

## Package leaflet: Information for the user

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

#### Active substances: Chlorhexidine Acetate, Cetrimide

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 Cetrimide 0.15% w/v, Irrigation Solution will be called Chlorhexidine and Cetrimide Irrigation Solution.

#### What is in this leaflet:

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

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

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

Chlorhexidine and Cetrimide Irrigation Solution is used:

- for cleaning (irrigating) the skin
- for wound and burn cleaning (irrigation).

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

Your doctor will not use Chlorhexidine and Cetrimide Irrigation Solution:

- 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.

Do not take/use Chlorhexidine and Cetrimide Irrigation Solution 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 and Cetrimide Irrigation Solution 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 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).

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#### Children

- Use with care in newborn babies, especially those born prematurely. Chlorhexidine and Cetrimide Irrigation Solution may cause chemical skin burns. Your doctor will not use Chlorhexidine and Cetrimide Irrigation Solution if any of the above apply.

If you are not sure talk to your doctor, nurse or pharmacist before using Chlorhexidine and Cetrimide Irrigation Solution.

Your doctor will take special care when giving you Chlorhexidine and Cetrimide Irrigation Solution. If you have had a reaction to any of the ingredients.

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

Chlorhexidine and Cetrimide Irrigation Solution contains:

- Sunset yellow (E110) may cause allergic reactions.

#### Other medicines and Chlorhexidine and Cetrimide Irrigation Solution

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 and Cetrimide Irrigation Solution 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 and Cetrimide Irrigation Solution

Chlorhexidine and Cetrimide 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 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 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.

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 and Cetrimide Irrigation Solution 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 increased urge to urinate.
- rash
- coughing or wheezing (Bronchospasm)

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- 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)

#### **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](http://www.mhra.gov.uk/yellowcard)

### **5. How to store Chlorhexidine and Cetrimide 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 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 and Cetrimide Irrigation Solution contains**

The active substances are chlorhexidine acetate 0.15 g and cetrimide 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 Cetrimide 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.

#### **Marketing Authorisation Holder and Manufacturer**

**The Marketing Authorisation Holder is**

**Baxter Healthcare Ltd**

Caxton Way

Thetford

Norfolk

IP24 3SE

United Kingdom

Send all enquiries to this address.

Chlorhexidine and Cetrimide Irrigation Solution is made at the above address.

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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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