

PACKAGE LEAFLET: INFORMATION FOR THE USER

Chlorhexidine Acetate BP 0.05% for Irrigation

Active substances: Chlorhexidine Acetate

Read all of this leaflet carefully before you start using 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, nurse or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet.

Throughout this leaflet, Chlorhexidine Acetate BP 0.05% for Irrigation will be called Chlorhexidine for Irrigation.

In this leaflet:

1. What Chlorhexidine for Irrigation is and what it is used for
2. What you need to know before you use Chlorhexidine for Irrigation
3. How to use Chlorhexidine for Irrigation
4. Possible side effects
5. How to store Chlorhexidine for Irrigation
6. Contents of the pack and other information

1. What Chlorhexidine for Irrigation is and what it is used for

Chlorhexidine for Irrigation contains a medicine called chlorhexidine acetate. This belongs to a group of medicines called 'antiseptics', which are used to kill bacteria.

Chlorhexidine for Irrigation is used:

- for cleaning (irrigating) the skin
- for wound and burn cleaning (irrigation)
- as a disinfectant for respirators.

2. What you need to know before you use Chlorhexidine for Irrigation

Your doctor will not use Chlorhexidine for Irrigation:

- if you are allergic (hypersensitive) to the active ingredients or any of the other ingredients (listed in

section 6)

- for irrigation of your eyes, mouth or ears
- for irrigation of the brain or spinal cord or surrounding membranes (meninges)
- by infusion into a vein
- for oral administration
- for irrigation of any body cavities.

Your doctor will not use Chlorhexidine for Irrigation if any of the above apply. If you are not sure talk to your doctor, nurse or pharmacist before using Chlorhexidine for Irrigation.

Your doctor will take special care when giving you Chlorhexidine for Irrigation if:

you are have had a reaction to Chlorhexidine for Irrigation in the past.

If you are not sure if this applies to you, talk to your doctor, nurse or pharmacist before having Chlorhexidine for Irrigation.

Do not take/use Chlorhexidine for Irrigation if you are allergic (hypersensitive) to chlorhexidine acetate or any of the other ingredients of Chlorhexidine for Irrigation (see section 6).

Warnings and precautions

- Chlorhexidine for Irrigation may in rare cases cause severe allergic reactions, leading to a drop in blood pressure and even to unconsciousness, which can be fatal. Early symptoms of a severe allergic reaction may be skin rash or asthma. If you notice these symptoms, stop using Chlorhexidine for Irrigation and contact your doctor as soon as possible (see under section 4: "Possible side effects").
- Use with care when this medicine is used to clean the skin, before an operation for your face or head
- Chlorhexidine must not come into contact with the eye due to the risk of visual damage. If it comes into contact with



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the eyes, wash out immediately and thoroughly with water. In case of any irritation, redness or pain in the eye, or visual disturbance, ask for medical advice promptly. Serious cases of persistent corneal injury (injury to the surface of the eye) potentially requiring corneal transplant have been reported when similar products have accidentally come in contact with the eye during surgical procedures, in patients under general anaesthesia (deep painless sleep).

Children

- Use with care in newborn babies, especially those born prematurely. Chlorhexidine and Cetrimide Irrigation Solution may cause chemical skin burns.

Using other medicines

Tell your doctor, nurse or pharmacist if you are taking or have recently taken any other medicines, including medicines you obtained without a prescription.

The following may affect the way Chlorhexidine for Irrigation works:

- alkaline pH, organic matter
- detergents (soaps) or blood. Chlorhexidine for Irrigation will not work properly if it come into contact with these
- tannins (from some plants).

Pregnancy and breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine. They will advise if you can have this treatment.

Driving and using machines

Chlorhexidine for Irrigation has little or no affect on your ability to drive or use machines. Please tell your doctor and they will advise you if you can drive or use machines.

3. How to use Chlorhexidine for Irrigation

Chlorhexidine for Irrigation may be used by a doctor or nurse, or in some cases you may use the solution yourself. Only use if the solution is clear and the seal is intact.

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose

- Your doctor will decide how much you will need and for how long it will be used. Your age, weight and clinical condition will be taken into account.
- The solution must be used undiluted and is for topical application. This means that it is for cleaning (irrigation) of your skin outside of your body.

If you have more Chlorhexidine for Irrigation Solution than you should

It is unlikely that you will be have or use more Chlorhexidine for Irrigation than you should.

If you accidentally swallow Chlorhexidine for Irrigation

If Chlorhexidine for Irrigation is accidentally swallowed, seek medical assistance. If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible Side Effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects may happen with this medicine.

If you experience any of the following reactions stop using Chlorhexidine for Irrigation and get immediate medical help: swelling of the face, lips, tongue or throat; a red itchy skin rash; wheezing or difficulty breathing; feeling faint and dizzy; a strange metallic taste in the mouth; collapse. You may be having an allergic reaction. Fatal anaphylactic reaction has been reported.

Other possible side effects

- Corneal injury (injury to the surface of the eye), and permanent eye damage including permanent visual impairment (following accidental ocular exposure during head, face and neck surgical procedures) in patients under general anaesthesia (deep painless sleep)

Very occasionally the following may be seen:

- low blood pressure (hypotension)
- tingling sensations in your skin (paraesthesia)
- difficulty breathing
- increased heart rate
- cold sweats
- reddening or itching of your skin
- loss of consciousness
- pain
- blood in your urine or an increase the urge to urinate
- rash
- coughing or wheezing (Bronchospasm)
- heart stops pumping (cardiac arrest)
- blood vessels stop working properly (circulatory collapse)
- shock
- Corneal injury (injury to the surface of the eye), and permanent eye damage including permanent visual impairment (following accidental ocular exposure during head, face and neck surgical procedures) in patients under general anaesthesia (deep painless sleep)

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Additional side effects in children

- Chemical burns

If you develop a rash or your skin becomes itchy, red, dry or inflamed where you have used the product as a skin wash, stop using it and talk to your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed below . By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom:

Via the Yellow Card Scheme at:

www.mhra.gov.uk/yellowcard

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 nurse straight away.

5. How to store Chlorhexidine for Irrigation

Keep this medicine out of the sight and reach of children.

Make sure that the product is stored and disposed of correctly and not used after the expiry date stated on the product. The storage conditions, should you need them, are given below.

- Do not store above 25°C and protect from light
- Do not use this medicine after the expiry date which is stated on the label after EXPIRY. The expiry date refers to the last day of that month
- Do not use this medicine if the container is damaged or the solution is not clear.
- Once opened: use immediately.

The solution should only be used once. Any leftover solution should be discarded. Do not throw away any medicine via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

This leaflet does not contain all the information about this medicine. If you have any questions or are not sure about anything, ask your doctor, nurse or pharmacist.

What Chlorhexidine for Irrigation contains

The active substances are chlorhexidine acetate 0.495 g in each 1000 ml.

The other ingredients are acetic acid and sterile water (called 'water for injections').

What Chlorhexidine for Irrigation looks like and contents of the pack

It is supplied as a clear, colourless solution for irrigation in a pour bottle or a form-fill-seal container.

Marketing Authorisation Holder and Manufacturers

The Marketing Authorisation holder is:

Baxter Healthcare Ltd
Caxton Way
Thetford
Norfolk
IP24 3SE
United Kingdom

Send all enquires to this address.

Manufacturer for Ireland

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This leaflet was last revised in August 2024

**For information about Chlorhexidine for Irrigation or to request this leaflet in formats such as audio or large print please contact the Marketing Authorisation Holder:
Tel: +44 (0)1635 206345.**

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