SCHEDULING STATUS S2

PROPRIETARY NAME (and dosage form)

INTUNGWA CHILDREN'S DIARRHOEA MIX (Emulsion)

COMPOSITION Each 5 ml contains:

Bismuth Salicylate 43,75 mg

Alcohol content 4,28% $^{v}/_{v}$

Preservatives: Methyl hydroxybenzoate 0,12 % $^{m}/_{v}$

Propyl hydroxybenzoate 0,012 % $^{m}/_{v}$

PHARMACOLOGICAL CLASSIFICATION

A 11.9 Antidiarrhoeals

PHARMACOLOGICAL ACTION

Bismuth Salicylate has antibacterial (Bi^{3+}) and local anti-inflammatory (salicylate) properties.

INDICATIONS For short-term use in the management of mild to moderate diarrhoea.

CONTRA-INDICATIONS Sensitivity to bismuth or salicylates. Haemophilia or haemorrhagic disorders.

WARNINGS

Do not use for more than 2 days, or in the presence of fever. Care must be taken when it is administered to children younger than 12 years because of the risk of Reye's syndrome.

This product contains salicylate. Do not take this product with other salicylate-containing products such as aspirin, unless directed by a doctor. If you are taking a prescription product for anticoagulation, diabetes, gout or arthritis, do not take this product unless directed by a doctor. The product should be administered with care to patients with impaired renal or hepatic function, dyspepsia or lesions of the gastric mucosa.

DOSAGE AND DIRECTIONS FOR USE

SHAKE THE BOTTLE BEFORE USE.

Under 3 months: Half x 5 ml dose twice a day.

3 – 6 months: Half x 5 ml dose three times a day.

7 months to 3 years: One 5 ml dose three times a day.

Children 3 – 6 years: 2 x 5 ml dose three times daily.

Children 6 – 12 years: 3 x 5 ml dose three times daily.

If the symptoms persist for longer than 48 hours or if the condition of the patient deteriorates, the product must be discontinued and a doctor consulted. In the treatment of diarrhoea it is important that hydration be maintained by administering adequate fluids and electrolytes.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS

Anorexia, headache, jaundice, stomatitis, renal failure leading to death has occurred. The syndrome of bismuth encephalopathy (confusion, tremor and impaired co-ordination) has been reported in patients with colostomies or ileostomies who have been given bismuth preparations in large doses. Effects of acute intoxication include gastro-intestinal disturbances, skin reactions and discolouration of mucous membranes, a characteristic blue line may appear on the gums. Liver damage may occur. Bone and joint disorders have occurred.

Precautions: Bismuth preparations should not be given in high doses for a prolonged period of time. Concomitant use with alcohol should be avoided.

Interactions: It has been reported that bismuth reduces bioavailability of tetracycline when administered concomitantly. Salicylates may enhance the effect of anticoagulants, sulphonylurea hypoglycaemic agents and methotrexate and may diminish the effects of probenecid and sulphinpyrazone.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

See "Side-effects and Special precautions". Treatment is symptomatic and supportive.

IDENTIFICATION

An off-white emulsion with a cinnamon odour and flavour.

PRESENTATION 50 ml and 100 ml PVC bottles.

STORAGE INSTRUCTIONS

Store in a cool place below 25°C.

KEEP OUT OF REACH OF CHILDREN.

REFERENCE NUMBER H879 (Act 101/1965)

NAME AND BUSINESS ADDRESS OF APPLICANT

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