

Package leaflet: Information for the user

Chlorhexidine Acetate 0.015% w/v and Cetrимide 0.15% w/v, Irrigation Solution

Active substances: Chlorhexidine Acetate, Cetrимide

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.

Throughout this leaflet, Chlorhexidine Acetate 0.015% w/v and Cetrимide 0.15% w/v, Irrigation Solution will be called Chlorhexidine and Cetrимide Irrigation Solution.

What is in this leaflet:

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

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

Chlorhexidine and Cetrимide Irrigation Solution contains medicines called chlorhexidine acetate and cetrимide. These belong to a group of medicines called 'antiseptics', which are used to kill bacteria.

Chlorhexidine and Cetrимide Irrigation Solution is used:

- for cleaning (irrigating) the skin
- for wound and burn cleaning (irrigation)
- for irrigation of body cavities such as the bladder
- as a disinfectant for respirators.

2. What you need to know before you use Chlorhexidine and Cetrимide Irrigation Solution

Talk to your doctor, pharmacist or nurse before using Chlorhexidine and Cetrимide Irrigation Solution:

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

Chlorhexidine acetate or cetrимide must not come into contact with the eye due to the risk of visual damage. If it comes into contact with 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).

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 or cetrимide which are ingredients 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 and Cetrимide Irrigation Solution may cause chemical skin burns.

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

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

Chlorhexidine and Cetrимide Irrigation Solution contains:

- Sunset yellow (E110) may cause allergic reactions.

Other medicines and Chlorhexidine and Cetrимide 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 and Cetrимide Irrigation Solution has little or 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 and Cetrимide Irrigation Solution

Chlorhexidine and Cetrимide 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 into 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 and Cetrimide Irrigation Solution than you should

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

If you accidentally swallow Chlorhexidine and Cetrimide Irrigation Solution

If Chlorhexidine and Cetrimide 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 for which it is not known how often they occur, are: • 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.
- Rash
- Coughing or wheezing (Bronchospasm)
- Heart stops pumping (cardiac arrest)
- Blood vessels stop working properly (circulatory collapse)
- Shock
- Allergic skin disorders such as dermatitis (inflammation of the skin)
- Pruritus (itch)
- Erythema (redness of the skin),
- Eczema,
- Urticaria (hives),

- Skin irritation and blisters
- 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).

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 HPRA Pharmacovigilance, Website: www.hpra.ie;

. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Chlorhexidine and Cetrime 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.
- Once opened: use immediately.

The solution should only be used once. Any left over 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 and Cetrime Irrigation Solution contains

The active substances are chlorhexidine acetate 0.15 g and cetrime 1.5 g in each 1000 ml.

The other ingredients are Sunset yellow (E110) 8.0 mg in each 1000 ml, acetic acid and sterile water (called 'water for injections').

What Chlorhexidine and Cetrime Irrigation Solution looks like and contents of the pack

It is supplied as a clear, yellow solution for irrigation in a 500 ml or 1000 ml plastic bottle.

Pack sizes:

1 bottle 500 ml

1 bottle or 6 bottles of 1000 ml

Not all pack sizes may be marketed

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

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For information about Chlorhexidine and Cetrimide 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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