

CIPLATON (Capsules)

Western herbal medicine – Combination product.

CIPLATON capsules have not been evaluated by the Medicines Control Council. **CIPLATON** capsules are not intended to diagnose, treat, cure or prevent any disease.

SCHEDULING STATUS:
Not scheduled.

PROPRIETARY NAME (AND DOSAGE FORM):
CIPLATON (Capsules).

COMPOSITION:
Each **CIPLATON** capsule contains:

ACTIVE INGREDIENT	QUANTITY
<i>Panax ginseng</i> root extract equivalent to <i>Panax ginseng</i> root powder	40 mg 200 mg
Vitamin A	1200 µg RE (4000 IU)
Vitamin B1	2 mg
Vitamin B2	2 mg
Nicotinamide	10 mg
Vitamin B6	1 mg
Folic acid	400 µg
Vitamin B12	1 µg
Pantothenic acid	10 mg
Vitamin C	60 mg
Vitamin D	10 µg (400 IU)
Vitamin E	10 mg α-TE
Calcium	103,5 mg
Copper	1 mg
Iron	10 mg
Magnesium	5 mg
Manganese	1 mg
Phosphorus	80 mg
Zinc	1 mg
Potassium	4 mg

Preservatives: Methyl parahydroxybenzoate 0,038 % w/w.
Propyl parahydroxybenzoate 0,013 % w/w.

Inactive ingredients are antifoam M, beeswax, butylated hydroxyanisole, gelatine, glycerine, hardened unsaturated oil, iron oxide black, lecithin, purified water, sodium calcium edetate, sorbitol and sunflower seed oil.

CIPLATON capsules contain sugar (sorbitol).

PHARMACOLOGICAL CLASSIFICATION:
D 22.2 Vitamins. Other.

PHARMACOLOGICAL ACTION:
Pharmacodynamic properties:

The combination of the active ingredients contained in this formulation exerts a stimulant effect at both physical and psychological levels through its action on the body's basic metabolic processes.

The ginseng extract raises the overall level of cellular activity, which is evident from a pronounced increase in mental and physical capacity. More than 200 constituents in ginseng root have been identified to date.

In situations of increased demands, the vitamins, minerals and trace elements rectify and prevent impairment of cell metabolism. Insufficient dietary intake of vitamins, minerals, and trace elements can cause disturbances, such as weakness, tiredness, decrease in vitality, reduced force of resistance, and slow recovery.

Pharmacokinetic properties:
The active ingredients in this formulation are well known. Pharmacokinetic studies have not been conducted due to its complex composition and the small quantities of the active ingredients it contains.

INDICATIONS:
CIPLATON capsules are indicated to support energy levels, relieve short-term tiredness and exhaustion, and to improve general health. *Panax ginseng* has been used in traditional Chinese medicine for more than 2000 years amongst others to enhance physical performance, reduce fatigue and to improve overall quality of life.

CONTRAINDICATIONS:
CIPLATON capsules are contraindicated in patients with:

- A hypersensitivity to any of the ingredients in **CIPLATON** capsules.
- A hypersensitivity to soya.
- Disturbances of calcium metabolism (e.g. hypercalcaemia and hypercalcauria).
- Hypervitaminosis A or D.
- Renal insufficiency.
- Concomitant therapy with retinoids (e.g. against acne) or vitamin D (see “**INTERACTIONS**”).
- Haemochromatosis or iron overload syndrome (see “**WARNINGS AND SPECIAL PRECAUTIONS**”).

WARNINGS AND SPECIAL PRECAUTIONS:
CIPLATON capsules should be used with care in patients with a family history of haemochromatosis (see “**CONTRAINDICATIONS**”).

CIPLATON capsules should be used with care in patients suffering from insomnia or hypertension (see “**SIDE-EFFECTS**”).

CIPLATON capsules contain iron. Keep out of the reach and sight of children, as overdose can be fatal (see “**KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT**”).

