gastrointestinal disorders:
Frequency unknown: Ischaemic colitis, hypersalivation.

Skin and subcutaneous tissue disorders:
Less frequent: Skin rash.
Frequency unknown: Sweating.

Renal and urinary disorders:
Less frequent: Urinary retention.
Frequency unknown: Difficulty in micturition.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:
Epigastric pain, nausea, vomiting, headache, anxiety, thirst, irritability, restlessness, sinus tachycardia, fever, dilated pupils, sweating, hallucinations, blurred vision, tremors, muscular weakness, hypertension, supraventricular and ventricular dysrhythmia, coma, convulsions and respiratory depression. Gastric lavage will remove any unabsorbed **IBUMAX COLD AND FLU** if recently taken and electrolytes may be corrected by intravenous infusions, if necessary.

IDENTIFICATION:
Orange to yellow, smooth, film-coated, round, biconcave tablet.

PRESENTATION:
Carton containing 12, 20 or 24 blister-packed tablets.

STORAGE INSTRUCTIONS:
Keep the blisters in the outer carton until required for use.
Store at or below 25 °C.
KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:
40/5.8/0218

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:
CIPLA MEDPRO (PTY) LTD
Building 9, Parc du Cap, Mispel Street,
Bellville, 7530, RSA.

DATE OF PUBLICATION OF THIS PACKAGE INSERT:
09 April 2014

CM530A/SA
7567
Pro-Print

Information for the Patient about IBUMAX COLD AND FLU TABLETS

SCHEDULING STATUS: S2

PROPRIETARY NAME (AND DOSAGE FORM):

IBUMAX COLD AND FLU (Film-coated tablets)

Read all of this leaflet carefully because it contains important information for you. IBUMAX COLD AND FLU is available without a doctor's prescription for you to treat a mild illness. Nevertheless you still need to use IBUMAX COLD AND FLU carefully to get the best results from it.
- **Keep this leaflet, you may need to read it again.**
- **Ask your pharmacist if you need more information or advice.**
- **You must see a doctor if your symptoms worsen or do not improve after 3 days.**

WHAT IBUMAX COLD AND FLU CONTAINS:
Each film-coated tablet contains 200 mg ibuprofen and 30 mg pseudoephedrine hydrochloride.
Inactive ingredients include colloidal silicon dioxide, croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, Opadry yellow, and sodium lauryl sulphate.
Contains lactose.

WHAT IBUMAX COLD AND FLU IS USED FOR:
IBUMAX COLD AND FLU tablets are used for the relief of cold and flu symptoms, including blocked nose, headache, fever and sore throat.

BEFORE YOU TAKE IBUMAX COLD AND FLU:
Do NOT take IBUMAX COLD AND FLU if:
- You are hypersensitive or allergic to ibuprofen, pseudoephedrine or any of the other components of **IBUMAX COLD AND FLU**.
- You have been diagnosed with heart failure.
- You are taking antidepressants of the type called monoamine oxidase inhibitors (MAOIs), such as phenelzine or moclobemide, or have taken MAOIs within the past 14 days (see **"Taking other medicines with IBUMAX COLD AND FLU"**).
- You are hypersensitive or allergic to other non-steroidal anti-inflammatory medicines, including aspirin, or if you experienced asthma, swelling of the face, lips, or tongue, hives, or runny nose after taking aspirin.
- You are pregnant or breastfeeding (see **"Pregnancy and breastfeeding"**).
- You are younger than 12 years.
- You have recently or previously been diagnosed with stomach or gut ulcers, bleeding or perforations.
- You have a history of bleeding from the gut or ulcers or perforations of the gut due to the previous use of non-steroidal anti-inflammatory medicines, including **IBUMAX COLD AND FLU**.

Take special care with IBUMAX COLD AND FLU:
Speak to your doctor or pharmacist if you are presently taking monoamine oxidase inhibitors (see **"Do NOT take IBUMAX COLD AND FLU if"**) or other medicines for depression, psychiatric or emotional conditions, or for high blood pressure before you take **IBUMAX COLD AND FLU**.

If you have an overactive thyroid gland, heart disease such as angina (chest pain due to inadequate blood supply to the heart muscle often brought on by exertion) or previously had a heart attack, if you have an abnormal heart rhythm or fast heartbeat, abnormal blood vessels with calcification of your arteries, balloon-like dilations of your blood vessels, diabetes mellitus or closed-angle glaucoma (raised pressure inside your eye that may cause blindness), you should not take **IBUMAX COLD AND FLU**. Please discuss this with your doctor or pharmacist if you are unsure.

If you have previously been diagnosed with angina, taking **IBUMAX COLD AND FLU** may cause an anginal attack.

Elderly patients have an increased risk of developing side-effects due to **IBUMAX COLD AND FLU**, especially bleeding from the stomach or gut, stomach ulcers, or perforation of ulcers, which may be fatal (see **"POSSIBLE SIDE-EFFECTS"**). The risk of developing these side-effects is higher with increasing doses and in patients who previously had ulcers. If you vomit blood or a substance resembling coffee grounds, if there is blood in your stool or if your stool is black, tarry and foul-smelling, immediately stop taking **IBUMAX COLD AND FLU** and report to your doctor as a matter of urgency.

Do not take **IBUMAX COLD AND FLU** if you have a disease / disorder of the gut, such as inflammation of the small or large bowel, heartburn or reflux.

If you develop a skin rash (especially if blisters are present), ulcers inside the mouth or on the lips, or if you have swelling of the lips, face or tongue, shortness of breath or tightness of the chest, immediately stop taking **IBUMAX COLD AND FLU** and report to your doctor as a matter of urgency (see **"POSSIBLE SIDE-EFFECTS"**).

Taking IBUMAX COLD AND FLU with food and drink:
Always take **IBUMAX COLD AND FLU** with food or milk.

Pregnancy and breastfeeding:
Do not take **IBUMAX COLD AND FLU** if you are pregnant or breastfeeding your baby (see **"Do NOT take IBUMAX COLD AND FLU if"**). It may harm your baby and may delay the onset of labour or increase the duration of labour.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking IBUMAX COLD AND FLU.

Driving and using machinery:
IBUMAX COLD AND FLU may cause dizziness, double or blurred vision, changes in colour perception or other visual disturbances that may influence your ability to drive or operate machinery. Do not drive a car or operate machinery or perform any other hazardous tasks until you know how **IBUMAX COLD AND FLU** affects you.

Important information about some of the ingredients in IBUMAX COLD AND FLU:
IBUMAX COLD AND FLU contains lactose. If you are lactose intolerant, please speak to your doctor or pharmacist before taking **IBUMAX COLD AND FLU**. If you suffer from hereditary galactose intolerance or glucose or galactose malabsorption, you should not take **IBUMAX COLD AND FLU**. You should also not take **IBUMAX COLD AND FLU** if you suffer from the rare Lapp lactase deficiency. Please discuss this with your doctor if you are unsure.

