

Package leaflet: Information for the user

Hibiwash 40 mg/ml cutaneous solution

chlorhexidine digluconate

[For medicines available only on prescription:]

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 pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

[For medicines available without a prescription:]

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

Always use this medicine exactly as described in this leaflet or as you doctor, pharmacist, or nurse have told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See Section 4.

What is in this leaflet

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

1. What <invented name> is and what it is used for

<invented name> contains the active substance chlorhexidine digluconate, which belongs to a group of medicines called antiseptics.

<invented name> is used to disinfect the hands and skin before or after an operation in adults and children, to help prevent infections.

2. What you need to know before you use <invented name>

Do NOT use <invented name>

- if you are allergic (hypersensitive) to chlorhexidine digluconate or any of the other ingredients of this medicine (listed in Section 6).
- in your eyes or your middle ear. If you accidentally get this medicine in your eyes or ears, wash it out immediately and thoroughly with lots of water.
- on nerve tissues such as the brain and meninges (the membranes surrounding your brain and spinal cord).

Warnings and precautions

Talk to your nurse, pharmacist or doctor before using <invented name>.

- If you have a head or spinal injury or a perforated ear drum (an ear drum with a hole or tear in it), your nurse, pharmacist or doctor will decide whether it is safe for you to use <invented name> before an operation.
- <invented name> 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).
- This medicine should not be used on deep and extensive wounds.
- Do not use too much of this medicine. Do not allow it to pool in skin folds, under the patient or drip onto materials in direct contact with the patient.
- Do not inject the medicine.
- Hospital and household bleaches (which contain chemicals called hypochlorites) can cause brown stains to develop on fabrics which have been in contact with this medicine.
- Do not use with other soaps because it may make this medicine less effective.
- This medicine is flammable (it can be set on fire). Do not use it with anything that could cause a fire until your skin is dry.
- This medicine should never be used for disinfection of surgical instruments.

Children

Use with care in newborn babies, especially premature babies, as this medicine may cause chemical burns.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to become pregnant, ask your doctor, nurse, or pharmacist for advice before using this medicine.

This medicine can be used during pregnancy. There are no known risks with use of this medicine during pregnancy or lactation. If you are breast-feeding, avoid using this medicine on your breasts.

Driving and using machines

This medicine has no effect on your ability to drive or operate machinery.

3. How to use <invented name>

[For medicines available on prescription only:]

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

[For medicines available without prescription:]

Always use this medicine exactly as described in this leaflet or as your nurse, pharmacist or doctor have told you. Check with your nurse, pharmacist or doctor if you are not sure.

This medicine should only be used on your skin.

Do not dilute <invented name> before use.

Before an operation: surgical hand disinfection

Rinse your hands and forearms with water. Use 5 ml of this medicine, wash your hands and forearms for about a minute. Clean your fingernails with a brush or scraper. Rinse thoroughly. Repeat the wash a second time for about two minutes before you rinse thoroughly and dry your hands and forearms.

Antiseptic skin and handwash

Wet the affected area with water and apply 5 ml of this medicine and wash for one minute. Rinse thoroughly and dry.

Before your operation – washing your body

Wash the whole of your body in the bath or the shower on at least two occasions, usually the day before an operation and on the day of your operation.

How to clean yourself the day before and on the day of your operation:

- Wash your whole body with 25 ml <invented name>. Use it as a soap. Start with your face and work down your body. Pay special attention to the skin around your nose, your armpits, around your belly button, between your legs, crotch and your bottom.
- Then rinse your whole body with water.
- Repeat the wash with an additional 25 ml <invented name>. This time, wash your hair as well (use it as a shampoo but avoid getting it in your eyes)
- Then thoroughly rinse your whole body with water and dry with a clean towel.

After your operation – washing your body

Wash the whole of your body in the bath or the shower, using the same method described above, avoiding the operation site. This is usually done on the third day after your operation.

Pre-operative disinfection of the surgical area

Remove hair from the surgical site, if necessary. Swab the skin with <invented name> for up to 2 mins, then swab the area with sterile water. Remove any foam and dry.

If you use more <invented name> than you should

If you or a child accidentally swallows the medicine you should go to your nearest emergency department or contact your doctor immediately. Take this leaflet and any other packaging with you so they know what you have swallowed.

If you have any further questions on the use of this medicine, ask your nurse, pharmacist or doctor.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following serious side effects may occur, though the frequency is not known and cannot be estimated from available data. At the first sign of any of these reactions, stop using <invented name> immediately and seek medical help as quickly as possible and go to your nearest hospital.

- Serious allergic reactions (hypersensitivity, including anaphylactic shock) - which can cause swelling of your lips, tongue and face, a rash, breathing difficulties, weakness and collapse.

Other side effects

Not known: the frequency cannot be estimated from the available data:

- Chemical burns in newborn babies (neonates).
- Allergic skin reactions which can occur straightaway or 2-3 days or more after using the medicine, which can cause swelling and redness of the skin, an itchy rash (contact dermatitis) or itching, blisters, and eczema.

- 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).

Reporting of side effects

If you get any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [the national reporting system](#) listed in [Appendix V](#).^{*} By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store <invented name>

Keep this medicine out of the sight and reach of children

Do not use this medicine after the expiry date which is printed on the bottle after “EXP”. The expiry date refers to the last day of that month.

Do not store above 25°C.

Do not throw away any medicines 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

What <invented name> contains

The active substance is chlorhexidine digluconate. 1 ml contains 40 mg of chlorhexidine digluconate.

The other ingredients are poloxamer, isopropyl alcohol, cocamidopropylamine oxide, glycerol (E422), macrogol-7 glycerol cocoate, D-gluconolactone, sodium hydroxide (for pH adjustment)(E524), and purified water.

What <invented name> looks like and contents of the pack

<invented name> is a clear, colourless, slightly viscous solution that is supplied in white plastic bottles and caps containing 125 ml, 250 ml, 500 ml or 5 litres of liquid.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

<[To be completed nationally]>

This leaflet was last revised in 2024-11-14.