

## 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

Your doctor will not use 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
- 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 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 Cetrимide Irrigation Solution than you should**

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

### **If you accidentally swallow Chlorhexidine and Cetrимide 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

- 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

#### **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, Earlsfort Terrace,

IRL – Dublin 2;

Tel: +353 1 6764971

Fax: +353 1 6762517

Website: [www.hpra.ie](http://www.hpra.ie);

E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

#### **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. 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 Ceftriaxone Irrigation Solution contains

The active substances are chlorhexidine acetate 0.15 g and ceftriaxone 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 Ceftriaxone 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**

Marketing Authorisation Holder:  
Baxter Holding B.V.  
Kobaltweg 49, 3  
542CE Utrecht,  
Netherlands

Send all enquiries to this address.

### **Manufacturer:**

Bieffe Medital S.P.A.  
Via Nuova Provinciale  
23034 Grosotto (SO)  
Italy

This leaflet was last revised in December 2021

For information about Chlorhexidine and Ceftriaxone 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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