Taking other medicines with IBUMAX COLD AND FLU:

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

Do not take **IBUMAX COLD AND FLU** in combination with the following medicines:
- Monoamine oxidase inhibitors, such as phenelzine or moclobemide, for the treatment of depression, since this may cause a severe increase in blood pressure resulting in a stroke or kidney damage (see **"Do NOT take IBUMAX COLD AND FLU if"**).
- Other non-steroidal anti-inflammatory medicines, such as aspirin or diclofenac, since this may result in an increase in side-effects.
- Corticosteroids for the treatment of inflammation in conditions such as asthma or arthritis, since it may increase your risk of developing bleeding from the gut or stomach ulcers.
- Blood thinning medicines, such as warfarin, since this may increase your risk of bleeding.
- Lithium for bipolar mood disorder, since the ibuprofen in **IBUMAX COLD AND FLU** may increase lithium plasma concentrations, thus increasing your risk of developing side-effects due to lithium toxicity.
- Methotrexate for cancer or to suppress the immune system, since the ibuprofen in **IBUMAX COLD AND FLU** may increase methotrexate plasma concentrations, thus increasing your risk of developing side-effects due to methotrexate.
- Digoxin for the treatment of heart failure or abnormal heart rhythms or quinidine for the treatment of abnormal heart rhythms, since **IBUMAX COLD AND FLU** in combination with these medicines may increase your risk of developing abnormal heart rhythms.
- Medicines, such as clopidogrel, that influence platelet function or antidepressants known as selective serotonin reuptake inhibitors (SSRIs), since this may increase your risk of bleeding from the gut. Please speak to your pharmacist if you are unsure.
- Venlafaxine for depression, sibutramine for weight loss, bisphosphonates (such as alendronate) for osteoporosis, or erlotinib for cancer, since combining **IBUMAX COLD AND FLU** with these medicines may increase your risk of developing bleeding from the gut.
- Zidovudine for the treatment of HIV, since this may result in low blood cell counts.
- Ritonavir for the treatment of HIV, since this may result in increased blood concentrations of ibuprofen, thus increasing your risk of developing side-effects due to the ibuprofen in **IBUMAX COLD AND FLU**.
- Tricyclic antidepressants for the treatment of depression, since this may increase your risk of developing abnormal heart rhythms. Please speak to your pharmacist if you are unsure.
- Medicines containing ergot derivatives for the treatment of migraine, because this may cause an increase in blood pressure. Please speak to your pharmacist if you are unsure.
- Antacids containing aluminium hydroxide, since this may increase the absorption of the pseudoephedrine in **IBUMAX COLD AND FLU**, while kaolin (for the treatment of loose stools) may decrease its absorption rate.
- Blood pressure lowering medicines, because **IBUMAX COLD AND FLU** may make these medicines less effective. Please speak to your pharmacist if you are unsure.

HOW TO TAKE IBUMAX COLD AND FLU:
Always take IBUMAX COLD AND FLU exactly as you have been instructed. You should check with your pharmacist if you are unsure.

Adults and children over 12 years:
Always take the lowest possible dose for the shortest possible duration of treatment.
Take one to two tablets every 4 to 6 hours. Do not take more than 6 tablets in any 24-hour period. Always take **IBUMAX COLD AND FLU** with food or milk.
If symptoms persist beyond 3 days, consult your doctor.

If you take more IBUMAX COLD AND FLU than you should:
If you take more **IBUMAX COLD AND FLU** tablets than you should, you may develop upper stomach pain, nausea, vomiting, headache, thirst, anxiety, restlessness, irritability, fever, rapid heart rate, sweating, dilated pupils, blurred vision, hallucinations (hear or see things that are not real), muscle weakness, tremors, high blood pressure, abnormal heart rhythms, convulsions (seizures), coma and depression of your lung function.
In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.
Do this even if you do not experience any discomfort or signs of intoxication. If you go to the doctor or hospital, take the box of **IBUMAX COLD AND FLU** tablets with you.

If you forget to take IBUMAX COLD AND FLU:
If you forget to take **IBUMAX COLD AND FLU**, take it as soon as you remember. However, if it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule of 1 to 2 tablets every 4 to 6 hours. Stop taking **IBUMAX COLD AND FLU** once your symptoms have cleared.

POSSIBLE SIDE-EFFECTS:
IBUMAX COLD AND FLU can have side-effects.
Not all side-effects reported for IBUMAX COLD AND FLU are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking IBUMAX COLD AND FLU, please consult your doctor, pharmacist or other healthcare professional for advice.

If you experience any of the following side-effects, you must stop taking **IBUMAX COLD AND FLU** and report to your doctor immediately:
- Those that occur less frequently:
  - o Swelling of the lips, tongue, or face, skin rash with itching or hives, tightness of the chest or shortness of breath, fever, nausea and vomiting, wheezing, coughing or hoarseness (see **"Take special care with IBUMAX COLD AND FLU"**).
  - o Fever, chills, sore throat, coughing with sputum production, pain in the flank, ulcers that will not heal, blood in the urine, bleeding from the gums, pin point red spots on the skin or easy bruising.
  - o Vomiting of blood or a substance resembling coffee grounds, or blood per rectum or passing foul-smelling, tarry black stools (see **"Take special care with IBUMAX COLD AND FLU"**).
  - o Severe stomach pain accompanied by loss of appetite, nausea and vomiting, generally feeling unwell, fever and chills, and distension of the stomach (see **"Take special care with IBUMAX COLD AND FLU"**).
  - o Yellow discolouration of the white of the eyes or skin (jaundice), nausea and vomiting, loss of appetite, fever and pain over the liver area.
  - o Any skin rash with blisters (see **"Take special care with IBUMAX COLD AND FLU"**).
  - o Swelling of the feet, ankles, legs or hands accompanied by severe tiredness, shortness of breath, and/or inability to lie flat due to shortness of breath.
  - o Inability to pass urine, fluid retention, lower back or flank pain or passing cloudy or dark urine.
  - o Hearing or seeing things that are not real.
  - o Headache with neck stiffness and nausea or vomiting.
  - o Loss of vision, blurred vision, or double vision.
  - o Decreased hearing or any change in hearing.
- Those that occur with unknown frequency:
  - o Chest pain.
  - o Coughing blood.
  - o Convulsions (seizures).
  - o Eye pain.
  - o Leaking of urine.

Stop taking **IBUMAX COLD AND FLU** and report to your doctor as soon as possible if you develop any of the following side-effects:
- Those that occur less frequently:
  - o Palpitations, high blood pressure.
  - o Confusion.
  - o Pins and needles in the arms or legs or abnormal sensation.
  - o Teary, red, dry, irritated or swollen eyes.
  - o Unexplained nose bleeds.
  - o Heartburn or reflux that is progressively getting worse, ulcers on the gums, or vomiting.
  - o Hives or itching or any other skin rash, including a skin rash over areas exposed to the sun.
- Those that occur with unknown frequency:
  - o You feel as if your thoughts and feelings are unreal or do not belong to you.
  - o Difficulty with pronouncing words.
  - o Migraine or severe headaches, fainting spells, trembling or twitching, or unusual weakness.
  - o Changes in colour perception (e.g. all objects appear to have a red or bluish tint).
  - o Loose stools (diarrhoea).
  - o Difficulty in swallowing, swelling of the tongue, painful tongue or inflammation of the tongue.
  - o Peeling of the skin.
  - o Muscle weakness.