When starting or stopping treatment with ginseng containing products, including **CIPLATON** capsules, patients taking warfarin (or other coumarin anticoagulants) should have increased monitoring of their INR (International Normalised Ratio) levels (see “**INTERACTIONS**”).

The use of *Panax ginseng*, as in **CIPLATON** capsules, in children and adolescents under 18 years of age is not recommended due to lack of adequate data (see “**DOSAGE AND DIRECTIONS FOR USE**”).

Vitamins or minerals obtained from other sources should be taken into consideration when taking **CIPLATON** capsules.

Effects on the ability to drive or use machinery:

No studies on the effect of **CIPLATON** capsules on the ability to drive or operate machines have been performed. It is unlikely that **CIPLATON** capsules will affect the ability to drive or operate machines.

CIPLATON capsules contain sorbitol and may have a laxative effect. Patients with the rare hereditary condition of sorbitol intolerance should not take **CIPLATON** capsules.

INTERACTIONS:

The vitamins and minerals in **CIPLATON** capsules are known to interact with the following medicines:

- Bisphosphonates: iron, magnesium and calcium can decrease absorption.
- Levodopa: iron can decrease absorption. Vitamin B6 can enhance metabolism.
- Levothyroxine: iron and calcium can decrease absorption.
- Methyldopa: iron can decrease absorption.
- Penicillamine: iron, zinc and copper can decrease absorption.
- Quinolone antibiotics: iron, magnesium, calcium, zinc and manganese can decrease absorption.
- Tetracycline antibiotics: iron, magnesium, calcium, zinc and manganese can decrease absorption.

Advise patients to take any of the above mentioned medicines at least 2 hours before or after **CIPLATON** capsules.

Calcium, as in **CIPLATON** capsules, can decrease absorption of sotalol. Advise patients to take sotalol at least 2 hours before or 4 to 6 hours after **CIPLATON** capsules.

Iron, as in **CIPLATON** capsules, can decrease absorption of mycophenolate mofetil and patients should be advised to take it 4 to 6 hours before or 2 hours after **CIPLATON** capsules.

Folic acid, as in **CIPLATON** capsules, may reduce the efficacy of methotrexate in the treatment of acute lymphoblastic leukaemia and other cancers. Advise cancer patients to consult their oncologist before using **CIPLATON** capsules.

Panax ginseng, as in **CIPLATON** capsules, may have immune system stimulating properties. Patients taking immunosuppressive medicines should use **CIPLATON** capsules with caution.

Folic acid, as in **CIPLATON** capsules, can have direct convulsant activity in some people. Patients taking phenobarbital or primidone should be monitored closely for increased seizure activity.

Folic acid, as in **CIPLATON** capsules, can antagonise the antiparasitic effects of pyrimethamine against toxoplasmosis and *Pneumocystis carinii* pneumonia. Patients taking pyrimethamine should avoid taking **CIPLATON** capsules.

Vitamin D, as in **CIPLATON** capsules, may induce the cytochrome P450 3A4 (CYP3A4) enzymes, resulting in a reduced bioavailability of atorvastatin and other CYP3A4 substrates. Advise patients to use **CIPLATON** capsules cautiously if they take medicines metabolised by CYP3A4. Some medicines metabolised by CYP3A4 include lovastatin, clarithromycin, ciclosporin, diltiazem, oestrogens, indinavir and triazolam.

There is some evidence that *Panax ginseng*, as in **CIPLATON** capsules, can inhibit the cytochrome P450 2D6 (CYP2D6) enzyme. Patients taking medicines metabolised by this enzyme should use **CIPLATON** capsules cautiously. Some of these medicines include amitriptyline, clozapine, codeine, desipramine, donepezil, ferlantini, flecainide, fluoxetine, meperidine (pethidine), methadone, metoprolol, clanzapine, ondansetron, tramadol and trazodone.

