1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S1

PROPRIETARY NAME AND DOSAGE FORM

THROFLAM (solution)

Read all of this leaflet carefully because it contains important information for you

THROFLAM is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless you still need to use THROFLAM carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share THROFLAM with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after a few days.

WHAT THROFLAM CONTAINS

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

The other ingredients are:

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

WHAT THROFLAM IS USED FOR

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

BEFORE YOU USE THROFLAM

Do not use THROFLAM

- If you have a history of being hypersensitive to any of the ingredients.
- If you are pregnant.
- In children under 6 years of age.

Take special care with THROFLAM

- Do not use continuously for more than 7 days, except under medical supervision.
- Avoid contact with eyes.

Pregnancy and breastfeeding

The safety of this medicine in pregnancy and breastfeeding has not been established.

If you are breastfeeding your baby while taking this medicine, please consult your healthcare provider for advice. Always tell your healthcare provider if you are taking any other medicine.

Important information about some of the ingredients in THROFLAM

THROFLAM contains sorbitol and may have a laxative effect. If you have been told that you

have an intolerance to somer sugars, you should not use THROFLAM.

Using other medicines with THROFLAM

If you are taking other medicines in a regular basis, including complementary or traditional medicines, the use of THROFLAM with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare provider, for advice.

HOW TO USE THROFLAM

Always use THROFLAM exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Do not share medicines prescribed for you with any other person.

The usual dose is:

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, as required. Do not swallow.

THROFLAM is generally be 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 able to do so, otherwise 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.

Your doctor will tell you how long your treatment with THROFLAM will last.

If you have the impression that the effect of THROFLAM is too strong or too weak, tell your doctor or pharmacist.

If you use more THROFLAM than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

POSSIBLE SIDE EFFECTS

THROFLAM can have side effects.

Not all side effects reported for THROFLAM are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using THROFLAM, please consult your healthcare provider for advice.

The following side effects have been reported but frequency is unknown:

Gastrointestinal disorders:

Oral numbness, a burning or stinging sensation. Dry mouth, thirst, gastrointestinal disturbances, nausea, vomiting, tingling and a warm feeling in the mouth are local adverse effects that may occur. An altered sense of taste may also occur.

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

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

STORING AND DISPOSING OF THROFLAM

Store at or below 25 °C.

Protect from light.

Keep bottles well-closed.

Keep in original packaging until required for use.

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

PRESENTATION OF THROFLAM

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.

IDENTIFICATION OF THROFLAM

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

REGISTRATION NUMBER

A40/16/0718

NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

PHARMACARE LIMITED

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DATE OF PUBLICATION

Date of registration: 05 March 2009

Date of the most recent amendment to the patient information leaflet as approved by the Authority: 05 March 2009