Side-effects that you should report to your doctor if they continue or become bothersome include:
- Those that occur frequently:
  - o Dizziness.
- Those that occur less frequently:
  - o Decreased appetite or loss of appetite, thirst, or unexplained weight loss.
  - o Depression, nervousness or irritability, trouble sleeping or inability to sleep, drowsiness, anxiety or restlessness.
  - o Ringing or buzzing in the ears, light-headedness or a sensation of motion when one is keeping still.
  - o Flushing or hot flashes.
- Those that occur with unknown frequency:
  - o Feeling disorientated or forgetfulness.
  - o Bitter taste or other taste change.
  - o Loosening or splitting of the nails or other nail changes.
  - o Increased sweating or strong-smelling urine.
  - o Muscle cramps or pain.
  - o Unexplained, unexpected and/or unusual heavy menstrual bleeding.
  - o Swelling of the lymph glands.
  - o General feeling of discomfort or illness.
  - o Excessive production of saliva.

Please report any other side-effects you think may be due to **IBUMAX COLD AND FLU**, especially if not mentioned in this leaflet.

STORAGE AND DISPOSING OF IBUMAX COLD AND FLU:
STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
Keep the blisters in the outer carton until required for use.
Store at or below 25 °C.
Do not use **IBUMAX COLD AND FLU** tablets after the expiry date stated on the packaging material.
Return all unused medicine to your pharmacist.
Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

PRESENTATION OF IBUMAX COLD AND FLU:
Carton containing 12, 20 or 24 blister packed tablets.

IDENTIFICATION OF IBUMAX COLD AND FLU:
Orange to yellow, smooth, film-coated, round, biconcave tablet.

REGISTRATION NUMBER:
40/5.8/0218

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:
CIPLA MEDPRO (PTY) LTD
Building 9, Parc du Cap, Mispel Street,
Bellville, 7530, RSA.

DATE OF PUBLICATION OF THIS PATIENT INFORMATION LEAFLET:
09 April 2014

CM530A/SA
7567
Pro-Print

SKEDULERINGSTATUS: S2

EIENDOMSNAAM (EN DOSEERVORM):

IBUMAX COLD AND FLU (Filmbedekte tablette)

SAMESTELLING:
Elke filmbedekte tablet bevat 200 mg ibuprofeen en 30 mg pseudoefedrienhidrochloried.
Onaktiewe bestanddele sluit kolloïdale silikondioksied, natriumkroskarmellose, laktosemonohidraat, magnesiumstearaat, mikrokristallyne sellulose, Opadry geel en natriumlourielsulfaat in.
Bevat laktose.

FARMAKOLOGIESE KLASSIFIKASIE:
A 5.8 Middels vir verkoue, insluitende nasale ontstuwingsmiddels.

FARMAKOLOGIESE WERKING:
Farmakodinamika:
Ibuprofeen is 'n nie-steroïdale anti-inflammatoriese verbinding met analgetiese, koorswerende en anti-inflammatoriese eienskappe.
Pseudoefedrienhidrochloried is 'n direk- en indirek-werkende simpatomimetiese middel. Dit is 'n vasokonstriktor en het nasale ontstuwingseienskappe.

Farmakokinetika:
Ibuprofeen:
Absorpsie:
Ibuprofeen word goed geabsorbeer. Biobeskikbaarheid na orale toediening van die rasemiese mengsel is meer as 80 %.
Verspreiding:
Na orale toediening van 'n enkele 800 mg dosis van die rasemiese mengsel duur dit 1,6 ± 0,3 uur om die piek serumkonsentrasie van 61,1 ± 5,5 µg/mℓ te bereik. Ibuprofeen is hoogs plasmaproteïen-gebonde (meer as 99 %) met 'n volume van verspreiding van 0,15 ± 0,02 ℓ/kg.
Metabolisme:
Ibuprofeen ondergaan hepatiese metabolisme en 90 % van 'n toegediende dosis word na hidroksilaat- of karboksilaatderivate gemetaboliseer. Die half-lewe is ongeveer 2 uur.
Eliminasie:
Die metaboliete word renaal uitgeskei met minder as 1 % van toegediende ibuprofeen wat onveranderd in die urine voorkom.

Pseudoefedrien:
Absorpsie:
Na orale toediening is die biobeskikbaarheid van pseudoefedrien ongeveer 100 %.
Verspreiding:
Pseudoefedrien is nie aan plasmaproteïene gebonde nie en het 'n volume van verspreiding van 2,64 – 3,51 ℓ/kg. Na toediening van 'n 60 mg onmiddellike-vrystelling tablet duur dit 1,4 – 2 uur om piek serumkonsentrasie te bereik.
Metabolisme:
Pseudoefedrien het 'n half-lewe van ongeveer 4,3 – 8 uur.
Eliminasie:
Ongeveer 43 – 96 % van 'n toegediende dosis word in die urine uitgeskei. By 'n hoë urinêre pH (> 7,0) word pseudoefedrien omvattend herabsorbeer; $t_{1/2}$ neem toe en opruiming verminder.

INDIKASIES:
IBUMAX COLD AND FLU tablette is vir die verligting van verkoue- en griepsimptome, insluitende nasale kongestie, hoofpyn, koors en seerkeel, aangedui.

KONTRA-INDIKASIES:
IBUMAX COLD AND FLU tablette is teenaangedui in:
- Pasiënte met hipersensitiwiteit vir ibuprofeen en pseudoefedrien of enige van die ander bestanddele van **IBUMAX COLD AND FLU**.
- Hartversaking.
- Pasiënte wie monoamienoksidase inhibeerders (MAOIs) gebruik of binne 14 dae na die beëindiging van MAOI-behandeling.
- Pasiënte met hipersensitiwiteit vir NSAIMs, insluitende pasiënte in wie asma-aanvalle, angio-edeem, urtikarie of rinitis deur aspirien aangebring word.
- Swanger of lakterende vroue (sien **"SWANGERSKAP EN LAKTASIE"**) of in kinders onder die ouderdom van 12 jaar.
- Pasiënte met aktiewe of 'n geskiedenis van terugkerende ulkus / bloeding / perforasies.
- Pasiënte met 'n geskiedenis van gastro-intestinale bloeding, ulserasie of perforasie (PUBs) as gevolg van vorige NSAIMs, insluitende **IBUMAX COLD AND FLU**.

WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS:
Pasiënte wie tans monoamienoksidase inhibeerders (sien **"KONTRA-INDIKASIES"**) of ander medisyne vir psigiatriese of emosionele toestande, depressie of hipertensie neem, moenie **IBUMAX COLD AND FLU** tablette neem voordat hulle dit met hulle dokter of apteker bespreek het nie.

IBUMAX COLD AND FLU tablette moenie aan pasiënte met hipertiroïdisme, feochromositoom, vergrote prostaat, kardiovaskulêre siekte soos iskemiese hartsiekte, disritmie of tagikardie, okklusiewe vaskulêre afwykings insluitende arteriosklerose, hipertensie of aneurismes, diabetes mellitus of nou-hoek gloukoom gegee word nie.
In pasiënte met angina pectoris kan angina pyn ontlok word.

As gevolg van **IBUMAX COLD AND FLU** se inherente potensiaal om vloeistofretensie en edeem te veroorsaak, kan hartversaking in sommige pasiënte gepresipiteer word. Omsigtigheid is nodig in pasiënte met 'n geskiedenis van hipertensie en/of hartversaking.

IBUMAX COLD AND FLU tablette moet met omsigtigheid in pasiënte gebruik word wie digoksien, guanidien of trisikliese antidepressante neem of in pasiënte wie narkose met gehalogeneerde narkosemiddels ondergaan (sien **"INTERAKSIES"**).