Thiazide diuretics decrease urinary calcium excretion, which could lead to hypercalcaemia if vitamin D, as in **CIPLATON** capsules, are taken concurrently. Advise patients to use **CIPLATON** capsules cautiously and monitor serum calcium levels if they take thiazides.

Panax ginseng, as in **CIPLATON** capsules, may potentially reduce the effect of oral anticoagulants (e.g. warfarin) when taken in conjunction. Patients taking anticoagulants or antiplatelet medicines should have their INR levels monitored more frequently when taking **CIPLATON** capsules (see “**WARNINGS AND SPECIAL PRECAUTIONS**”).

Theoretically, *Panax ginseng*, as in **CIPLATON** capsules, may enhance the blood glucose lowering effects of anti-diabetic medicines. Patients on anti-diabetic medicines should monitor their glucose levels closely when taking **CIPLATON** capsules.

Theoretically, *Panax ginseng*, as in **CIPLATON** capsules, can interfere with MAOI therapy. Patients taking MAOI's should use **CIPLATON** capsules with caution.

Panax ginseng, as in **CIPLATON** capsules, can have an additive effect when used in combination with other stimulants. Patients taking stimulants should use **CIPLATON** capsules with caution.

Taking **CIPLATON** capsules with retinoids, vitamin A or vitamin D can contribute to the development of hypervitaminosis A or D (see “**CONTRAINDICATIONS**”).

PREGNANCY AND LACTATION:

The safety and efficacy of **CIPLATON** capsules during pregnancy and lactation have not been established. **CIPLATON** capsules should therefore not be taken during pregnancy and lactation.

DOSAGE AND DIRECTIONS FOR USE:

The recommended daily dosage should not be exceeded.

Adults (18 years and older):

Take 1 capsule daily with breakfast.

Children (under 18 years of age):

Not recommended for use (see “**WARNINGS AND SPECIAL PRECAUTIONS**”).

CIPLATON capsules are recommended for a treatment period of 4 weeks to treat short-term tiredness and exhaustion. If symptoms have not improved after 4 weeks, advise patients to consult a healthcare practitioner.

CIPLATON capsules may be taken for a period of up to 12 weeks.

SIDE-EFFECTS:

The following side-effects may occur with the use of **CIPLATON** capsules:

Immune system disorders:

Frequency unknown: Hypersensitivity reactions, including urticaria and pruritus.

Psychiatric disorders:

Frequency unknown: Insomnia, euphoria (see “**WARNINGS AND SPECIAL PRECAUTIONS**”).

Nervous system disorders:

Frequent: Headache.

Frequency unknown: Dizziness, nervousness.

Vascular disorders:

Frequency unknown: Hypertension, oedema (see “**WARNINGS AND SPECIAL PRECAUTIONS**”).

Gastrointestinal disorders:

Frequent: Nausea, vomiting.

Less frequent: Diarrhoea.

Frequency unknown: Abdominal pain, stomach discomfort, constipation.

Skin and subcutaneous tissue disorders:

Frequency unknown: Rash, pruritus.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

The following symptoms may be experienced in the event of an overdose: Nervousness, nausea, vomiting, diarrhoea, abdominal pain, haemetemesis, rectal bleeding, lethargy and circulatory collapse. Hyperglycaemia and metabolic acidosis can also occur.

The toxicity of **CIPLATON** capsules in large overdoses is caused by the toxicity of the liposoluble vitamins A and D. Prolonged intake of large amounts (corresponding to 25 capsules for Vitamin A and 5 capsules for Vitamin D) can cause symptoms of chronic toxicity, such as vomiting, headache, drowsiness and diarrhoea. Acute toxic symptoms are only seen at even higher doses.

Serious acute iron toxicity has been reported from doses of 168 mg iron (corresponding to 16 capsules) per day and more (see “**WARNINGS AND SPECIAL PRECAUTIONS**”).

