SCHEDULING STATUS: **S0**

PROPRIETARY NAME: **PHIPP'S ® MILK OF MAGNESIA**
PHIPP'S ® MILK OF MAGNESIA - TUTTI FRUTTI FLAVOUR
(AND DOSAGE FORM) **(SUSPENSION)**

COMPOSITION:
Each 5 ml contains 425 mg magnesium hydroxide
Sugar free

PHARMACOLOGICAL CLASSIFICATION:
A 11 Medicines acting on the gastrointestinal tract

PHARMACOLOGICAL ACTION:
In smaller doses magnesium hydroxide has acid neutralising properties and diminishes the activity of pepsin in gastric secretion. In larger doses it acts as a saline laxative by osmotic action.

INDICATIONS:
Antacid: For the relief of acid indigestion, heartburn, hyperacidity, dyspepsia, gastritis, oesophageal reflux with heartburn and peptic ulceration.
Laxative: For the relief of occasional constipation.

CONTRAINDICATIONS:
Should not be used in patients with impaired renal function as it may lead to hypermagnesaemia (see **'KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT')**
Contraindicated in alkalosis.
Hypersensitivity to any of the ingredients.

WARNINGS:
Do not use this product if you have kidney disease, except under the advice and supervision of a doctor.
Do not use this product as a laxative in the presence of abdominal pain, nausea or vomiting. Frequent or prolonged use of this preparation as a laxative may result in dependence on laxatives and loss of normal bowel function.
If you have noticed a sudden change in bowel habits that has persisted for a period longer than 2 weeks, consult a doctor before using the laxative.
Rectal bleeding or failure to have a bowel movement after use of a laxative may indicate a serious condition. Discontinue use and consult a doctor.
Contains the following number of mmol of magnesium in the maximum daily antacid or laxative doses:
Antacid: Adults and children over 12 years: 87,36 mmol magnesium (per 60 ml)

Laxative:	Adults and children over 12 years:	87,36 mmol magnesium (per 60 ml)
	Children: 6 to 11 years:	43,68 mmol magnesium (per 30 ml)
	2 to 5 years:	21,84 mmol magnesium (per 15 ml)
	Under 2 years:	0,728 mmol magnesium (per 0,5 ml/kg/dose)

DOSAGE AND DIRECTIONS FOR USE:

Antacid: Adults and children over 12 years: 1 to 3 medicine measures (5 to 15 ml) with a little water up to 4 times a day, or as directed by a doctor.

Do not take more than the maximum recommended daily dose in a 24 hour period or use the maximum dosage for more than 2 weeks except under the advice and supervision of a doctor.

Laxative: The following dosages may be administered as a single dose at bedtime or upon rising followed by a full glass of water. Bowel movement is produced in half an hour to six hours.

Adults and children over 12 years: 6 to 12 medicine measures (30 to 60 ml)

Children: 6 to 11 years: 3 to 6 medicine measures (15 to 30 ml)

2 to 5 years: 1 to 3 medicine measures (5 to 15 ml)

Under 2 years: 0,5 ml per kg per dose or as recommended by a doctor.

Do not use as a laxative for a period longer than one week unless directed by a doctor.

SIDE EFFECTS AND SPECIAL PRECAUTIONS:

Magnesium hydroxide may cause diarrhoea. Hypermagnesaemia may occur if renal function is impaired. This product may interfere with the absorption of other medicines if taken concomitantly.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

See "**SIDE EFFECTS AND SPECIAL PRECAUTIONS**" above.

Gastrointestinal irritation and watery diarrhoea. Hypermagnesaemia, important signs of which are loss of deep tendon reflexes and respiratory depression, both due to neuromuscular blockade.

Other symptoms of hypermagnesaemia may include nausea, vomiting, flushing of the skin, thirst, hypotension due to peripheral vasodilatation, drowsiness, confusion, muscle weakness, bradycardia, coma and cardiac arrest.

