BETADINE SORE THROAT SPRAY 0.45%W/V

Please read the insert before use. For further information, please contact your doctor or pharmacist.

Product Description

Active ingredient: Povidone-iodine 0.45%w/v

Composition: Glycerol, Ethanol, Levomenthol, Eucalyptus Oil, Potassium Iodide, Purified water.

Product Appearance

A pale-brown slightly viscous liquid with distinctive perfume and sweet taste supplied in a 25ml or 50ml HDPE bottle container with a spray pump and cap.

What is this medicine used for?

BETADINE[®] **Sore Throat Spray** is indicated for protection and symptomatic relief of sore throat and mouth ulcers. For oral hygiene prior to, during and after dental and oral surgery.

How much and how often should you use this medicine?

For use in adults and children over 6 years of age. One spray into the back of the throat every 3-4 hours as needed, to a maximum of three sprays a day.

What should you do if you miss a dose?

If it is almost time for you to apply the next dose, skip the dose you missed, and apply your next dose when you are meant to.

When should you consult your doctor?

Talk to a healthcare professional if:

- Symptoms do not improve or worsen
- You have an allergy or skin irritation such as redness, small blister, itching, or a rash which may occur immediately
- You have received radioactive iodine treatments within the last 4 weeks

When should you not take this medicine?

This medicine should be avoided:

- If you have an allergy to iodine or any ingredients in Betadine® Sore Throat Spray
- If you have a thyroid problem
- In children under 6 years of age
- If you are to receive or currently receiving radioactive iodine treatments
- If you are pregnant or breast feeding

Betadine® **Sore Throat Spray** should not be used for more than 14 days, or if you are pregnant, or breast feeding unless under medical supervision.

Undesirable effects

• **Betadine® Sore Throat Spray** can cause side effects such as cough, irritation, redness, swelling, small blisters, itching, tiredness, weakness, confusion, rapid shallow breathing, passing little or no urine, fluid retention and swelling of legs, ankle and feet.

Tell your doctor or pharmacist immediately if you have any of the following signs or symptoms:

Allergic reactions that occur quickly and include an itchy raised skin rash (hives), a body
rash, sudden breathing problems, feeling faint, swelling of the mouth, face, lips, tongue
or throat - seek medical help straight away

Symptoms of a thyroid problem may include feeling nervous, moody, difficulty sleeping, hand tremors, fast or irregular heartbeat, trouble breathing, feeling very hot or sweaty, weight loss, weight gain and tiredness.

What other products you should avoid whilst taking this medicine?

Other antiseptics or medications can affect how **Betadine® Sore Throat Spray** works. Avoid preparations containing hydrogen peroxide, silver, taurolidine or octenidine.

Signs & symptoms of overdose

Consult your doctor or pharmacist immediately if you accidentally swallow large quantities of **Betadine® Sore Throat Spray**. Some signs and symptoms may include discomfort in the stomach area, swelling of throat, difficulty in breathing, shortness of breath or wheezing, difficulty in urinating and heart problems.

What you should note when taking this medicine?

- Tell your doctor that you are using **Betadine® Sore Throat Spray** before any diagnostic test.
- If accidentally swallowed or comes in contact with the eyes, seek medical advice immediately.
- For Oral Use Only.
- Betadine® Sore Throat Spray does not stain. However, if product accidentally comes in contact with your clothes, wash immediately with water.
- Avoid contact with jewellery, especially silver containing articles.

Effects on Ability to Drive and Use Machinery

Betadine® Sore Throat Spray does not affect your ability to drive or use machinery.

How should you keep this medicine?

After opening, store at or below 30°C for up to 3 months. Do not store in your vehicle. Keep out of reach of children. Do not heat prior to application.

Shelf-life:

3 years from the date of manufacturing. Do not exceed the expiry date stated on the label.

Manufactured by:

Mundipharma Pharmaceuticals Ltd., 13, Othellos str., Dhali Industrial Zone, P.O. Box 23661, 1685 Nicosia, Cyprus.

Date of revision

March 2022

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