SKEDULERINGSTATUS
Ongeskeduleerd

EIENDOMSNAAM (EN DOSEERVORM)

Lacteol Forte
Kapsules en Sakkies

SAMESTELLING
Gevriesdroogde dooie mikrobe selle van Lactobacillus LB*:
Kapsules: 5 biljoen mikrobe selle per kapsule
Sakkies: 10 biljoen mikrobe selle per sakkie

*Bestaande uit: *Lactobacillus delbrueckii* en *Lactobacillus fermentum*.

FARMAKOLOGIESE KLASSIFIKASIE
A 32 Ander - Supplemente

FARMAKOLOGIESE WERKING
In vitro eksperimentele studies het getoon dat die dooie mikrobiese liggame beskryf as Lactobacillus LB* vasheg aan die oppervlakte van die intestinale selle en die intestinale flora sodoende normaliseer deur kompeterende uitsluiting. Deur in te meng met die intestinale vashegting van ander mikro-organismes word oor-kolonisasie van hierdie organismes verhoed.

LACTEOL FORTE is nie-toksies en geen newe-effekte of interaksies met ander medisyne is aangemeld nie.

INDIKASIES
LACTEOL FORTE is supplemente vir gebruik as deel van 'n voorgeskrewe dieet om intestinale mikrobiese wanbalanse te normaliseer.

INTERAKSIES
LACTEOL FORTE is nie-toksies en geen newe-effekte of interaksies met ander medisyne is aangemeld nie.

SWANGERSKAP EN LAKTASIE
Alhoewel LACTEOL FORTE dooie mikrobiese liggame bevat, beskryf as Lactobacillus LB*, en nie geabsorbeer word vanuit die spysverteringskanaal nie, is veiligheid gedurende swangerskap en laktasie nog nie bewys nie.

KONTRA-INDIKASIES
Geen.

WAARSKUWING
Dit is belangrik dat LACTEOL FORTE aangevul word met rehidrasie terapie (bv. ELECTROPAK FRAMBOOSGEGEURDE POEIER VIR OPLOSSING) waar dehidrasie vermoed word, veral by klein kinders en bejaardes.

DOSIS EN GEBRUIKSAANWYSINGS

EERSTE DAG				
	1ste DOSIS		2de DOSIS	
	KAPSULES	SAKKIES	KAPSULES	SAKKIES
KINDERS 12 jaar en jonger	2	1 – 2	2	1
VOLWASSENES (> 12 jaar)	4	2	2	1
OPVOLGENDE DAE				
	1ste DOSIS		2de DOSIS	
	KAPSULES	SAKKIES	KAPSULES	SAKKIES
KINDERS 12 jaar en jonger	2	1	2	1
VOLWASSENES (>12 jaar)	2	1	2	1

DIE INHOUD VAN DIE KAPSULE KAN OOK MET WATER GEMENG WORD INDIEN SO VERKIES.

Die kapsule moet met 'n bietjie water afgesluk word.
Die inhoud van die sakkie kan in 'n klein bietjie water (30 – 50 ml) opgelos en afgesluk word of, in die geval van babas, in 'n bababottel aangebied word. Die poeier van die sakkies kan ook droog ingesluk word.

NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREËLS
Geen.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN
LACTEOL FORTE word nie sistemies geabsorbeer nie en is nie-toksies nie.

VOORWAARDES VAN REGISTRASIE
Geen.

IDENTIFIKASIE
Kapsules: Wit, opaak, grootte 2 harde gelatien kapsules. Die inhoud bestaan uit 'n room- tot geel gekleurde poeier.
Sakkies: Aluminium/papier gelamineerde sakkies met lemoen/piesang gegeurde, room- tot geel gekleurde poeier.

AANBIEDING
Kapsules: Aluminium-gelamineerde stroke kapsules – 12 kapsules per karton.
Sakkies: Kartonne met 10 sakkies.

BERGINGSAANWYSINGS
Bewaar in 'n koel, droë plek, benede 25 °C.