The following treatment is suggested to minimise or prevent further absorption of the active ingredients in **CIPLATON** capsules:

- Induce vomiting e.g. by administration of an emetic.
- In cases of severe poisoning, shock and/or coma with high iron levels (serum iron > 90 µmol/l in children, > 142 µmol/l in adults) can occur and can be treated as follows:
- Immediate supportive measures plus intravenous infusion of desferrioxamine.

In cases of less severe poisoning:

- Intramuscular desferrioxamine is recommended (1 g, 4 - 6 hourly in children; 50 mg/kg up to a maximum dose of 4 g in adults).

IDENTIFICATION:

An oblong, black, soft gelatine capsule.

PRESENTATION:

Blister strips of 10 capsules each packed in an outer carton of 30 or 60 capsules.

STORAGE INSTRUCTIONS:

Store at or below 25 °C in a dry place.

Protect from light.

KEEP OUT OF REACH OF CHILDREN.

Keep the blisters in the outer carton until required for use.

NAME AND BUSINESS ADDRESS OF THE HOLDER OF CERTIFICATE OF REGISTRATION:

CIPLA MEDPRO (PTY) LTD
Building 9
Parc du Cap
Mispel Street
Bellville
7530
RSA

DATE OF PUBLICATION OF THIS PACKAGE INSERT:

April 2017.

PATIENT INFORMATION LEAFLET Information for the Patient about CIPLATON (Capsules)

Western herbal medicine – Combination product.

CIPLATON capsules have not been evaluated by the Medicines Control Council. **CIPLATON** capsules are not intended to diagnose, treat, cure or prevent any disease.

SCHEDULING STATUS:
Not scheduled.

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:
CIPLATON (Capsules).

COMPOSITION:
Each **CIPLATON** capsule contains:

ACTIVE INGREDIENT	QUANTITY
<i>Panax ginseng</i> root extract equivalent to <i>Panax ginseng</i> root powder	40 mg 200 mg
Vitamin A	1200 µg RE (4000 IU)
Vitamin B1	2 mg
Vitamin B2	2 mg
Nicotinamide	10 mg
Vitamin B6	1 mg
Folic acid	400 µg
Vitamin B12	1 µg
Pantothenic acid	10 mg
Vitamin C	60 mg
Vitamin D	10 µg (400 IU)
Vitamin E	10 mg α-TE
Calcium	103,5 mg
Copper	1 mg
Iron	10 mg
Magnesium	5 mg
Manganese	1 mg
Phosphorus	80 mg
Zinc	1 mg
Potassium	4 mg

Preservatives: Methyl parahydroxybenzoate 0,038 % w/w.
Propyl parahydroxybenzoate 0,013 % w/w.

Inactive ingredients are antifoam M, beeswax, butylated hydroxyanisole, gelatine, glycerine, hardened unsaturated oil, iron oxide black, lecithin, purified water, sodium calcium edetate, sorbitol and sunflower seed oil.

CIPLATON capsules contain sugar (sorbitol).

PHARMACOLOGICAL CLASSIFICATION:
D 22.2 Vitamins. Other.

PHARMACOLOGICAL ACTION:
Pharmacodynamic properties:

The combination of the active ingredients contained in this formulation exerts a stimulant effect at both physical and psychological levels through its action on the body's basic metabolic processes.

The ginseng extract raises the overall level of cellular activity, which is evident from a pronounced increase in mental and physical capacity. More than 200 constituents in ginseng root have been identified to date.

In situations of increased demands, the vitamins, minerals and trace elements rectify and prevent impairment of cell metabolism. Insufficient dietary intake of vitamins, minerals, and trace elements can cause disturbances, such as weakness, tiredness, decrease in vitality, reduced force of resistance, and slow recovery.

Pharmacokinetic properties:
The active ingredients in this formulation are well known. Pharmacokinetic studies have not been conducted due to its complex composition and the small quantities of the active ingredients it contains.

INDICATIONS:
CIPLATON capsules are indicated to support energy levels, relieve short-term tiredness and exhaustion, and to improve general health. *Panax ginseng* has been used in traditional Chinese medicine for more than 2000 years amongst others to enhance physical performance, reduce fatigue and to improve overall quality of life.

