

GELUSIL PEPPERMINT

SCHEDULING STATUS:

S0

PROPRIETARY NAME (AND DOSAGE FORM):

Gelusil Peppermint (tablet)

COMPOSITION:

Each tablet contains:

| | |
|-------------------------------|--------|
| Aluminium Hydroxide Dried Gel | 250 mg |
| Magnesium Trisilicate | 500 mg |

(Magnesium content: 3,3 mmol per tablet)

PHARMACOLOGICAL CLASSIFICATION:

A: 11.4.1 Antacids - Acid neutralisers.

PHARMACOLOGICAL ACTION:

Gelusil Peppermint has acid-neutralising properties.

INDICATIONS:

For the relief of hyperacidity and gastritis, and in the management of peptic ulcer, heartburn and acid indigestion.

CONTRA-INDICATIONS:

Sensitivity to any of the ingredients. Impaired renal function.

DOSAGE AND DIRECTIONS FOR USE:

Adults:

One or two tablets chewed or allowed to disintegrate in the mouth up to 4 to 8 times a day, preferably between meals, or as directed by a doctor. Do not take more than 16 tablets in a 24 hour period.

Do not use the maximum dosage of this product for more than 2 weeks, except under the advice or supervision of a doctor.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS:

Aluminium hydroxide may cause nausea, vomiting and constipation. Large doses can cause intestinal obstruction. Aluminium hydroxide in patients with low-phosphate diets may lead to phosphate depletion accompanied by increased resorption and urinary excretion of calcium with the risk of osteomalacia. Osteomalacia, and also encephalopathy and dementia, have occurred in patients with chronic renal failure who received relatively high doses of aluminium hydroxide as a phosphate-binding agent.

Magnesium may cause diarrhoea. Although magnesium is poorly absorbed following oral administration, hypermagnesaemia has occurred after the excessive use of magnesium-containing

antacids and especially in renal insufficiency. Symptoms may include flushing of the skin, thirst, hypotension due to peripheral vasodilatation, drowsiness, confusion, loss of tendon reflexes due to neuromuscular blockade, muscle weakness, respiratory depression, cardiac arrhythmias, coma, and cardiac arrest.

Interactions:

Gelusil Peppermint used concurrently with oral tetracyclines, digoxin, oral iron preparations, anticholinergic drugs, barbiturates, quinines, quinidine, warfarin, vitamins, H₂-receptor antagonists, oral isoniazid, sucralfate, sodium fluoride, ketoconazole, phenytoin, phenothiazines and methenamine may reduce the absorption of these agents.

In general, patients should be advised not to take any oral medication within at least 2 hours of taking antacids.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

See Side-effects and Special precautions.

Treatment: Symptomatic and supportive.

IDENTIFICATION:

A white, flat, round, bevel-edged tablet with green specks, monogrammed G on one side.

PRESENTATION:

Blisters of 16, 24, 96 and containers of 500 tablets.

STORAGE INSTRUCTIONS:

Store in a cool (below 25°C), dry place.
KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

Z/11.4.1/243

NAME AND BUSINESS ADDRESS OF APPLICANT:

Pharma Dynamics (Pty) Ltd.
F02 Grapevine House,
Steenberg Office Park,
Westlake,
7945

DATE OF PUBLICATION OF THIS PACKAGE INSERT:

30 March 1993.

GELUSIL PEPPERMINT

SKEDULERINGSSTATUS:

S0

EIENDOMSNAAM (EN DOSEERVORM):

Gelusil Peppermint (tablet)

SAMESTELLING:

Elke tablet bevat:

| | |
|----------------------------------|--------|
| Gedroogde Aluminiumhidroksiedjel | 250 mg |
| Magnesiumtrisilikaat | 500 mg |

(Magnesium inhoud: 3,3 mmol per tablet)

FARMAKOLOGIESE KLASSIFIKASIE:

A: 11.4.1 Teensure - Suurneutraliseerders.

FARMAKOLOGIESE WERKING:

Gelusil Peppermint het suurneutraliserende eienskappe.

INDIKASIES:

Vir die verligting van oormatige suur en gastritis, en die beheer van peptiese maagseer, sooibrand en slegte spysvertering.

KONTRA-INDIKASIES:

Sensitiwiteit vir enige van die bestanddele. Verswakte nierfunksie.

DOSIS EN GEBRUIKSAANWYSINGS:

Volwassenes:

Een of twee tablette gekou of opgelos in die mond 4 tot 8 maal per dag, verkieslik tussen maaltye, of soos voorgeskryf deur 'n geneesheer. Moet nie meer as 16 tablette in 'n 24 uur periode inneem nie.

Moet nie die maksimum dosis van hierdie produk vir meer as 2 weke gebruik nie, behalwe op aanbeveling of onder toesig van 'n geneesheer.

NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREëLS:

Aluminiumhidroksied kan naarheid, vomering en konstipasie veroorsaak. Groot dosisse kan intestinale obstruksie veroorsaak. By pasiënte wat op laefosfaatdiëte is, kan aluminium lei tot fosfaatuitputting wat met verhoogde resorpsie en urinêre uitskeiding van kalsium gepaard gaan, met die risiko van osteomalasie. Osteomalasie, sowel as enkefalopatie en demensie, het al voorgekom by pasiënte met chroniese nierversaking wat relatief hoë dosisse aluminiumhidroksied as 'n fosfaatbinder ontvang het.

Magnesium kan diaree veroorsaak. Alhoewel die absorpsie van magnesium na mondelikse toediening swak is, het hipermagnesemie al na oormatige gebruik van teensuurmiddels wat

magnesium bevat, en veral in die geval van renale ontoereiktheid, voorgekom. Simptome kan velgloede, dors, hipotensie weens perifere vasodilasie, lomerigheid, verwarring, verlies van tendonreflekse as gevolg van neuromuskulêre versperring, spierswakheid, respiratoriese onderdrukking, kardiaal aritmieë, koma en hartstilstand insluit.

Interaksies:

Gelyktydige gebruik van **Gelusil Peppermint** met mondelike tetrasiklene, digoksien, mondelike ysterpreparate, anticholinergiese geneesmiddels, barbiturate, kinien, kinidien, warfarien, vitamien, H₂-reseptor-antagoniste, mondelike isoniasied, sukralfaaf, natriumfluoried, ketokonasool, fenitoen, fenotiasiene en metenamien kan die absorpsie van hierdie middels verminder.

In die algemeen moet pasiënte aangeraai word om geen ander mondelike medikasie binne minstens 2 uur nadat teensure gebruik is, in te neem nie.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN:

Sien Newe-effekte en Spesiale voorsorgmaatreëls.

Behandeling: Simptomaties en ondersteunend.

IDENTIFIKASIE:

'n Wit, plat, rond, afgeskuinste tablet met groen spikkels en die monogram G aan die een kant.

AANBIEDING:

Stulpverpakkings met 16, 24, 96 tablette en houers met 500 tablette.

BERGINGSINSTRUKSIES:

Bewaar op 'n koel (benede 25°C), droë plek.
HOU BUITE BEREIK VAN KINDERS.

REGISTRASIENOMMER:

Z/11.4.1/243

NAAM EN BESIGHEIDSADRES VAN APPLIKANT:

Pharma Dynamics (Edms) Bpk.
F02 Grapevine House,
Steenberg Office Park,
Westlake,
7945

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