REGISTRASIENOMMER (OF VERWYSINGSNOMMER)
Kapsules: 003621
Sakkies: 003620

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE REGISTRASIESERTIFIKAAT
Mirren (Edms) Bpk
18 Goldenrylaan
Morehill
Benoni
1501
Suid-Afrika

'N PRODUK VAN:
Aptalis Pharma Canada Inc.
597 Sir-Wilfrid-Laurier Boulevard
Mont-Saint-Hilaire
Quebec
Kanada J3H 6C4

DATUM VAN PUBLIKASIE VAN HIERDIE VOUBILJET
01 Februarie 2006

Hierdie medisyne is nog nie geëvalueer deur die Medisynebeheerraad nie. Hierdie medisyne is nie bedoel om enige siekte te diagnoseer, te behandel, te genees of te voorkom nie.

LF-PI-PR-15/02
Pro-Print

SCHEDULING STATUS
Unscheduled

PROPRIETARY NAME (AND DOSAGE FORM)

Lacteol Forte
Capsules en Sachets

COMPOSITION
Lyophilizate of killed Lactobacillus LB* equivalent to:
Capsules: 5 billion microbial cells per capsule
Sachets: 10 billion microbial cells per sachet

*Corresponding to *Lactobacillus delbrueckii* and *Lactobacillus fermentum*.

PHARMACOLOGICAL CLASSIFICATION
A 32 Other – Nutritional supplement

PHARMACOLOGICAL ACTION
In vitro experimental studies have shown that the dead microbial bodies described as Lactobacillus LB* adhere to the surface of intestinal cells and normalise the intestinal flora by competitive exclusion. By interfering with the intestinal adherence of other micro-organisms, over-colonisation of these organisms is prevented.

LACTEOL FORTE is non-toxic and no adverse effects or incompatibilities with other medications have been reported.

INDICATIONS
LACTEOL FORTE is a dietary supplement to be used as part of a prescribed diet to assist in the normalisation of intestinal microbiological imbalances.

INTERACTIONS
LACTEOL FORTE is non-toxic and no adverse effects or incompatibilities with other medications have been reported.

PREGNANCY AND LACTATION
Although LACTEOL FORTE contains dead microbial bodies described as Lactobacillus LB* and are not absorbed from the gastro-intestinal tract, safety during pregnancy and lactation has not been established.

CONTRA-INDICATIONS
None.

WARNINGS
It is important that LACTEOL FORTE should be supplemented with re-hydration therapy (e.g. ELECTROPAK RASPBERRY FLAVOURED POWDER FOR SOLUTION) where dehydration is suspected, especially in small children and the aged.

DOSAGE AND DIRECTIONS FOR USE

FIRST DAY				
	1st DOSE		2nd DOSE	
	CAPSULES	SACHETS	CAPSULES	SACHETS
CHILDREN 12 years and younger	2	1 – 2	2	1
ADULTS (> 12 years)	4	2	2	1
FOLLOWING DAYS				
	1st DOSE		2nd DOSE	
	CAPSULES	SACHETS	CAPSULES	SACHETS
CHILDREN 12 years and younger	2	1	2	1
ADULTS (>12 years)	2	1	2	1

THE CONTENTS OF THE CAPSULE MAY ALSO BE MIXED WITH WATER IF SO WISHED.

The capsule should be swallowed with a little water.
The contents of the sachet can be dissolved in a little water (30 – 50 ml) and swallowed or, in the case of infants, given in a feeding bottle. The powder from the sachet can also be swallowed dry.

SIDE EFFECTS AND SPECIAL PRECAUTIONS
None.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT
LACTEOL FORTE is not systemically absorbed and is non-toxic.

CONDITIONS OF REGISTRATION
None.

IDENTIFICATION
Capsules: White opaque, size 2 hard gelatine capsules. The contents consist of a cream to yellow coloured powder.
Sachets: Aluminium/paper laminated sachets containing orange/banana flavoured, cream to yellow-coloured powder.

PRESENTATION
Capsules: Aluminium-laminated strips of capsules –
12 capsules per carton.
Sachets: Cartons containing 10 sachets.

STORAGE INSTRUCTIONS
Store in a cool, dry place, below 25 °C.

REGISTRATION NUMBER (OR REFERENCE NUMBER)
Capsules: 003621
Sachets: 003620

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION
Mirren (Pty) Ltd
18 Golden Drive
Morehill
Benoni
1501
South Africa

A PRODUCT OF:
Aptalis Pharma Canada Inc.
597 Sir-Wilfrid-Laurier Boulevard
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DATE OF PUBLICATION OF THIS PACKAGE INSERT
01 February 2006

This medicine has not been evaluated by the Medicines Control Council. This medicine is not intended to diagnose, treat, cure or prevent any disease.