

Package leaflet: Information for the user

Chlorhexidine Acetate BP 0.05% w/v Irrigation Solution

Active substance: 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.
- If you get any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

Throughout this leaflet, Chlorhexidine Acetate BP 0.05% w/v Irrigation Solution will be called Chlorhexidine Irrigation Solution.

What is in this leaflet:

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

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

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

Chlorhexidine Irrigation Solution 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 Irrigation Solution

Your doctor will not use Chlorhexidine Irrigation Solution:

- if you are allergic to Chlorhexidine acetate or any of the other ingredients of this medicine (listed in section 6)
- for irrigation of your eyes, mouth or ears
- for irrigation of the brain or spinal cord or surrounding membranes (meninges).

Warnings and precautions

- anaphylactic reactions have been reported following use of products containing chlorhexidine in patients with an allergy to this ingredient. Sometimes these reactions have been fatal
- some patients may be hypersensitive to chlorhexidine which is an ingredient in this medicine.
- Use with care when this medicine is used to clean the skin, before an operation for your face or head

Children

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

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

This solution is not for intravenous administration and must not be taken orally.

Other medicines and Chlorhexidine Irrigation Solution

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

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

3. How to use Chlorhexidine Irrigation Solution

Chlorhexidine Irrigation Solution may be used by a doctor or nurse, or 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 recommended 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 in to account.
- The solution must be used undiluted and is for topical application. This means that it is for cleaning (irrigation) of your skin on the outside of your body.

If you have more Chlorhexidine Irrigation Solution than you should

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

If you accidentally swallow Chlorhexidine Irrigation Solution

If Chlorhexidine Irrigation Solution is accidentally swallowed, seek medical assistance. This can be treated with a stomach wash of milk, egg white, gelatine or mild soap.

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.

Tell your doctor, nurse or pharmacist straight away if you notice any of the following side effects:

- allergic reaction. The signs of this may include eczema, rash, and itching. If you have a reaction to the medicine, it will be stopped.
Fatal anaphylactic reaction has been reported.

Other possible side effects

- low blood pressure (hypotension). This may cause you to feel lightheaded, dizzy or to faint.
- tingling sensations in your skin (paraesthesia)
- difficulty breathing
- increased heart rate
- cold sweats
- reddening or itching of your skin
- loss of consciousness.
- Rash
- Coughing or wheezing (Bronchospasm)
- Heart stops pumping (cardiac arrest)
- Blood vessels stop working properly (circulatory collapse)
- Shock

Additional side effects in children

- Chemical burns

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRC Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2;

Tel: +353 1 6764971 Fax: +353 1 6762517 Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Chlorhexidine Irrigation Solution

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. Store in the original package in order to 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.

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 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 Irrigation Solution contains

The active substance is chlorhexidine acetate 0.5 g in each 1000 ml.
The other ingredients are acetic acid and sterile water (called 'water for injections').

What Chlorhexidine Irrigation Solution looks like and contents of the pack

It is supplied as a clear, colourless solution for irrigation in a 1000 ml plastic bottle.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Baxter Holding B.V.
Kobaltweg 49,
3542CE Utrecht,
Netherlands

Send all enquiries to this address.

Manufacturer:

Bieffe Medital S.P.A.
Via Nuova Provinciale
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For information about Chlorhexidine Irrigation Solution 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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