CONTRAINDICATIONS:
CIPLATON capsules are contraindicated in patients with:

- A hypersensitivity to any of the ingredients in **CIPLATON** capsules.
- A hypersensitivity to soya.
- Disturbances of calcium metabolism (e.g. hypercalcaemia and hypercalcauria).
- Hypervitaminosis A or D.
- Renal insufficiency.
- Concomitant therapy with retinoids (e.g. against acne) or vitamin D (see “**INTERACTIONS**”).
- Haemochromatosis or iron overload syndrome (see “**WARNINGS AND SPECIAL PRECAUTIONS**”).

WARNINGS AND SPECIAL PRECAUTIONS:
CIPLATON capsules should be used with care in patients with a family history of haemochromatosis (see “**CONTRAINDICATIONS**”).

CIPLATON capsules should be used with care in patients suffering from insomnia or hypertension (see “**SIDE-EFFECTS**”).

CIPLATON capsules contain iron. Keep out of the reach and sight of children, as overdose may cause death (see “**KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT**”).

When starting or stopping treatment with ginseng containing products, including **CIPLATON** capsules, patients taking warfarin (or other coumarin anticoagulants) should have increased monitoring of their INR (International Normalised Ratio) levels (see “**INTERACTIONS**”).

The use of *Panax ginseng*, as in **CIPLATON** capsules, in children and young people under 18 years of age is not recommended (see “**HOW TO TAKE CIPLATON CAPSULES**”).

Vitamins or minerals can be obtained from other sources, e.g. daily diet and other supplements. Please take this into consideration when taking **CIPLATON** capsules.

Taking CIPLATON capsules with food and drink:
CIPLATON capsules should be taken with meals.

Pregnancy and breastfeeding:
Safety of **CIPLATON** capsules during pregnancy and breastfeeding has not been established. Avoid taking **CIPLATON** capsules if you are pregnant or breastfeeding your baby.

Driving and using machinery:

No studies on the effect on the ability to drive and use machinery have been performed. It is unlikely that **CIPLATON** capsules will impair your ability to drive or use machines. However, please exercise care when driving or operating machinery until you know how **CIPLATON** capsules affects you.

Important information about some of the ingredients of CIPLATON capsules:
CIPLATON capsules may contain soya. You should not take **CIPLATON** capsules if you are allergic to soya.

CIPLATON capsules contain sorbitol and may have a laxative effect. If you have been told that you have an intolerance to some sugars, you should not take **CIPLATON** capsules.

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

Please discuss the use of the following medicines in combination with **CIPLATON** capsules with your doctor or pharmacist:

- Bisphosphonates such as alendronate and risedronate, for the treatment of osteoporosis (low bone mineral density resulting in bones that are brittle and easily fracture).
- Levodopa for the treatment of Parkinson's disease.
- Levothyroxine for the treatment of under active thyroid gland.
- Methyldopa for the treatment of high blood pressure.
- Penicillamine for the treatment of rheumatoid arthritis.
- Quinolone antibiotics such as ciprofloxacin, levofloxacin and moxifloxacin.
- Tetracycline antibiotics such as doxycycline and minocycline.
- Thiazide diuretics (“water tablets”) such as hydrochlorothiazide and indapamide since their use in combination with **CIPLATON** capsules can lead to abnormally high calcium levels.
- Warfarin or other blood thinning medicines. **CIPLATON** capsules may potentially reduce the effect of blood thinning medicines. You may have to arrange increased monitoring of your INR levels when taking **CIPLATON** capsules (see “**Take special care with CIPLATON capsules**”).
- Antidiabetic medicines (such as insulin, glimepiride and pioglitazone) as **CIPLATON** capsules may further lower blood sugar levels. Monitor your blood glucose / sugar levels regularly if you are using **CIPLATON** capsules and antidiabetic medicines in combination.
- MAOI's (monoamine oxidase inhibitors) such as moclobemide.
- Medicines with a stimulant effect such as caffeine.
- Retinoids (Vitamin A derived medicines) used for the treatment of acne, such as isotretinoin and tretinoin, vitamin A or vitamin D (see “**DO NOT TAKE CIPLATON CAPSULES**”).
- Medicines which are broken down by the liver as **CIPLATON** capsules can influence the absorption and effectiveness of these medicines. Please discuss the use of **CIPLATON** capsules in combination with any other medicines with your doctor or pharmacist.