Bejaardes het 'n verhoogde frekwensie van ongewenste reaksies vanweë NSAIMs, insluitende **IBUMAX COLD AND FLU**, veral gastro-intestinale bloeding, ulserasie en perforasie (PUBs), wat noodlottig kan wees.

Die risiko vir gastro-intestinale bloeding of perforasie (PUBs) is hoër met toenemende dosisse van **IBUMAX COLD AND FLU**, in pasiënte met 'n geskiedenis van ulkusse en in bejaardes.

Indien gastro-intestinale bloeding of ulserasie in pasiënte wie **IBUMAX COLD AND FLU** neem voorkom, moet behandeling met **IBUMAX COLD AND FLU** gestaak word.

IBUMAX COLD AND FLU moet met omsigtigheid aan pasiënte met 'n geskiedenis van gastro-intestinale siekte (bv. ulseratiewe kolitis, Crohn se siekte, hiatusbreuk, gastro-esofageale refluksiekte, angiodisplasie) gegee word, aangesien die toestand vererger kan word.

Ernstige velreaksies, waarvan sommige noodlottig was, insluitende eksfoliatiewe dermatitis, Stevens-Johnson sindroom en toksiese epidermale nekrolise, was gemeld. **IBUMAX COLD AND FLU** moet met die eerste teken van veluitslag, slymvliesletsels of enige ander teken van hipersensitiwiteit gestaak word.

IBUMAX COLD AND FLU bevat laktose. Die gebruik daarvan is nie aanbeveel in pasiënte met galaktose onverdraagsaamheid, die Lapp laktase tekort of glukose of galaktose wanabsorpsiesindroom nie.

Effekte op die vermoë om te bestuur en om masjinerie te gebruik:
IBUMAX COLD AND FLU kan 'n geringe tot matige invloed op 'n pasiënt se vermoë om te bestuur of masjinerie te gebruik, uitoefen. **IBUMAX COLD AND FLU** kan duiseligheid, dubbele of dowwe visie, veranderinge in kleurpersepsie of ander visuele versteurings veroorsaak. Pasiënte moet aangeraai word om nie 'n motor te bestuur of masjinerie te gebruik totdat hulle weet hoe **IBUMAX COLD AND FLU** hulle affekteer nie.

INTERAKSIES:
Ibuprofeen:
- NSAIMs: die gelyktydige gebruik van twee of meer NSAIMs, insluitende aspirien, moet vermy word aangesien dit tot 'n toename in newe-effekte kan lei.
- Kortikosteroïede: daar is 'n verhoogde risiko vir gastro-intestinale ulserasie of bloeding wanneer ibuprofeen, soos in **IBUMAX COLD AND FLU**, saam met kortikosteroïede gebruik word.
- Bloedverdunners (warfarien): ibuprofeen kan die effekte van antistolmiddels, soos warfarien en fenielbutasoon, verhoog.
- Litium, metotreksaat en digoksien: ibuprofeen kan 'n toename in die plasmakonsentrasies van hierdie middels veroorsaak.
- Antiplaatjiemiddels, soos klopidogrel en selektiewe serotonien heropname inhibeerders (SSRIs): daar is 'n verhoogde risiko vir gastro-intestinale bloeding wanneer ibuprofeen saam met hierdie middels toegedien word.
- Die serotonien norepinefrien heropname inhibeerder (SNRI) venlafaksien, sibutramien, bisfosfonate, erlotinib, pentoksifillien: die risiko vir gastro-intestinale bloeding is verhoog wanneer ibuprofeen saam met hierdie geneesmiddels gebruik word.
- Sidovudien: daar kan 'n verhoogde risiko vir hematotoksisiteit wees indien sidovudien met ibuprofeen gebruik word.
- Ritonavir: ritonavir kan die plasmakonsentrasie van ibuprofeen verhoog.

Pseudoefedrien:
- As gevolg van die potensiaal vir pseudoefedrien om 'n hipertensiewe krisis te veroorsaak in pasiënte wie MAOIs neem, insluitende die omkeerbare inhibeerders van monoamienoksidase tipe-A (RIMA), is die gebruik van **IBUMAX COLD AND FLU** saam met fenelsien of moklobemied teenaangedui (sien **"KONTRA-INDIKASIES"**).
- 'n Verhoogde risiko vir disritmieë kan voorkom as pseudoefedrien aan pasiënte wie digoksien, kinidien of trisikliese antidepressante gebruik, gegee word en daar is 'n verhoogde risiko vir vasokonstriktoriese of bloeddruk-verhogende effekte in pasiënte wie ergotalkaloïede of oksitosien gebruik.
- Aluminiumhidroksied mengsel kan die absorpsietempo van pseudoefedrien verhoog, terwyl kaolien die absorpsietempo verminder.

Algemeen:
Die werking van antihipertensiewe middels kan omgekeer word en daarom word spesiale sorg aanbeveel in pasiënte wie gesamentlik antihipertensiewe terapie gebruik.

Interaksies met geneesmiddels wat alfa- en beta-reseptore blokkeer kan ingewikkeld wees.

Interaksies met reserpien, trisikliese antidepressante, digoksien en alfa-metieldopa is moontlik (sien hierbo).

IBUMAX COLD AND FLU tablette moet met omsigtigheid in pasiënte wie digoksien, guanidien of trisikliese antidepressante neem of in pasiënte wie narkose met gehalogeneerde narkosemiddels ondergaan, gebruik word (sien **"WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS"**).

SWANGERSKAP EN LAKTASIE:
IBUMAX COLD AND FLU moenie deur swanger of lakterende vroue gebruik word nie (sien **"KONTRA-INDIKASIES"**).

Die gebruik van nie-steroïdale anti-inflammatoriese middels (NSAIMs), soos **IBUMAX COLD AND FLU**, gedurende die derde trimester van swangerskap kan tot voortydige sluiting van die fetale ductus arteriosus *in utero* en moontlik tot volgehoue pulmonale hipertensie van die pasgeborene lei. Die aanvang van kraam mag vertraag word en die duur daarvan verleng word.

DOSIS EN GEBRUIKSAANWYSINGS:
Volwassenes en kinders ouer as 12 jaar:
Neem altyd die laagste moontlike dosis vir die kortste moontlike duur van behandeling.
Neem een tot twee tablette elke 4 tot 6 uur. Moenie meer as 6 tablette in enige 24-uur-periode neem nie. Neem **IBUMAX COLD AND FLU** altyd met kos of melk.
Adviseer pasiënte om hul dokter te raadpleeg indien simptome vir langer as 3 dae voortduur.

NEWE-EFFEKTE:
IBUPROFEEN:
Infeksies en infestasies:
Frekwensie onbekend: Urienweginfeksie.

Immuunsisteem afwykings:
Minder dikwels: Anafilakse of anafilaktoïede reaksies, angiïtis (vaskulitis) (sien **"Vaskulêre afwykings"**), angio-edeem, brongospastiese allergiese reaksies, hepatotoksisiteit en aseptiese meningitis as gevolg van hipersensitiwiteitsreaksies (sien **"Senusisteem afwykings"** en **"Hepatobiliêre afwykings"**), allergiese rinitis, reaksie soortgelyk aan serumsiekte, sindroom soortgelyk aan sistemiese lupus eritematose.
Frekwensie onbekend: Hipersensitiwiteitsreaksies insluitende koors, asma, veluitslag (sien **"Vel- en subkutane weefselafwykings"**), laringeale edeem as gevolg van 'n allergiese reaksie, Loeffler sindroom (eosinofiliese pneumonitis).