Treatment is symptomatic and supportive. In case of suspected overdosage consult a doctor or take the patient to the nearest hospital immediately.

IDENTIFICATION:

PHIPP'S MILK OF MAGNESIA: A smooth, white, opaque, viscous suspension. Practically odourless and with a bland taste.

PHIPP'S MILK OF MAGNESIA - TUTTI FRUTTI FLAVOUR: A smooth, pink, opaque, viscous suspension. Odour and taste characteristic of tutti frutti.

PRESENTATION:

100 ml and 350 ml in blue PVC or HDPE bottles.

STORAGE INSTRUCTIONS:

Store at or below 25 °C in well-closed containers. Do not freeze.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

PHIPP'S MILK OF MAGNESIA: E/11/628

PHIPP'S MILK OF MAGNESIA - TUTTI FRUTTI FLAVOUR: 35/11/0047

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

Tiger Consumer Brands

2 Purlin Street

Isando

Kempton Park

1600

DATE OF PUBLICATION OF THIS PACKAGE INSERT:

PHIPP'S MILK OF MAGNESIA: October 3, 1995

PHIPP'S MILK OF MAGNESIA TUTTI FRUTTI FLAVOUR: May 21, 2002

SKEDULERINGSTATUS: **S0**

EIENDOMSNAAM: **PHIPP'S® MILK OF MAGNESIA**
PHIPP'S® MILK OF MAGNESIA - TUTTI FRUTTI FLAVOUR
(EN DOSEERVORM) **(SUSPENSIE)**

SAMESTELLING:
Elke 5 ml bevat 425 mg magnesiumhidroksied
Suikervry

FARMAKOLOGIESE KLASSIFIKASIE:
A 11 Medisyne wat op die maagdermkanaal werk

FARMAKOLOGIESE WERKING:
Magnesiumhidroksied beskik oor suur-neutraliserende eienskappe in kleiner dosisse en verminder die aktiwiteit van pepsien in maagsappe. In groter dosisse tree dit op as 'n soutlakseermiddel deur osmotiese werking.

INDIKASIES:
Teensuurmiddel: Vir die verligting van suurindigestie, sooibrand, oormaat suur, swak spysvertering, maagontsteking, slukdermrefluks met sooibrand en maagrouseervorming.
Lakseermiddel: Vir die verligting van toevallige hardlywigheid.

KONTRA-INDIKASIES:
Moet nie gebruik word by pasiënte met belemmerde nierfunksie nie, aangesien dit kan lei tot oormaatbloedmagnesium (sien **'BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN'**).
Teenaangedui in alkalose.
Hipersensitiwiteit teenoor enige van die bestanddele.

WAARSKUWINGS:
Moet nie hierdie produk gebruik indien u aan niersiekte ly nie, behalwe op aanbeveling en onder toesig van 'n geneesheer.
Moet nie hierdie produk gebruik as 'n lakseermiddel in die teenwoordigheid van maagpyn, naarheid of vomering nie. Gereelde of langdurige gebruik van hierdie medisyne as 'n lakseermiddel kan lei tot die afhanklikheid van lakseermiddels.
Indien 'n skielike verandering in maagdermgewoontes opgemerk word wat langer as 2 weke duur, moet 'n geneesheer geraadpleeg word, voordat die lakseermiddel gebruik word.
Rektale bloeding of die onvermoë om te ontlas na die gebruik van 'n lakseermiddel kan 'n ernstige toestand aandui. Staak die gebruik daarvan en raadpleeg 'n geneesheer.

Bevat die volgende getal mmol van magnesium in die maksimum daaglikse teensuur-, of lakseerdosis:
Teensuurmiddel: Volwassenes en kinders ouer as 12 jaar: 87,36 mmol magnesium (per 60 ml).
Lakseermiddel: Volwassenes en kinders ouer as 12 jaar: 87,36 mmol magnesium (per 60 ml).
Kinders: 6 tot 11 jaar: 43,68 mmol magnesium (per 30 ml)
2 tot 5 jaar: 21,84 mmol magnesium (per 15 ml)
Onder 2 jaar: 0,728 mmol magnesium (per 0,5 ml/ kg/dosis).

