SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Compound Thymol Glycerin B.P. 1988

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Thymol 0.05% w/v
Glycerol 10.0% v/v

For excipients, see 6.1.

3. PHARMACEUTICAL FORM

Gargle

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

As a gargle and mouthwash it is taken orally but not swallowed.

4.2. Posology and method of administration

Adults, children and the elderly

Dilute one part with three parts of warm water and use immediately as a gargle or mouthwash; Do not swallow.

Discard any unused diluted solution.

4.3. Contraindications

Hypersensitivity to any of the ingredients.

4.4. Special warnings and precautions for use

The product is to be used after dilution of one part with three parts of warm water; all unused diluted solution should be discarded due to the possible contamination with resistant micro-organisms. It should not be swallowed.

4.5. Interactions with other medicinal products and other forms of interaction

None known.

4.6. Pregnancy and lactation

No adverse problems have been reported. As with all medicines, is should only be used under medical supervision in pregnant women or nursing mothers.

4.7. Effects on ability to drive and use machines

None.

4.8 Undesirable effects

It can be irritant to the gastric mucosa; rashes may occur. Its prolonged use should be avoided.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

4.9. Overdose

The product is not intended for ingestion, but, in the case of ingestion (accidental or otherwise) resulting in overdosage, treatment measures include gastric lavage with intensive symptomatic supportive therapy.

The symptoms of acute poisoning (mostly due to borax present in the product at the 2% w/v level) are vomiting and diarrhoea; convulsions, changes in body temperature and renal damage may occur; cumulative toxicity due to slow excretion may lead to

anorexia, debility, confusion, dermatitis, menstrual disorders, anaemia, convulsions and alopecia.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

The product is used as a mouthwash and as a gargle and as such has a mechanical cleansing action and freshens the mouth. Thymol has a disinfectant action which is diminished through combination with protein though it is less toxic and has a more powerful disinfectant action than phenol. Its lower solubility in water than phenol and its loss of potency in the presence of protein reduce its overall effectiveness as a disinfectant.

Glycerol is used mainly as a solvent for the thymol and the various essential oils and other substances which are used as flavouring agents in the product.

5.2. Pharmacokinetic properties

Thymol is absorbed from the intestine and excreted in the urine as unchanged drug and as the glucuronide.

Glycerol is absorbed from the intestine and metabolised as carbon dioxide and glycogen or it is used in the synthesis of body fats.

5.3. Preclinical safety data

No relevant data.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Carmine
Sodium metabisulphite
Sodium benzoate
Strong ammonia solution
Ethanol 96%
Borax
Sodium bicarbonate
Sodium salicylate

Menthol
Cineole
Pumilio pine oil
Methyl salicylate
Potable Water

6.2. Incompatibilities

No major incompatibilities have been reported.

6.3. Shelf life

36 months.

6.4. Special precautions for storage

Do not store above 25^{o}C.

6.5. Nature and contents of container

Dispensing packs

500 ml, 1000 ml and 2000 ml amber glass bottles with plastic screw cap and aluminium foil lined expended polyethylene liner.

Patient or OTC packs as appropriate

200 ml and 300 ml amber glass bottles with plastic “J” cap closures.

Not all pack sizes may be marketed.

6.6. Instructions for use/handling

None.

7. MARKETING AUTHORISATION HOLDER

Wise Pharmaceuticals Ltd
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8. MARKETING AUTHORISATION NUMBER(S)

PL 18374/0021

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

9th March 2005

10 DATE OF REVISION OF THE TEXT

28/06/2016