1.3.1.1 PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

SCHEDULING STATUS S1

PROPRIETARY NAME AND DOSAGE FORM

THROFLAM (solution)

COMPOSITION

Each 15 ml of THROFLAM solution contains 22,5 mg of benzydamine hydrochloride

Excipients:

Disodium edetate, ethanol, flavour cherry, flavour spearmint, levomenthol, macrogol glycerol hydroxystearate, purified water, sorbitol, wincoat green

Preservatives:

Sodium methyl parahydroxybenoate 0,180 % *m/v*

Sodium propyl parahydroxybenoate 0,020 % *m/v*

Contains alcohol 9,98 % *v/v*

Contains sugar: Sorbitol 1,8 g

CATEGORY AND CLASS

A.16 Ear, nose and throat preparations

PHARMACOLOGICAL ACTION

Pharmacodynamic properties

Benzydamine hydrochloride has local analgesic and anti-inflammatory properties. Benzydamine hydrochloride exerts this action by stabilizing the cell membrane and inhibiting the synthesis of prostaglandins.

INDICATIONS

THROFLAM can be used for the relief of minor infections as well as painful inflammatory conditions of the mouth and throat.

CONTRAINDICATIONS

Hypersensitivity to any of the ingredients in the formulation. THROFLAM should not be used in children under 6 years of age. The safety in pregnancy and lactation has not been established.

WARNINGS AND SPECIAL PRECAUTIONS

THROFLAM should not be used uninterrupted for longer than 7 days except under medical supervision.

Allow at least 30 minutes between the use of toothpaste and THROFLAM.

Contact with the eyes should be avoided.

Excipients

THROFLAM contains sorbitol and may have a laxative effect.

Patients with the rare hereditary condition of sorbitol intolerance should not use THROFLAM.

INTERACTIONS

See WARNINGS AND SPECIAL PRECAUTIONS.

HUMAN REPRODUCTION

The safety of this formulation in pregnancy and lactation has not been established.

DOSAGE AND DIRECTIONS FOR USE

For use as a gargle:

Gargle with 15 ml (approximately one tablespoon) for at least 30 seconds.

Repeat at 1½ to 3 hourly intervals, as required.

Do not swallow.

For use as a rinse for oral lesions:

Rinse with 15 ml (approximately one tablespoon).

Hold the solution in the mouth and swirl around for at least 30 seconds.

Repeat at 1½ to 3 hourly intervals throughout the day as required. Do not swallow.

THROFLAM is generally used undiluted, but the solution can be diluted with water should stinging occur.

Children (6 to 12 years):

Use 5 ml to 15 ml (one to three medicine measures) as a gargle if they are able to do so, otherwise use as an oral rinse, 3 hourly.

Do not swallow.

As a Spray:

5 to 10 sprays directly onto the painful of inflamed area.

Repeat every 1½ to 3 hours as required.

Contact with the eyes should be avoided.

SIDE EFFECTS

Gastrointestinal disorders:

Have been reported (frequency unknown):

Oral numbness, a burning or stinging sensation.

Dry mouth, thirst, gastrointestinal disturbances, nausea, vomiting, tingling and a warm feeling in the mouth are other local adverse effects that may occur.

An altered sense of taste may also occur.

Prolonged use may result in reversible discolouration of the teeth or tongue and silicate or composite restorations.

The main consequence of ingestion is mucosal irritation but systemic toxicity is rare.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENTS

Symptoms

Adverse central nervous system effects have been known to occur following overdosage with high doses of THROFLAM.

Refer to SIDE EFFECTS and WARNINGS AND SPECIAL PRECAUTIONS for further information.

Treatment

As there is no specific antidote for benzydamine, treatment should be symptomatic and supportive.

IDENTIFICATION

A bright, clear, green solution with a spearmint odour.

PRESENTATION

200 ml is packed in a round clear polyethylene terephthalate bottle with a white polifin polypropylene tamper evident screw cap, with a expanded polyethylene liner. The bottle is placed in an outer cardboard carton together with a leaflet.

30 ml is packed in a clear glass bottle with a round flat topped white polypropylene screw-on cap, with a low density polyethylene liner and a white polyethylene actuator with a low density polyethylene diptube. The bottle, actuator and diptube are packed in an outer cardboard carton together with a leaflet.

Not all packs and pack sizes are necessarily marketed.

STORAGE INSTRUCTIONS

Store at or below 25 °C.

Protect from light.

Keep bottles well-closed.

Keep in original packaging until required for use.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

A40/16/0718

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

PHARMACARE LIMITED

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DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

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