Hematologiese en limfatiese sisteem afwykings:
Minder dikwels: Agranulositose (granulositopenie), anemie, aplastiese anemie (pansitopenie), eosinofilie, hemolitiese anemie, leukopenie (neutropenie), trombositopenie met of sonder purpura.
Frekwensie onbekend: Suiwer witsel-aplasie, beenmurgonderdrukking, gedissemineerde intravaskulêre stolling, ekchimose / kneusing, hipostolbaarheid, petegieë.

Metaboliese en voedingsafwykings:
Minder dikwels: Vloeistofretensie/edeem, hiperkalemie, verminderde eetlus of verlies van eetlus.
Frekwensie onbekend: Hiponatremie, aanhoudende dors, onverklaarbare gewigsverlies.

Psigiatriese afwykings:
Minder dikwels: Hallusinasies, depressie, senuweeagtigheid of prikkelbaarheid.
Frekwensie onbekend: Disoriëntasie, gevoel van depersonalisasie, psigotiese reaksie, angs.

Senusisteem afwykings:
Dikwels: Duiseligheid.
Minder dikwels: Verwarring, aseptiese meningitis (sien **"Immuunsisteem afwykings"**), perifere neuropatie, lomerigheid, moeilike slaap.
Frekwensie onbekend: Konvulsies, disartrie, hoofpyn (insluitende erge hoofpyn, veral soggens), vergeetagtigheid, skeelhoofpyn, sinkopee, tremor of spiertrekkings, ongewone swakheid met geen ander tekens of simptome nie.

Oogafwykings:
Minder dikwels: Toksiese ambliopie, visuele versteurings soos dowwe of dubbele visie, konjunktivitis, droë, geïrriteerde of geswelde oë, skotoom.
Frekwensie onbekend: Veranderinge in visuele kleurpersepsie, korneale ondeursigtigheid, retinale of makulêre versteurings, korneale neerslae, oogpyn, palpebrale edeem, retinale bloeding, fotofobie.

Oor- en labirintafwykings:
Minder dikwels: Verminderde gehoor of enige verandering in gehoor, tinnitus (loei of suising in die ore).
Frekwensie onbekend: Vertigo / lighoofdigheid.

Kardiale afwykings:
Minder dikwels: Disritmieë, kongestiewe hartversaking of verergering daarvan, tagikardie.
Frekwensie onbekend: Angina pectoris of verergering van borskaspyn, perikarditis.

Vaskulêre afwykings:
Minder dikwels: Verhoogde bloeddruk (mag hipertensiewe vlakke bereik), blosing of warmgloede.

Respiratoriese, torakale en mediastinale afwykings:
Minder dikwels: Kortasemheid of moeilike asemhaling, onverklaarbare neusbloeding.
Frekwensie onbekend: Brongospasma in pasiënte met asma, hemoptise, pulmonale edeem.

Gastro-intestinale afwykings:
Dikwels: Geringe tot matige abdominale krampe, pyn of ongemak, geringe tot matige epigastriese pyn of ongemak, sooibrand, naarheid.
Minder dikwels: Gastro-intestinale bloeding of hemorragie, gastro-intestinale perforasie, gastro-intestinale ulserasie, insluitende esofageale, gastriese of peptiese ulserasie, veelvuldige gastro-intestinale ulserasies en perforasie van reeds-bestaande sigmoïedletsels, bv. divertikels, karsinoom, gastritis, gingivale ulserasie, afteuse stomatitis, pankreatitis, opgeblase gevoel of winderigheid, hardlywigheid, diarree, slegte spysvertering, braking, irritasie, droogheid of seerheid van die mond.
Frekwensie onbekend: Peptiese ulkus, dispepsie, kolitis of verergering daarvan, enterokolitis, streeksenteritis of verergering daarvan, buikopsetting, disfagie, esofagitis, gastro-enteritis, glossitis, swelling van die lippe en tong, bitter smaak of ander smaaksteuring.

Hepatobiliêre afwykings:
Minder dikwels: Toksiese hepatitis of geelsug.
Frekwensie onbekend: Hepatitis, lewerversaking, cholestatiese hepatitis of geelsug, verhoogde lewertransaminase waardes in pasiënte met chroniese hepatitis C-infeksie.
Hepatotoksisiteit as gevolg van hipersensitiwiteitsreaksies (sien **"Immuunsisteem afwykings"**).

Vel- en subkutane weefselafwykings:
Minder dikwels: Bulleuse uitbarstings/blase, galbulte en jeuk as gevolg van 'n allergiese reaksie (sien **"Immuunsisteem afwykings"**), eritema multiforme, Stevens-Johnson sindroom (dikwels met hepatotoksisiteit geassosieer), toksiese epidermale nekrolise, fotosensitiewe of foto-allergiese dermatologiese reaksie.
Frekwensie onbekend: Bulleuse leukositoklastiese vaskulitis, ekseem, eksfoliatiewe dermatitis, afskilfering, eritema of ander velverkleuring, eritema nodosum, fotosensitiwiteitsreaksies wat soos porfirie cutanea tarda en epidermolise bullosa voordoen, loslating of afsplyting van vingernaels of ander naelafwyking, vermeerderde sweet.

Muskuloskeletale, bindweefsel- en beenafwykings:
Frekwensie onbekend: Spierkrampe of -pyn, spierswakheid.

Renale en urinêre afwykings:
Minder dikwels: Renale inkorting of versaking, renale papillêre of tubulêre nekrose, hematurie, sistitis, poliurie.
Frekwensie onbekend: Nefrotoksisiteit soos interstisiële nefritis, nefrotiese sindroom, sistitis, glomerulitis of glomerulonefritis, nefrose, oligurie/anurie, toename in serumkreatinien konsentrasie, akute flankpyn, omkeerbare renale disfunksie, blaaspyn, kristalurie, nierstene of ureterale obstruksie, uretritis, disurie, gereelde drang om te urineer, inkontinensie, proteïenurie, sterk-ruikende urine.

Voortplantingstelsel en borsafwykings:
Minder dikwels: Onverklaarbare, onverwagte en/of ongewone swaar menstruele bloeding.

Algemene afwykings:
Frekwensie onbekend: Borskaspyn, koors met of sonder kouekoors, limfadenopatie, algemene gevoel van ongemak of siekte.

PSEUDOEFEDRIEN:
Metaboliese en voedingsafwykings:
Frekwensie onbekend: Veranderde metabolisme, insluitende versteurings van glukosemetabolisme.

Psigiatriese afwykings:
Dikwels: Angs, rusteloosheid.
Minder dikwels: Hallusinasies, veral in kinders.

Senusisteem afwykings:
Dikwels: Slaaploosheid.
Minder dikwels: Konvulsies.

Kardiale afwykings:
Dikwels: Tagikardie.

Respiratoriese, torakale en mediastinale afwykings:
Frekwensie onbekend: Dispnee.

Gastro-intestinale afwykings:
Frekwensie onbekend: Iskemiese kolitis, hipersalivering.

