FINAL APPROVED ENGLISH PACKAGE INSERT

SCHEDULING STATUS:

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PROPRIETARY NAME [and dosage form]:

BEHOEDMIDDEL VIR KINDERS (Suspension)

COMPOSITION:

Each 5 ml contains:

Light Magnesium Carbonate	210,00 mg
Prepared Chalk	79,85 mg
Alcohol (100%)	6,48% v/v

PHARMACOLOGICAL CLASSIFICATION:

A 11.4.1 : Antacids - Acid neutralisers.

PHARMACOLOGICAL ACTION:

Behoedmiddel vir Kinders has acid neutralising properties.

INDICATIONS:

Where the use of an antacid is indicated.

CONTRA-INDICATIONS:

Patients with impaired renal function. Sensitivity to any of the active ingredients.

WARNINGS:

This product contains a high percentage of alcohol.

Use with care in patients with renal failure. May enhance the cardiac effects of digitalis glycosides.

May interfere with the absorption of other medicines given concomitantly.

DOSAGE AND DIRECTIONS FOR USE:

SHAKE THE BOTTLE BEFORE USE:

Children:	Per dose	
Up to 6 months:	1,5 ml - 2 ml	(or 30 to 40 drops)
		(2,24 to 3 mEq)
6 months to 2 years:	2,5 ml - 5 ml	(4 to 7,7 mEq)
3 to 10 years:	5 ml - 7,5 ml	(7,7 to 11,55 mEq)

Not more than three to four times per 24 hour period. Do not give this medicine to babies with a body mass less than 2,5 kg.

Calibrated measuring-cup:-

SIDE-EFFECTS AND SPECIAL PRECAUTIONS:

Magnesium carbonate can cause diarrhoea; mucosal irritation and absorption of magnesium may occur if there is gastro-intestinal atony or obstruction. If renal function is impaired, hypermagnesaemia may result producing adverse effects including flushing of the skin, thirst, hypotension due to vasodilation, drowsiness, loss of tendon reflexes due to neuromuscular blockade, weakness, respiratory depression, cardiac arrhythmias, coma and cardiac arrest.

Magnesium carbonate in common with other magnesium salts may interfere with the absorption of other medicines, e.g. tetracyclines, when these are taken concomitantly. Release of carbon dioxide may cause discomfort.

Prepared chalk may cause constipation. Flatulence from released carbon dioxide is usually not serious, eructations may occur in some patients. Hypercalcemia and alkalosis can occur following regular use of prepared chalk. Milk-alkali syndrome has occurred usually in patients taking high doses.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

See “Side-effects and Special Precautions”.Treatment is symptomatic.

IDENTIFICATION:

An off-white suspension with a sweet taste and aniseed odour.

PRESENTATION:

Bottles of 20 ml and 50ml with a calibrated measuring cup.

STORAGE INSTRUCTIONS:

Store below 25^{o}C in a tightly closed container.

KEEP OUT OF REACH OF CHILDREN

REGISTRATION NUMBER:

E/11.4.1/1528

NAME AND BUSINESS ADDRESS OF APPLICANT:

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