

## PACKAGE LEAFLET: INFORMATION FOR THE USER

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### STOMATIDIN

1 mg / ml mouthwash

HEXETIDINE

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*• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.*

*• 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 you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •*

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#### What is in this leaflet?

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

#### *1. WHAT STOMATIDIN IS AND WHAT IT IS USED FOR*

STOMATIDIN 1 mg/ml contains Hexetidine which is an anti-bacterial and anti-fungal agent. It acts against bacteria and fungi, and it is used in the treatment of the infections of the throat and mouth, including lesions / mouth ulcers (aphthous ulcers), fungal infection in the mouth (oral candidiasis), sore or bleeding gums (gingivitis), bad breath (halitosis), as well as pharyngitis.

This medicine can also be used before and after dental (tooth) surgery to help prevent the infection.

#### *2. BEFORE YOU TAKE STOMATIDIN*

##### **Do not take STOMATIDIN**

- If you are allergic to Hexetidine, or other ingredients of this medicine (listed in Section 6: Further information)

##### **Take special care with STOMATIDIN**

- If your symptoms are persistent and last long, talk to your doctor or pharmacist.

### ***Taking other medicines***

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines obtained without a prescription and herbal medicines. There are no known interactions with other medicines.

### ***Pregnancy and breast-feeding***

Ask your doctor or pharmacist for advice before taking any medicine.

Talk to your pharmacist or doctor before taking STOMATIDIN Mouthwash if you are pregnant, planning to become pregnant or are breast feeding.

### ***Driving and using machines***

It is not likely that STOMATIDIN will affect your ability to drive and use machines.

### ***Other warnings***

STOMATIDIN 1 mg / ml mouthwash contains propylene glycol, which may cause skin irritation.

STOMATIDIN 1 mg / ml mouthwash contains ethanol 96%; 1 ml of solution contains 80.9 mg of ethanol 96%, ie, 15 ml (single dose) contains 1213.5 mg of ethanol 96%. In case of accidental ingestion of the solution, given content can be harmful for alcoholics, pregnant women or nursing mothers, children, and high risk patients, such as patients with liver disease or epilepsy.

STOMATIDIN 1 mg / ml mouthwash contains azo dye azorubine (E122), which may cause allergic-type reactions (important in the case of accidental ingestion of the solution).

## ***3. HOW TO TAKE STOMATIDIN***

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

### ***Method of administration***

STOMATIDIN 1 mg / ml mouthwash is intended only for topical application in the oral cavity, which means it should not be swallowed or used internally (internal application).

- Do not dilute the solution.
- Do not swallow the solution.

### ***Dosage***

#### **Adults and children aged 6 years and older**

Rinse your mouth or gargle for 30 seconds, with at least 15 ml (approximately 1 tablespoon) of undiluted solution, two to three times per day (unless otherwise recommended).

#### **Children younger than 6 years**

STOMATIDIN 1 mg / ml mouthwash is not intended for use in children younger than 6 years.

### ***If you take more STOMATIDIN than you should***

If you take more of this medicine than you should, talk to a doctor or go to a hospital straight away. If someone accidentally swallows this solution, they need to contact a doctor or the nearest hospital with an emergency department. Take the medicine pack with you.

### ***If you forget to take STOMATIDIN***

If you miss a dose, take the next dose at the usual time and continue to take the medicine as instructed by a doctor.

Do not take a double dose to make up for a forgotten dose.

### ***If you stop taking STOMATIDIN***

Use this medicine as long as your doctor has prescribed.

Talk to your doctor or pharmacist if you have any additional questions.

### ***4. POSSIBLE SIDE EFFECTS***

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

If you experience the following, stop using STOMATIDIN and tell your doctor:

- Swelling of the face, lips, mouth, tongue or throat, which may cause difficulty in swallowing or breathing;
- Allergic reactions, including itchy rash;
- Irritation, tingling or numbness of the tongue and / or tissue inside the mouth;
- Shortness of breath;
- Cough;
- Dry mouth;
- Nausea;
- Vomiting;
- Increase of salivary glands;
- Disturbance or loss of taste;
- Pain, swelling, redness or heat;
- Change in color of the tongue or teeth;
- Blistering or ulceration (skin lesions or damage to mucous membranes).

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.

### ***5. HOW TO STORE STOMATIDIN***

Keep out of the reach and sight of children.

Do not store above 25 °C.

Do not use STOMATIDIN after the expiry date which is stated on the label, 2 years from the date of manufacture.

### ***6. FURTHER INFORMATION***

#### ***What STOMATIDIN contains***

1 ml of solution contains: 1 mg of hexetidine.

STOMATIDIN 1 mg / ml mouthwash contains the following excipients: propylene glycol, polysorbate 20, citric acid, sodium saccharin, menthol, racemic, methyl salicylate, azorubine (E122), 96% ethanol and purified water.

#### ***What STOMATIDIN looks like and contents of the pack***

STOMATIDIN 1 mg / ml mouthwash is bright, red colored solution.

STOMATIDIN is packed in brown glass bottles with aluminum pilfer-Proof closures PP28. Bottles containing 200 ml of solution are packed in boxes.

#### ***Regime of dispensing***

The medicine is issued without doctor's prescription.

#### ***Manufacturer***

Bosnalijek d.d., Jukićeva 53, Sarajevo, Bosna i Hercegovina