Vel- en subkutane weefselafwykings:
Minder dikwels: Veluitslag.
Frekwensie onbekend: Sweet.

Renale en urinêre afwykings:
Minder dikwels: Urienretensie.
Frekwensie onbekend: Moeilike urinering.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN:
Epigastriese pyn, naarheid, braking, hoofpyn, angs, dors, prikkelbaarheid, rusteloosheid, sinus tagikardie, koors, vergrote pupille, sweet, hallusinasies, dowwe visie, tremors, spierswakheid, hipertensie, supraventrikulêre en ventrikulêre disritmie, koma, konvulsies en respiratoriese onderdrukking. Gastriese spoeling sal enige ongeabsorbeerde **IBUMAX COLD AND FLU** verwyder indien dit onlangs geneem is en elektroliete kan deur intraveneuse infusie reggestel word, indien nodig.

IDENTIFIKASIE:
Oranje tot geel, gladde, filmbedekte, ronde, bikonkawe tablet.

AANBIEDING:
Kartonhouer met 12, 20 of 24 tablette in stulpverpakte stroke.

BERGINGSINSTRUKSIES:
Hou die stulpverpakte stroke in die buitenste karton totdat dit vir gebruik benodig word.
Berg teen of benede 25 °C.
HOU BUITE BEREIK VAN KINDERS.

REGISTRASIENOMMER:
40/5.8/0218

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE SERTIFIKAAT VAN REGISTRASIE:
CIPLA MEDPRO (EDMS) BPK
Gebou 9, Parc du Cap, Mispelstraat,
Bellville, 7530, RSA.

DATUM VAN PUBLIKASIE VAN HIERDIE VOUBILJET:
09 April 2014

CM530A/SA
7567
Pro-Print

Inligting vir die Pasiënt oor IBUMAX COLD AND FLU TABLETTE

SKEDULERINGSTATUS: S2

EIENDOMSNAAM (EN DOSEERVORM):

IBUMAX COLD AND FLU (Filmbedekte tablette)

Lees hierdie inligtingstuk sorgvuldig deur want dit bevat belangrike inligting vir u. IBUMAX COLD AND FLU is sonder 'n doktersvoorskrif beskikbaar sodat u 'n geringe siekte kan behandel. Nogtans moet u IBUMAX COLD AND FLU versigtig gebruik om die beste resultate daarvan te verkry.
- **Hou hierdie inligtingstuk; dit mag nodig wees om dit later weer te lees.**
- **Raadpleeg u apteker indien u enige verdere navrae het of inligting benodig.**
- **U moet 'n dokter raadpleeg indien u simptome vererger of nie na 3 dae verbeter nie.**

WAT IBUMAX COLD AND FLU BEVAT:
Elke filmbedekte tablet bevat 200 mg ibuprofeen en 30 mg pseudoefedrienhidrochloried.
Onaktiewe bestanddele sluit kolloïdale silikondioksied, natriumkroskarmellose, laktosemonohidraat, magnesiumstearaat, mikrokristallyne sellulose, Opadry geel en natriumlourielsulfaat in.
Bevat laktose.

WAARVOOR IBUMAX COLD AND FLU GEBRUIK WORD:
IBUMAX COLD AND FLU tablette word vir die verligting van verkoue- en griepsimptome, insluitende toeneus, hoofpyn, koors en seerkeel gebruik.

VOORDAT U IBUMAX COLD AND FLU GEBRUIK:
MOENIE IBUMAX COLD AND FLU neem indien:
- U hipersensitief of allergies vir ibuprofeen, pseudoefedrien of enige van die ander komponente van **IBUMAX COLD AND FLU** is nie.
- U met hartversaking gediagnoseer is nie.
- U antidepressante, van die tipe wat monoamienoksidase inhibeerders (MAOIs) genoem word, soos fenelsien of moklobemied, neem of indien u MAOIs binne die afgelope 14 dae geneem het nie (sien **"Neem van ander medisyne saam met IBUMAX COLD AND FLU"**).
- U hipersensitief of allergies vir ander nie-steroïdale anti-inflammatoriese middels, insluitende aspirien, is nie, of indien u voorheen asma, swelling van die gesig, lippe of tong, galbulte of loopneus ervaar het nadat u aspirien geneem het nie.
- U swanger is of borsvoed nie (sien **"Swangerskap en borsvoeding"**).
- U jonger as 12 jaar is nie.
- U onlangs of voorheen met maag- of dermsere, bloeding of perforasies gediagnoseer is nie.
- U 'n geskiedenis van bloeding van die ingewande of maagsere of perforasies van die ingewande, as gevolg van vorige gebruik van nie-steroïdale anti-inflammatoriese middels, insluitende **IBUMAX COLD AND FLU**, het nie.

Neem spesiale sorg met IBUMAX COLD AND FLU:
Indien u tans monoamienoksidase inhibeerders (sien **"MOENIE IBUMAX COLD AND FLU neem indien"**) of ander medisyne vir depressie, psigiatriese of emosionele toestande, of vir hoë bloeddruk neem, moenie **IBUMAX COLD AND FLU** neem voordat u dit nie met u dokter of apteker bespreek het nie.

Indien enige van die volgende toestande op u betrekking het, moet u nie **IBUMAX COLD AND FLU** neem voordat u dit nie met u dokter of apteker bespreek het nie: 'n ooraktiewe skildklier, hartsiektes soos angina (borskaspyn weens onvoldoende bloedtoevoer na die hartspier wat dikwels deur inspanning meegebring word), 'n hartaanval vantevore, 'n abnormale hartritme of vinnige hartklop, abnormale bloedvate met verkalking van u are, ballonagtige uitstulpings van u bloedvate, diabetes mellitus of nou-hoek gloukoom (verhoogde druk binne-in u oog wat tot blindheid kan lei). Bespreek dit asseblief met u dokter of apteker indien u onseker is.

Indien u voorheen met angina gediagnoseer is, kan die gebruik van **IBUMAX COLD AND FLU** 'n angina-aanval veroorsaak.

Bejaarde pasiënte het 'n verhoogde risiko vir die ontwikkeling van newe-effekte as gevolg van **IBUMAX COLD AND FLU**, veral bloeding van die maag of ingewande, maagsere of perforasie van maagsere, wat noodlottig mag wees (sien **"MOONTLIKE NEWE-EFFEKTE"**). Die risiko vir die ontwikkeling van hierdie newe-effekte is hoër met toenemende dosisse en in pasiënte wie voorheen maagsere gehad het. Indien u bloed of 'n substans wat soos koffiemoer (gemaalde koffiebone) lyk braak, indien daar bloed in u stoelgang is, of as u stoelgang swart, teeragtig en onwelriekend is, moet u onmiddellik ophou om **IBUMAX COLD AND FLU** te neem en dit dringend aan u dokter meld.

Moenie **IBUMAX COLD AND FLU** neem indien u aan 'n siekte / toestand van die ingewande, soos inflammasie van die dun- of dikderm, sooibrand of refluks van maagsuur, ly nie.

Indien u 'n veluitslag (veral indien blase teenwoordig is) of sere in die mond of op die lippe ontwikkel, of indien u swelling van die lippe, gesig of tong, kortasemheid of benoude bors ondervind, moet u onmiddellik ophou om **IBUMAX COLD AND FLU** te neem en dit dringend aan u dokter meld (sien **"MOONTLIKE NEWE-EFFEKTE"**).

