# **FRONT**

140 mm

# **BACK**

140 mm

## **Difflam**<sup>®</sup> For Children Throat **SPRAY**

### Presentation

White metered dose pump with a green lid containing 30mL of clear solution

### What Difflam® For Children Throat Spray contains

Active ingredient

Each mL of Difflam® For Children Throat Spray contains benzydamine hydrochloride

Each spray delivers approximately 0.25mg of benzydamine hydrochloride.

### Inactive ingredients

It also contains ethanol, saccharin, methylparahydroxybenzoate, glycerol, polysorbate 20, sodium bicarbonate, purified water and mint flavouring.

It does not contain gluten, lactose, sugar or colour

### How does Difflam® For Children Throat Spray work

Difflam® For Children Throat Spray contains benzydamine hydrochloride. It is an anti-inflammatory and analgesic agent. It helps to reduce swelling and pain.

### What Difflam® For Children Throat Spray is used for

Difflam® For Children Throat Spray is used

for relief from the symptoms of tonsilitis. sore throat, mouth ulcers, pharyngitis, swelling, redness and inflammatory conditions, pain following mouth or throat surgery and pain following dental procedures

## How to use Difflam® For Children Throat

Adults and children over 12 years: 4-8 sprays (1-2 mg) directly onto the sore/inflamed area and swallow gently. Repeat every 11/2 to 3 hours as necessary.

Children (6-12 years): 4 sprays (1 mg) directly onto sore/inflamed area and swallow gently. Repeat every 1½ to 3 hours

Children under 6 years: Not recommended.

Uninterrupted treatment should not exceed seven days, unless under medical supervision.

Cleaning Instructions: After use, wipe the nozzle with a clean tissue to prevent blockage.

### Contraindications

Patients with known hypersensitivity to benzydamine hydrochloride or to any other ingredients present in Difflam® For Children

If a sore throat is either caused or complicated by a bacterial infection, appropriate anti-bacterial therapy should be considered in addition to the use of Difflam® For Children Throat Spray

**ARTWORK** 

## Before using Difflam® For Children Throat humans. Seek your doctor's advice if you

Tell your doctor or pharmacist if you have any of the following conditions:

- liver problems
- kidney problems

### Side effects

Difflam® For Children Throat Spray is generally well tolerated and side effects are minor.

The most commonly reported reaction is oral numbness and has been reported in 2.6% of treated cases. Occasional burning or stinging sensation may occur (1.4%). Other local adverse effects are less common and included dryness or thirst (0.2%), tingling (0.2%), warm feeling in mouth and altered sense of taste (0.1%).

Systemic side effects are rare. These include nausea, vomiting, retching, gastro-intestinal disorders (0.4%), dizziness treatment should be symptomatic. (0.1%), headache and drowsiness (0.1%) Hypersensitivity reactions occur very rarely but may be associated with rash, urticaria, photodermatitis and occasionally laryngospasm or bronchospasm.

### Use in pregnancy

The safety of benzydamine hydrochloride has not been established in pregnant patients. Seek your doctor's advice if you are pregnant or likely to be pregnant during your course of medication

### Use during breastfeeding

Use of benzydamine hydrochloride during lactation has not been established in

are breastfeeding or likely to breastfeed during your course of medication.

### Use in children

Because of the lack of sufficient clinical experience, Difflam® For Children Throat Spray is not recommended in children under 6 years of age.

### Interactions with other medicines

There are no known drug interactions with Difflam® For Children Throat Spray.

There are no known cases of overdosage with Difflam® For Children Throat Spray. Adverse CNS effects have been reported following overdosage with high doses of benzydamine hydrochloride in solution form. There is no specific antidote for benzydamine hydrochloride and should excessive quantities be ingested, the

Protect from light and store below 25°C.

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Job No. : JB-02401 V Q : 104426

A5544\_DIFFLAM 0.15%THROAT SPRAY 30ML **Component**: LEAFLET

Country: SG Dieline Ref: PP-1267 EMO: ANGELINI Printer: Xxxxxx Xxxxxxxxxxxx

**G247 File Name:** 94418 A5544 DIFFLAM 0.15%THROAT SPRAY 30ML\_SG\_LT\_V9

Colour 100%

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Moving forward when possible any additional information and technical check required by EMO on the Artwork BEFORE APPROVING.