

PACKAGE LEAFLET

Package leaflet: Information for the patient

Hibiscrub® 4% w/v Cutaneous Solution

Chlorhexidine gluconate

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

1. What Hibiscrub is and what it is used for

Hibiscrub belongs to a group of medicines called antiseptics. This means that it helps to prevent infections by killing germs on the skin.

Hibiscrub cutaneous solution contains the active ingredient chlorhexidine gluconate 4% w/v (40 mg/ml), which has antimicrobial properties.

Hibiscrub is used to disinfect the hands and skin prior to or after an operation or clean procedure (pre- and post-operative hand and skin disinfection / antisepsis).

Hibiscrub is also used to disinfect hands after handling infected materials (antiseptic handwashing).

2. What you need to know before you use Hibiscrub

Do not use Hibiscrub

- if you are allergic (hypersensitive) to chlorhexidine gluconate or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Hibiscrub.

- Avoid contact with the eyes, brain, meninges (the membranes surrounding the brain and spinal cord) and middle ear. If Hibiscrub comes into contact with the eyes, wash out immediately and thoroughly with water.
- In patients with head or spinal injuries or a perforated ear drum (an ear drum with a hole or tear in it), the benefit of use in pre-operative preparation should be evaluated against the risk of contact.
- Common bleaches (which contain hypochlorites) may cause brown stains to develop on fabrics which have previously been in contact with chlorhexidine.
- Hibiscrub's action may be reduced if used with soap or detergents.
- If you go into hospital, let your doctor know if you are using Hibiscrub.

Children

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

Hibiscrub contains Herbacol (fragrance)

This medicine contains fragrance with 3-Methyl-4-(2,6,6-trimethyl-2-cyclohexen-1-yl)-3-buten-2-one, Amyl cinnamal, Amylcinnamyl alcohol, Anisyl alcohol, Benzyl alcohol, Benzyl benzoate, Benzyl cinnamate, Benzyl salicylate, Cinnamal, Citral, Citronellol, Coumarin, d-Limonene, Eugenol, Farnesol, Geraniol, Hexyl cinnamaldehyde, Hydroxymethylpentyl-cyclohexenecarboxaldehyde, Isoeugenol, Lilial, Linalool, Methyl heptine carbonate, Oak moss and Tree moss. These may cause allergic reactions.

3. How to use Hibiscrub

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

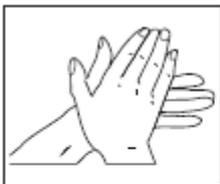
FOR EXTERNAL USE ONLY

Do not inject. Do not use in the body's internal spaces.

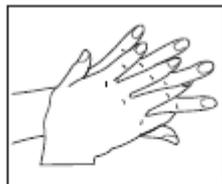
Chlorhexidine must not be used in direct contact with nerve tissue, for example brain and spinal cord tissue.

For Pre-operative Surgical Hand Disinfection

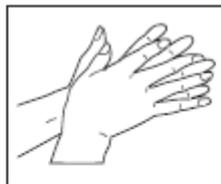
Wet the hands and forearms. Wash with 5 ml of Hibiscrub using the following procedure, each step consisting of five strokes backwards and forwards.



1. Palm to palm.



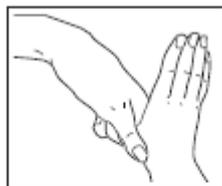
2. Right palm over left dorsum and left palm over right dorsum.



3. Palm to palm fingers interlaced.



4. Back of fingers to opposing palms with fingers interlocked.



5. Rotational rubbing of right thumb clasping in left palm and vice versa.



6. Rotational rubbing backwards and forwards of tips of fingers and thumb of right hand in left palm and vice versa.

Continue washing hands and wrists until one minute has elapsed. Clean the fingernails with a brush or scraper. Rinse thoroughly. For pre-operative use repeat the wash a second time for two minutes.

The Hibiscrub handwashing technique is based on a procedure described by Ayliffe GAJ et al. J Clin Path 1978; 31: 923.

For Antiseptic Handwashing on the Ward

Wet the hands and forearms, apply 5 ml of Hibiscrub and wash for one minute. Rinse thoroughly and dry.

For Preventing Infection Before Your Operation

Wash the whole of your body in the bath or the shower on at least two occasions. This is usually done on the day before the operation and the day of the operation. Use the following method:

- Use 25 ml of Hibiscrub as a soap solution.
- Wash the whole body. Start with the face. Work down the body. Pay special attention to the skin around the nose, under the arms, around the belly button, between the legs and around the bottom.
- Rinse the whole body.
- Repeat the wash. Use the same amount of Hibiscrub. This time, wash the hair as well.
- Rinse the whole body and dry thoroughly with a clean towel.

For Preventing Infection After Your Operation

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

If you accidentally swallow any Hibiscrub

You should go to your nearest Accident and Emergency department or contact your doctor immediately. Take this leaflet and any other packaging with you so they know what you have taken.

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 occur; it is not known how often they occur but available data suggests these are very rare (probably affect fewer than 1 in every 10,000 people).

- Serious allergic reactions which can cause breathing difficulties, weakness, collapse and death, and can sometimes be preceded by swelling (in particular lip/tongue and facial swelling), or rash.

Allergic reactions to chlorhexidine-impregnated patches have been reported rarely when used in newborn babies.

At the first sign of any of these reactions, tell your doctor, pharmacist or nurse and application of Hibiscrub should be stopped immediately.

Other possible side effects, for which it is not known how often they occur, are: allergic skin disorders such as dermatitis (inflammation of the skin), pruritus (itch), erythema (redness of the skin), eczema, rash, urticaria (hives), skin irritation and blisters.

Inflammation of the membranes of the brain and spinal cord has been reported when they have come into direct contact with chlorhexidine.

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:

Ireland

HPRA Pharmacovigilance
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie

United Kingdom

Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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 Hibiscrub

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. Store in the original package.

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 Hibiscrub contains

- The active substance is chlorhexidine gluconate 4% w/v (40 mg/ml).
- The other ingredients are poloxamer 237, isopropyl alcohol, lauryl dimethyl amine oxide, glycerol, macrogol 7 glycerol cocoate, gluconolactone, perfume (Herbacol), ponceau 4R (E124), sodium hydroxide and purified water.

What Hibiscrub looks like and contents of the pack

Hibiscrub is a clear, red, slightly viscous solution and comes in white bottles containing 125 ml, 250 ml, 500 ml or 5 litres of liquid.

Marketing Authorisation Holder

Regent Medical (Overseas) Limited, Medlock Street, Oldham, Lancashire, OL1 3HS, UK.

Manufacturer

BCM Ltd., Thane Road, Beeston, Nottingham, NG90 2PR, UK.

This leaflet was last revised in 06/2018.