

BETADINE[®] SORE THROAT SPRAY 0.45% W/V

Povidone-Iodine (0.45% w/v)

What is in this leaflet

1. What **BETADINE[®]** Sore Throat Spray is used for
2. How **BETADINE[®]** Sore Throat Spray works
3. Before you use **BETADINE[®]** Sore Throat Spray
4. How to use **BETADINE[®]** Sore Throat Spray
5. While you are using it
6. Side effects
7. Storage and Disposal of **BETADINE[®]** Sore Throat Spray
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision
11. Serial Number

What **BETADINE[®]** Sore Throat Spray is used for

Relief of throat chapping, throat pain, throat swelling, throat discomfort and hoarseness caused by inflammation of the throat.

How **BETADINE[®]** Sore Throat Spray works

BETADINE[®] Sore Throat Spray contains a medicine called Povidone- Iodine. Povidone Iodine has a broad application in medicine as an antiseptic and disinfectant for various purposes.

Before you use **BETADINE[®]** Sore Throat Spray

- When you must not use it

- If you are allergic to iodine or povidone or any of the ingredients of this product (refer as stated under ingredients);
- If you have a thyroid problem;
- If you are to receive or are currently receiving radioactive iodine therapy;
- If you are using products containing mercury such as thiomersal;

- In children under 1 year of age.

- Pregnancy and lactation

Always inform your doctor or pharmacist if you are pregnant or planning a pregnancy, before using **BETADINE[®]** Sore Throat Spray.

This medicine is not recommended for use in pregnancy or breastfeeding.

Seek medical advice from your doctor or pharmacist.

-Before you start to use it

Tell your doctor or pharmacist if you:

- are allergic to iodine or povidone;
- have a thyroid problem;
- are pregnant or planning a pregnancy;
- are breastfeeding your baby;
- have a history of allergic symptoms induced by drug, etc.
- have severe oral mucosa erosion;
- received radioactive iodine treatments within the last 4 weeks;
- Use in children between 1 to 6 years of age;
- are using **BETADINE[®]** Sore Throat Spray before any diagnostic test.

-Taking other medicines

The concomitant use of other externally applied wound healing medicines/ preparations may alter the effect of

BETADINE[®] Sore Throat Spray or both. Products containing enzymatic component, hydrogen peroxide, silver, octenidine and taurolidine may interact with Povidone-Iodine and should not be used at the same time.

Simultaneous use with mercury products may lead to the formation of a substance, which can damage the skin.

Using this treatment may interfere with tests or thyroid function and can make a planned treatment of the thyroid with iodine impossible. After the end of the treatment an interval of at least 1-2 weeks should be allowed before a new

scintigram is carried out.

Several types of tests for detecting occur (not visible) blood in faeces or blood in urine may be affected (i.e. produce false positive results).

Do not start a new treatment medication without telling your doctor.

For more information about any other possible risks associated with this medicine, please consult your doctor or pharmacist.

How to use **BETADINE[®]** Sore Throat Spray

-How much to use

For mouth and throat only.

Spray **BETADINE[®]** Sore Throat Spray to the mucous membrane of the throat several times a day (every 3-4 hours).

Steps to use:

1. Direct the nozzle toward the affected area of the throat and apply 2 or 3 times while saying "Ha" aloud. (If you apply while breathing in, the

liquid may get into the bronchi or lungs);

2. Children should be supervised by

their guardians while using this product.

3. This product is only for spraying the throat; do not ingest or use for cuts or burns.

4. Take care so that this product does not get into the eyes. Should it get into the eyes, immediately rinse them with water or lukewarm water and see an ophthalmologist if you develop a severe irritation.

If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

-When to use it

Use as directed by your doctor or pharmacist.

-How long to use it

Continue taking **BETADINE**[®] Sore Throat Spray for as long as your doctor or pharmacists recommends.

-If you forget to use it

Use as soon as you remember.

-If you use too much (overdose)

In an unlikely event, if you should experience any of the following symptoms: abdominal pain, failure of the kidney to produce urine, problem in blood circulation, suffocation, fluid accumulation in the lungs or any other abnormalities due to metabolic disorder, consult your doctor immediately.

Therapy: Symptomatic and supportive treatment should be provided with special attention to electrolyte balance and renal and thyroid function.

While you are using it

-Things you must do

Use **BETADINE**[®] Sore Throat Spray exactly as your doctor or pharmacist has told you. For oral use only.

Tell all the doctors and pharmacists treating you that you are using **BETADINE**[®] Sore Throat Spray.

Tell your doctor immediately if you become pregnant while using this Throat Spray.

Tell your doctor if symptoms do not improve after 5 days of use or worsen, or you have an allergy or skin irritation such as redness, small blisters, itching, or a rash which may occur immediately.

-Things you must not do

Do not use together with alkali, hydrogen peroxide, tauridine, tannic acid, acetylsalicylic acid, all silver, bismuth and mercury salts.

-Things to be careful of

BETADINE[®] Sore Throat Spray is intended for mouth and throat use only and not for use on extensive body area.

If accidentally swallowed or comes in contact with the eyes, seek medical advice immediately.

Special caution is needed after the end of the treatment to look for the early symptoms of possible overactive thyroid and if necessary the thyroid function should be monitored.

If you have kidney failure, special caution is needed when regular applications to broken skin.

In instances of local irritation or sensitivity, discontinue use.

BETADINE[®] Sore Throat Spray does not affect your ability to drive or use machinery.

Side effects

Like all medicines, **BETADINE**[®] Sore Throat Spray can cause side effects, although not everybody gets them.

The 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.

Visit your doctor or pharmacist immediately if you experience any side effects as listed below after using:

- 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.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of BETADINE[®] Sore Throat Spray

-Storage

Store below 30°C.

Keep out of the reach of children.

-Disposal

Ask your pharmacist how to dispose of used Throat Spray.

Product Description

-What it looks like

BETADINE[®] Sore Throat Spray is a pale-brown slightly viscous liquid with distinctive perfume and sweet taste.

BETADINE[®] is a Registered Trademark of iNova Pharma SG Pte Ltd.

-Ingredients

- Active ingredient
Povidone-Iodine 0.45% w/v
- Inactive ingredients:
Ethanol 96%
Glycerol
Levomenthol
Eucalyptus Oil
Potassium Iodide
Purified water

-MAL Number:

MAL15065026XCZ

Manufacturer

Mundipharma Pharmaceutical Ltd
13-15, Othellos Street,
Dhali Industrial Area,
2540 Nicosia- Cyprus.

Product Registration Holder

iNova Pharmaceuticals (S) Pte Ltd.
Malaysia Branch
5F-2, 5th Floor,
Tower 2, @ PFCC,
Jalan Puteri 1/2,
47100 Puchong,
Selangor, Malaysia.

Date of revision

6th March 2025

Serial Number

NPRA(R2/3)230227/1020