Neem van IBUMAX COLD AND FLU met kos en drank:
Neem **IBUMAX COLD AND FLU** altyd met kos of melk.

Swangerskap en borsvoeding:
Moenie **IBUMAX COLD AND FLU** neem indien u swanger is of u baba borsvoed nie (sien **"MOENIE IBUMAX COLD AND FLU neem indien"**). Dit kan u baba skade aandoen en kan die aanvang van kraam vertraag of die duur van kraam verleng.

Indien u swanger is of u baba borsvoed, win asseblief advies by u dokter, apteker of ander professionele gesondheidsorgwerker in voordat u IBUMAX COLD AND FLU neem.

Bestuur of die gebruik van masjinerie:
IBUMAX COLD AND FLU kan duiseligheid, dubbele of dowwe visie, veranderinge in kleurpersepsie of ander visuele versteurings veroorsaak wat u vermoë om te bestuur of masjinerie te gebruik, kan beïnvloed. Moenie 'n motor bestuur of masjinerie gebruik of enige ander gevaarlike take verrig totdat u weet hoe **IBUMAX COLD AND FLU** u affekteer nie.

Belangrike inligting oor van die bestanddele in IBUMAX COLD AND FLU:
IBUMAX COLD AND FLU bevat laktose. Indien u laktose-onverdraagsaam is, praat asseblief met u dokter of apteker voor u **IBUMAX COLD AND FLU** neem. Indien u aan oorerflike galaktose onverdraagsaamheid of glukose of galaktose wanabsorpsie ly, moet u nie **IBUMAX COLD AND FLU** neem nie. U moet ook nie **IBUMAX COLD AND FLU** neem indien u aan die seldsame Lapp laktase tekort ly nie. Bespreek dit asseblief met u dokter indien u onseker is.

Neem van ander medisyne saam met IBUMAX COLD AND FLU:

Vertel altyd u professionele gesondheidsorgwerker indien u enige ander medisyne op 'n gereelde grondslag neem of gebruik. (Insluitend komplementêre of tradisionele middels.)

Moenie **IBUMAX COLD AND FLU** in kombinasie met die volgende medisyne neem nie:
- Monoamienoksidase inhibeerders, soos fenelsien of moklobemied, vir die behandeling van depressie, want dit kan tot 'n ernstige toename in bloeddruk, wat 'n beroerte of nierskade kan veroorsaak, lei (sien **"MOENIE IBUMAX COLD AND FLU neem indien"**).
- Ander nie-steroïdale anti-inflammatoriese middels, soos aspirien of diklofenak, aangesien dit tot 'n toename in newe-effekte kan lei.
- Kortikosteroïede vir die behandeling van inflammasie in toestande soos asma of artritis, aangesien dit u risiko vir die ontwikkeling van bloeding van die ingewande of maagsere kan verhoog.
- Bloedverdunners, soos warfarien, aangesien dit u risiko vir bloeding kan verhoog.
- Litium vir bipolêre gemoedversteuring, aangesien die ibuprofeen in **IBUMAX COLD AND FLU** litium plasmakonsentrasies kan verhoog en sodoende u risiko vir die ontwikkeling van newe-effekte as gevolg van litiumtoksisiteit kan verhoog.
- Metotreksaat vir kanker of om die immuunstelsel te onderdruk, aangesien die ibuprofeen in **IBUMAX COLD AND FLU** metotreksaat plasmakonsentrasies kan verhoog en sodoende u risiko vir die ontwikkeling van newe-effekte as gevolg van metotreksaat kan verhoog.
- Digoksien vir die behandeling van hartversaking of abnormale hartritmes of kinidien vir die behandeling van abnormale hartritmes, aangesien **IBUMAX COLD AND FLU** in kombinasie met hierdie middels u risiko vir die ontwikkeling van abnormale hartritmes kan verhoog.
- Medisyne, soos klopidogrel, wat 'n invloed op plaatjiefunksie het of antidepressante wat as selektiewe serotonien heropname inhibeerders (SSRIs) bekend staan, aangesien dit u risiko vir bloeding van die ingewande kan verhoog. Bespreek dit asseblief met u apteker indien u onseker is.
- Venlafaksien vir depressie, sibutramien vir gewigsverlies, bisfosfonate (soos alendronaat) vir osteoporose of erlotinib vir kanker, aangesien die kombinasie van **IBUMAX COLD AND FLU** met hierdie middels u risiko vir die ontwikkeling van bloeding van die ingewande kan verhoog.
- Sidovudien vir die behandeling van MIV, aangesien dit tot lae bloedseltellings kan lei.
- Ritonavir vir die behandeling van MIV, aangesien dit tot verhoogde bloedkonsentrasies van ibuprofeen kan lei en sodoende u risiko vir die ontwikkeling van newe-effekte as gevolg van die ibuprofeen in **IBUMAX COLD AND FLU** kan verhoog.
- Trisikliese antidepressante vir die behandeling van depressie, aangesien dit u risiko vir die ontwikkeling van abnormale hartritmes kan verhoog. Bespreek dit asseblief met u apteker indien u onseker is.
- Medisyne wat ergotderivate vir die behandeling van skeelhoofpyn bevat, aangesien dit tot 'n toename in bloeddruk kan lei. Bespreek dit asseblief met u apteker indien u onseker is.
- Teensuurmiddels wat aluminiumhidroksied bevat, aangesien dit die opname van die pseudoefedrien in **IBUMAX COLD AND FLU** kan verhoog, terwyl kaolien (vir die behandeling van los stoelgange) die tempo van opname kan verminder.
- Medisyne wat bloeddruk verlaag, aangesien **IBUMAX COLD AND FLU** hierdie medisyne minder effektief kan maak. Bespreek dit asseblief met u apteker indien u onseker is.

HOE OM IBUMAX COLD AND FLU TE NEEM:
Neem IBUMAX COLD AND FLU altyd presies soos aangedui. U moet met u dokter of apteker bevestig indien u onseker is.

Volwassenes en kinders ouer as 12 jaar:
Neem altyd die laagste moontlike dosis vir die kortste moontlike duur van behandeling.
Neem een tot twee tablette elke 4 tot 6 uur. Moenie meer as 6 tablette in enige 24-uur-periode neem nie. Neem **IBUMAX COLD AND FLU** altyd met kos of melk.
Indien simptome vir langer as 3 dae voortduur, moet u u dokter raadpleeg.

Indien u meer IBUMAX COLD AND FLU geneem het as wat u moes:
Indien u meer **IBUMAX COLD AND FLU** tablette geneem het as wat u behoort, kan u boonste maagpyn, naarheid, braking, hoofpyn, dors, angs, rusteloosheid, prikkelbaarheid, koors, vinnige hartklop, sweet, vergrote pupille, dowwe visie, hallusinasies (hoor of sien dinge wat nie werklik is nie), spierswakheid, bewerasie, hoë bloeddruk, abnormale hartritmes, konvulsies (stuiptrekkings), koma en onderdrukking van u longfunksie ervaar.
In die geval van oordosering, kontak u dokter of apteker. Indien geeneen van hulle beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.
Doen dit selfs as u geen ongerief of tekens van vergiftiging ervaar nie. Indien u na die dokter of hospitaal gaan, neem die **IBUMAX COLD AND FLU** pakkie met u saam.

