

PACKAGE LEAFLET: Information for the user

JODEX

Spray, solution – 8.5%

(Povidone-iodine)

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Jodex is and what it is used for
2. Before you use Jodex
3. How to use Jodex
4. Possible side effects
5. How to store Jodex
6. Further information

1. WHAT JODEX IS AND WHAT IT IS USED FOR

Jodex contains the active substance povidone-iodine. Povidone-iodine is a complex of iodine with povidone (polyvinylpyrrolidone), whereas povidone is a hydrophilic synthetic polymer which is used as a carrier for iodine.

This polymer does not have antibacterial activity, but has a high affinity for the cell membrane, whereas in the form of complex with iodine, in the form of povidone-iodine, it gradually releases iodine closely to the bacterial cell surface.

Jodex 8.5% spray is indicated as an otorhinolaryngologic disinfectant. The main active substance is iodine, which is released during contact of povidone-iodine with the mucosa. Allantoin

protects mucosa from damage.

This medicine is used:

- as an additional treatment in the infections of the oral cavity, palate, throat and tongue;
- in post-surgery infections of the oral cavity;
- during flu associated with scratches and sore throat;
- in oral chronic infections;
- in streptococcal angina (in combination with antibiotics).

2. BEFORE YOU USE JODEX

Do not use Jodex:

- if you are hypersensitive (allergic) to povidone-iodine or to any of the other ingredients of the medicinal product because allergic reactions may appear (including anaphylaxis).

Prolonged and regular use should be avoided in patients with thyroid pathology or in patients who are being treated with lithium.

Medicines containing iodine must not be used 2 weeks before and after the treatment with radioactive iodine and also if the patient has severe damages of the pulmonary function.

In patients with liver impairment, this medicine should be used only with medical prescription.

This medicine must not be used in children under 8 years old.

Take special care with Jodex

Ask your doctor before you use Jodex.

During spraying in oral mucosa, you should close your eyes! Do not swallow and do not breathe!

These recommendations are particularly relevant for children.

When povidone-iodine is used at the same time in the mouth with other medicines, you should consult a doctor.

Povidone-iodine should not be used during pregnancy and breastfeeding.

If you do not have signs of improvement or if side effects appear, you should consult a doctor.

Taking other medicines

Please, tell your doctor or pharmacist if you are taking / using, have recently taken / used any other medicines, including medicines obtained without a prescription. Do not forget to inform your doctor about your treatment with Jodex if you are given another medicine during treatment.

Important clinical interactions are observed after systemic absorption of Jodex.

It is particularly important to inform your doctor that you are treated with silver sulfadiazine or chlorhexidine because concomitant use with povidone-iodine may cause inactivation of iodine.

Pregnancy and breastfeeding

Ask for your doctor or pharmacist advice before using this medicine.

It is advised to avoid use of this medicine during pregnancy and breastfeeding.

Driving and using machines

There are no known effects of this medicine on the ability to drive or use machines.

Important information about some of the excipients of Jodex

Jodex contains propylene glycol, which may cause skin irritation.

This medicine also contains 0.25 ml ethanol 96% in 1 ml solution. It may cause a burning sensation on damaged skin.

3. HOW TO USE JODEX

Always use Jodex according to the advice of the doctor or pharmacist. It is important to strictly follow their advice and never change the dose yourself, no matter how you feel. If you are not sure, contact your doctor or pharmacist.

Jodex spray should be sprayed carefully in the surface of the mouth mucosa, without inserting the tube too deeply.

Children over 8 years and adults: 2-3 sprays on the right and left side, up to four times a day.

In particular cases, it may be applied more often (every 4 hours).

Before use, the mouth should be rinsed with warm water.

If you use more Jodex than you should

If you use more Jodex than you should, or if the children take it accidentally, please contact your doctor, the hospital, or any medical care site to seek advice on the risk and the appropriate measures.

Side effects because of overdose with Jodex are rare.

If you forget to use Jodex

If you forget to use one dose of Jodex, use it as soon as possible. If it is about the time for the next dose, use it and skip the missed dose. Do not use a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Jodex can cause side effects, although not everybody gets them.

Most of the side effects are dose-related and disappear when the dose is reduced or the treatment is stopped. Some side effects may appear in the beginning of the treatment and disappear spontaneously during treatment.

Povidone-iodine can cause hypersensitivity reactions which appear with irritation of the skin and mucous membranes, redness and itching at the application site.

If it is swallowed, it may cause gastrointestinal irritation.

Talk to your doctor or pharmacist if you notice other side effects not listed above.

5. HOW TO STORE JODEX

Store in dry, cool places, at temperatures less than 25°C.

Protect from light.

Do not freeze.

Do not use Jodex after the expiry date.

Keep your medicine in a safe place where your children can not reach it. Your medicine may harm them.

6. FURTHER INFORMATION

What Jodex 8.5% spray, solution contains

The active substance is povidone-iodine.

1 ml solution contains 0.085 g povidone-iodine.

Other ingredients: allantoin, propylene glycol, ethanol, menthol, citric acid, sodium citrate, water for injection.

Content of the pack

Box with 1 plastic flacon of 30 ml with a spraying system.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. “Skënder Vila”,

Tirana, Albania.

Tel.: +355 4 23 89 602

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