DOSIS EN GEBRUIKAANWYSINGS:
Teensuurmiddel: Volwassenes en kinders ouer as 12 jaar: 1 tot 3 medisynemate (5 tot 15 ml) met 'n bietjie water, tot 4 keer per dag of soos aanbeveel deur 'n geneesheer.
Moet nie meer as die maksimum voorgeskrewe daaglikse dosis in 24 uur oorskry nie of die maksimum dosis vir langer as 2 weke gebruik nie, behalwe op aanbeveling en onder toesig van 'n geneesheer.
Lakseermiddel: Die volgende dosis kan gegee word as 'n enkele dosis met slaaptyd of vroegoggend met 'n vol glas water. Ontlasting vind plaas in 'n halfuur tot ses ure.
Volwassenes en kinders ouer as 12 jaar: 6 tot 12 medisynemate (30 tot 60 ml)
Kinders: 6 tot 11 jaar: 3 tot 6 medisynemate (15 tot 30 ml)
2 tot 5 jaar: 1 tot 3 medisynemate (5 tot 15 ml)
Onder 2 jaar: 0,5 ml per kg per dosis of soos aanbeveel deur ‘n geneesheer.
Moet nie as 'n lakseermiddel gebruik vir ‘n periode langer as een week, behalwe as ‘n geneesheer dit voorskryf nie.

NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREËLS:
Magnesiumhidroksied kan diaree veroorsaak. Hipermagnesemie kan voorkom as nierfunksie belemmer is. Hierdie produk kan met die absorpsie van ander medisyne inmeng as dit gesamentlik ingeneem word.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN:
Sien **‘NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREËLS’** hierbo.
Gastroïntestinale irritasie en waterige diaree. Hipermagnesemie, waarvan belangrike tekens verlies van diep seningreflekse en asemhalingsdepressie is, albei weens neuromuskulêre-blokkering.
Ander simptome van hipermagnesemie sluit in naarheid, vomering, warmgloede van die vel, dorsheid, hipotensie weens perifere vasodilatasie, lomerigheid,verwarring, spierswakheid, stadige hartslag, koma en hartstilstand.
Behandeling is simptomaties en ondersteunend. In geval van oordosering raadpleeg ‘n dokter of neem die pasiënt onmiddellik na die naaste hospitaal.

IDENTIFIKASIE:
PHIPP’S MILK OF MAGNESIA: ‘n Gladde, wit, ondeurskynende, taaivloeibare suspensie. Feitlik geurloos en met ‘n neutrale smaak.
PHIPP’S MILK OF MAGNESIA - TUTTI FRUTTI FLAVOUR: ‘n Gladde, pienk, ondeurskynende, taaivloeibare suspensie. Geur en smaak kenmerkend van “tutti frutti”.

AANBIEDING:

100 ml en 350 ml in bloukleurige PVC of HDPE bottels.

BERGINGSAANWYSINGS:

Bêre teen benede 25 °C in diggeslote houers. Moet nie vries nie.

HOU BUITE BEREIK VAN KINDERS.

REGISTRASIENOMMER:

PHIPP'S MILK OF MAGNESIA: E/11/628

PHIPP'S MILK OF MAGNESIA - TUTTI FRUTTI FLAVOUR: 35/11/0047

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE REGISTRASIESERTIFIKAAT:

Tiger Consumer Brands

2 Purlin Street

Isando

Kempton Park

1600

DATUM VAN PUBLIKASIE VAN HIERDIE VOUBILJET:

PHIPP'S MILK OF MAGNESIA: 3 Oktober, 1995.

PHIPP'S MILK OF MAGNESIA - TUTTI FRUTTI FLAVOUR: 21 Mei 200