

PATIENT INFORMATION LEAFLET

OSEPTIN 1mg/g antiseptic solution

For external use.

- **Active ingredient:** Octenidine dihydrochloride
- **Excipients:** Phenoxyethanol, cocoamidopropyl betaine, sodium gluconate, glycerine, citric acid anhydrate, sodium dihydrogen phosphate dihydrate, purified water.

Please read this INSTRUCTIONS FOR USE carefully because it contains important information for you.

This medicine is available without a prescription and is for you to treat a mild illness with the advice of your pharmacist without the help of a doctor. However, in order to get the best results from OSEPTIN, you still need to use it carefully.

- *Keep this instruction. You can need to read again.*
- *If you have extra questions, please talk your doctor or pharmacist.*
- *This medicine has been prescribed for you personally, do not give it to others.*
- *When you go to the doctor or hospital during the use of this medicine, tell your doctor that you are using this medicine.*
- *Follow exactly what is written in this instruction. Do not use **high or low doses** other than the dose recommended to you about the drug.*

In this Instruction for use:

- 1. What OSEPTIN is and what it is used for?***
- 2. Things to consider before using OSEPTIN***
- 3. How to use OSEPTIN?***
- 4. What are the possible side effects?***
- 5. Storage of OSEPTIN***

Headings are included.

1. What OSEPTIN is and what it is used for?

OSEPTIN contains octenidine dihydrochloride as an active ingredient.

OSEPTIN is a clear and colorless solution presented in plastic bottles of 250, 500 and 1000 ml, closed with a white cap.

The microbiological effect of OSEPTIN antiseptic solution is on bacteria, fungi and viruses. It is used to purify mucous membranes, wounds and skin from bacteria, fungi and viruses.

It is also used in the antiseptic treatment of small superficial wounds and skin disinfection before non-surgical procedures.

2. Things to consider before using OSEPTIN

DO NOT USE OSEPTIN in the following conditions

- It should not be used if you are allergic to octenidine dihydrochloride or any of the ingredients in the product.
- It should not be used for washing the abdominal cavity (during surgery) and the bladder.
- It should not be applied directly to the eardrum.

USE OSEPTIN CAREFULLY in the following situations

- It should not be swallowed. In case of ingestion of large amounts, erosion occurs in the gastric and intestinal mucosa.
- To avoid possible tissue damage, the product should not be injected or pressurized into the tissue. Appropriate drainage should be provided from the wound cavities.
- After the application area of OSEPTIN is completely dry, it can be covered with a bandage or gauze.

Using OSEPTIN with food and drink:

It has no known interactions with food and drink.

Pregnancy

Consult your doctor or pharmacist before using this medication.

If you realize that you are pregnant during your treatment, consult your doctor immediately.

OSEPTIN contains 0,5 % phenoxyethanol. Phenoxyethanol causes serious toxicity in nursing mothers and children. Therefore, it should not be used in breastfeeding mothers and children.

Breast-feeding

Consult your doctor or pharmacist before using this medication

Oseptin contains 0,5 % phenoxyethanol. Phenoxyethanol causes serious toxicity in nursing mothers and children. Therefore, it should not be applied to the breast area in nursing mothers.

Vehicle and machine use

It has no known effects on the ability to drive and use machines.

Important information about some excipients in the content of OSEPTIN

There are no excipients requiring warning.

Concomitant use with other drugs

OSEPTIN should not be used concomitantly with PVP (polyvinylpyrrolidone) tincture. It should not be mixed with other compounds or products.

Do not use OSEPTIN with anionic surfactants (soap, detergent) as this may reduce or destroy its effectiveness.

If you are currently using or have recently used any prescription or non-prescription drugs, please inform your doctor or pharmacist about them

3. How to use OSEPTIN?

Instructions for proper use and dose / frequency of administration:

Unless advised otherwise by the physician:

Adults once a day.

Application route and method:

Treatment area boundaries are carefully determined. If no other arrangement is made, it is applied directly to the treated skin area.

Do not use OSEPTIN for more than 2 weeks without consulting your doctor.

Apply OSEPTIN thoroughly until the area to be treated is completely moist. After use, you should wait at least two minutes before applying other measures to the treated area (such as

applying a wound dressing). This is because this medicine only needs to work with OSEPTIN to achieve the full desired effect.

Different age groups:

Use in children:

Oseptin contains 0,5 % phenoxyethanol. Phenoxyethanol causes severe toxicity in children. Therefore, it should not be used in children.

Use in the elderly:

No special dose adjustment is required.

Special use cases:

Kidney/liver failure:

There are no specific reports of kidney/liver failure.

If you have the impression that the effect of OSEPTIN is too strong or too weak, talk to your doctor or pharmacist.

If you use more OSEPTIN than you should:

If you have used more than you should use from OSEPTIN, talk to a doctor or pharmacist.

If you forget to use OSEPTIN:

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

Effects that may occur when treatment with OSEPTIN is terminated

No adverse effects are expected when treatment with OSEPTIN is terminated.

4. What are the possible side effects?

Side effects are listed as shown in the following categories:

Very common: may occur in at least 1 in 10 patients.

Common: less than 1 in 10 patients, but more than 1 in 100 patients.

Uncommon: less than 1 in 100 patients, but more than 1 in 1,000 patients.

Rare: less than 1 in 1,000 patients, but more than 1 in 10,000 patients.

Very rare: less than 1 in 10,000 patients.

Unknown: Cannot be estimated from available data.

Like all medicines, there may be side effects in people who are sensitive to the ingredients of OSEPTIN.

If any of the following occur, stop using OSEPTIN and IMMEDIATELY inform your doctor or go to the nearest hospital emergency department:

Rare:

- Slight burning sensation
- Redness
- Itching

Very rare:

- Allergic contact reaction
- Temporary redness at the application site

If you experience any side effects not mentioned in this leaflet, inform your doctor or pharmacist.

5. Storage of OSEPTIN

Keep OSEPTIN out of the sight and reach of children and in its package.

Store at room temperature below 25°C.

Use in accordance with expiration dates.

Do not use OSEPTIN after the expiry date stated on the package.

Use OSEPTIN within 12 months after first opening. Do not use OSEPTIN if you notice any defects in the product and/or its packaging.

Do not throw away expired or unused medicines! Give it to the collection system determined by the Ministry of Environment and Urbanization.

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