Indien u vergeet om IBUMAX COLD AND FLU te neem:
Indien u vergeet het om **IBUMAX COLD AND FLU** te neem, neem dit so gou as moontlik. Indien dit amper tyd vir u volgende dosis is, slaan die vergete dosis oor en sit u gewone doseringskedule van 1 tot 2 tablette elke 4 tot 6 uur voort. U moet ophou om **IBUMAX COLD AND FLU** te neem sodra u simptome opgeklaar het.

MOONTLIKE NEWE-EFFEKTE:
IBUMAX COLD AND FLU mag newe-effekte veroorsaak.
Nie alle newe-effekte wat vir IBUMAX COLD AND FLU gemeld is, is in hierdie inligtingstuk vervat nie. Indien u algemene gesondheid agteruitgaan of as u enige ongewenste effekte ervaar terwyl u IBUMAX COLD AND FLU neem, raadpleeg asseblief u dokter, apteker of ander professionele gesondheidsorgwerker vir advies.

Indien u enige van die volgende newe-effekte ervaar, moet u ophou om **IBUMAX COLD AND FLU** te neem en dit onmiddellik aan u dokter meld:
- Dié wat minder dikwels voorkom:
  - o Swelling van die lippe, tong of gesig, veluitslag met jeuk of galbulte, benoude bors of kortasemheid, koors, naarheid en braking, fluitbors, hoes of heesheid (sien **"Neem spesiale sorg met IBUMAX COLD AND FLU"**).
  - o Koors, kouekoors, seerkeel, hoes met sputumproduksie, pyn in die flank, sere wat nie gesond word nie, bloed in die urine, bloeding van die tandvleis, speldepunt rooi kolle op die vel of maklike kneusing.
  - o Braking van bloed of 'n stof wat soos gemaalde koffiebone lyk of passering van bloed per rektum of onwelriekende, teeragtige swart stoelgange (sien **"Neem spesiale sorg met IBUMAX COLD AND FLU"**).
  - o Ernstige maagpyn vergesel van verlies van eetlus, naarheid en braking, oor die algemeen siek voel, koors en kouekoors en opsetting van die maag (sien **"Neem spesiale sorg met IBUMAX COLD AND FLU"**).
  - o Geel verkleuring van die wit van die oë of vel (geelsug), naarheid en braking, verlies van eetlus, koors en pyn oor die lewerarea.
  - o Enige veluitslag met blase (sien **"Neem spesiale sorg met IBUMAX COLD AND FLU"**).
  - o Swelling van die voete, enkels, bene of hande vergesel van erge moegheid, kortasemheid en/of onvermoë om plat te lê as gevolg van kortasemheid.
  - o Onvermoë om te urineer, vloeistofretensie, lae rug- of flankpyn of passering van troebel of donker urine.
  - o Hoor of sien dinge wat nie werklik is nie.
  - o Hoofpyn met 'n stywe nek en naarheid of braking.
  - o Verlies van visie, dowwe visie of dubbele visie.
  - o Gehoorverlies of enige verandering in gehoor.
- Dié waarvan die frekwensie onbekend is:
  - o Borskaspyn.
  - o Bloed ophoes.
  - o Konvulsies (stuiptrekkings).
  - o Oogpyn.
  - o Lekkasie van urine.

U moet ophou om **IBUMAX COLD AND FLU** te neem en dit so gou moontlik aan u dokter meld indien u enige van die volgende newe-effekte ontwikkel:
- Dié wat minder dikwels voorkom:
  - o Hartkloppings, hoë bloeddruk.
  - o Verwarring.
  - o Spelde en naalde in die arms of bene of abnormale sensasie.
  - o Tranerige, rooi, droë, geïrriteerde of geswelde oë.
  - o Onverklaarbare neusbloedings.
  - o Sooibrand of suur-refluks wat progressief vererger, sere op die tandvleis of braking.
  - o Galbulte of jeuk of enige ander veluitslag, insluitende 'n veluitslag oor areas wat aan die son blootgestel word.
- Dié waarvan die frekwensie onbekend is:
  - o U voel asof u gedagtes en gevoelens onwerklik is of nie aan u behoort nie.
  - o Moeilike uitspraak van woorde.
  - o Skeelhoofpyn of erge hoofpyn, floutes, bewing of rukking, of ongewone swakheid.
  - o Veranderinge in kleurpersepsie (bv. alle voorwerpe vertoon 'n rooi of blouerige skynsel).
  - o Los stoelgange (diarree).
  - o Moeilike sluk, swelling van die tong, pynlike tong of inflammasie van die tong.
  - o Afskilfering van die vel.
  - o Spierswakheid.

Newe-effekte wat u aan u dokter moet meld indien dit voortduur of u begin pla:
- Dié wat dikwels voorkom:
  - o Duiseligheid.
- Dié wat minder dikwels voorkom:
  - o Verminderde eetlus of verlies van eetlus, dors of onverklaarbare gewigsverlies.
  - o Depressie, senuweeagtigheid of irritasie, sukkel om te slaap of onvermoë om te slaap, lomerigheid, angs of rusteloosheid.
  - o Loei of suising in die ore, lighoofdigheid of 'n sensasie van beweging terwyl u stilstaan.
  - o Blosing of warmgloede.
- Dié waarvan die frekwensie onbekend is:
  - o Gevoel van verwardheid of vergeetagtigheid.
  - o Bitter smaak of ander smaakveranderinge.
  - o Loslating of afsplyting van die naels of ander naelveranderinge.
  - o Vermeerderde sweet of sterk-ruikende urine.
  - o Spierkrampe of -pyn.
  - o Onverklaarbare, onverwagte en/of ongewone swaar menstruele bloeding.
  - o Swelling van die limfkliere.
  - o Algemene gevoel van ongemak of siekte.
  - o Oormatige speekselproduksie.

Meld asseblief enige ongewenste effekte aan wat u dink as gevolg van **IBUMAX COLD AND FLU** mag wees, veral indien dit nie in hierdie inligtingstuk vervat is nie.

BERGING EN WEGDOEN VAN IBUMAX COLD AND FLU:
STOOR ALLE MEDISYNE BUITE BEREIK VAN KINDERS.
Hou die stulpverpakte stroke in die buitenste karton totdat dit vir gebruik benodig word.
Berg teen of benede 25 °C.
Moenie **IBUMAX COLD AND FLU** tablette na die vervaldatum op die verpakkingsmateriaal gebruik nie.
Neem alle ongebruikte medisyne na u apteker terug.
Moenie ongebruikte medisyne in afvoerpype of rioolsisteme (bv. toilette) weggooi nie.

AANBIEDING VAN IBUMAX COLD AND FLU:
Kartonhouer met 12, 20 of 24 tablette in stulpverpakte stroke.

IDENTIFIKASIE VAN IBUMAX COLD AND FLU:
Oranje tot geel, gladde, filmbedekte, ronde, bikonkawe tablet.

REGISTRASIENOMMER:
40/5.8/0218

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE SERTIFIKAAT VAN REGISTRASIE:
CIPLA MEDPRO (EDMS) BPK
Gebou 9, Parc du Cap, Mispelstraat,
Bellville, 7530, RSA.

DATUM VAN PUBLIKASIE VAN HIERDIE INLIGTINGSTUK:
09 April 2014

CM530A/SA
7567
Pro-Print