HOW TO TAKE CIPLATON CAPSULES:

Always take CIPLATON capsules exactly as directed. You should check with your pharmacist if you are unsure. DO NOT EXCEED THE RECOMMENDED DAILY DOSAGE.

Adults (18 years and older):

Take 1 capsule daily with breakfast.

Children (under 18 years of age):

Not recommended for use (see “**Take special care with CIPLATON capsules**”).

Take **CIPLATON** capsules for a period of 4 weeks to treat short-term tiredness and exhaustion. If your symptoms have not improved after 4 weeks, consult a healthcare practitioner.

CIPLATON capsules may be taken for a period of up to 12 weeks.

If you take more CIPLATON capsules than you should:

If you take more **CIPLATON** capsules than you should, you may experience nervousness, nausea, vomiting, diarrhoea (loose stools), stomach pain and a lack of energy. More severe symptoms may be experienced at very high doses (16 capsules and more) due to the iron content (see “**Take special care with CIPLATON capsules**”). **In the event of overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.**

If you forget to take CIPLATON capsules:

Always take **CIPLATON** capsules as directed. If you miss a dose, take it as soon as you remember. If you do not remember the missed dose until the next dose is due, skip the missed dose and go back to your regular dosing schedule of one capsule per day. Do not take a double dose to make up for forgotten individual doses.

POSSIBLE SIDE-EFFECTS:

CIPLATON capsules may have side-effects.

Not all side-effects reported for CIPLATON capsules are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking CIPLATON capsules, please consult your doctor, pharmacist or other healthcare professional for advice.

Serious side-effects that you (or a family member if you are unable to) should report to your doctor immediately include:

- An allergic reaction possibly presenting with shortness of breath / difficult breathing, wheezing, hives, or itching, swelling of the face, tongue, or whole body, lightness of the chest.

Side-effects that you should report to your doctor as soon as possible:

- High blood pressure (see “**Take special care with CIPLATON capsules**”).
- Swollen feet and ankles.

Side-effects that you should report to your doctor or pharmacist if they continue or become bothersome include:

- Headache, dizziness, nervousness, sleeplessness or an intense feeling of well-being (see “**Take special care with CIPLATON capsules**”).
- Gastrointestinal disturbances, such as:
 - Stomach discomfort, stomach pain, diarrhoea / loose stools, constipation, nausea and vomiting.

If you notice any side-effects not mentioned in this leaflet, please inform your doctor or pharmacist.

STORING AND DISPOSING OF CIPLATON CAPSULES:

Store at or below 25 °C in a dry place.
Protect from light. Keep the blisters in the outer carton until required for use.
Do not take the capsules after the expiry date stated on the packaging material. Return all unused capsules to your pharmacist.
Do not dispose of unused capsules in drains or sewerage systems (e.g. toilets).
STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

PRESENTATION OF CIPLATON CAPSULES:

Blister strips of 10 capsules each packed in an outer carton of 30 or 60 capsules.

IDENTIFICATION OF CIPLATON CAPSULES:

An oblong, black, soft gelatine capsule.

NAME AND BUSINESS ADDRESS OF THE REGISTRATION HOLDER:

CIPLA MEDPRO (PTY) LTD
Building 9
Parc du Cap
Mispel Street
Bellville
7530
RSA

DATE OF PUBLICATION OF THIS PATIENT INFORMATION LEAFLET:

April 2017.