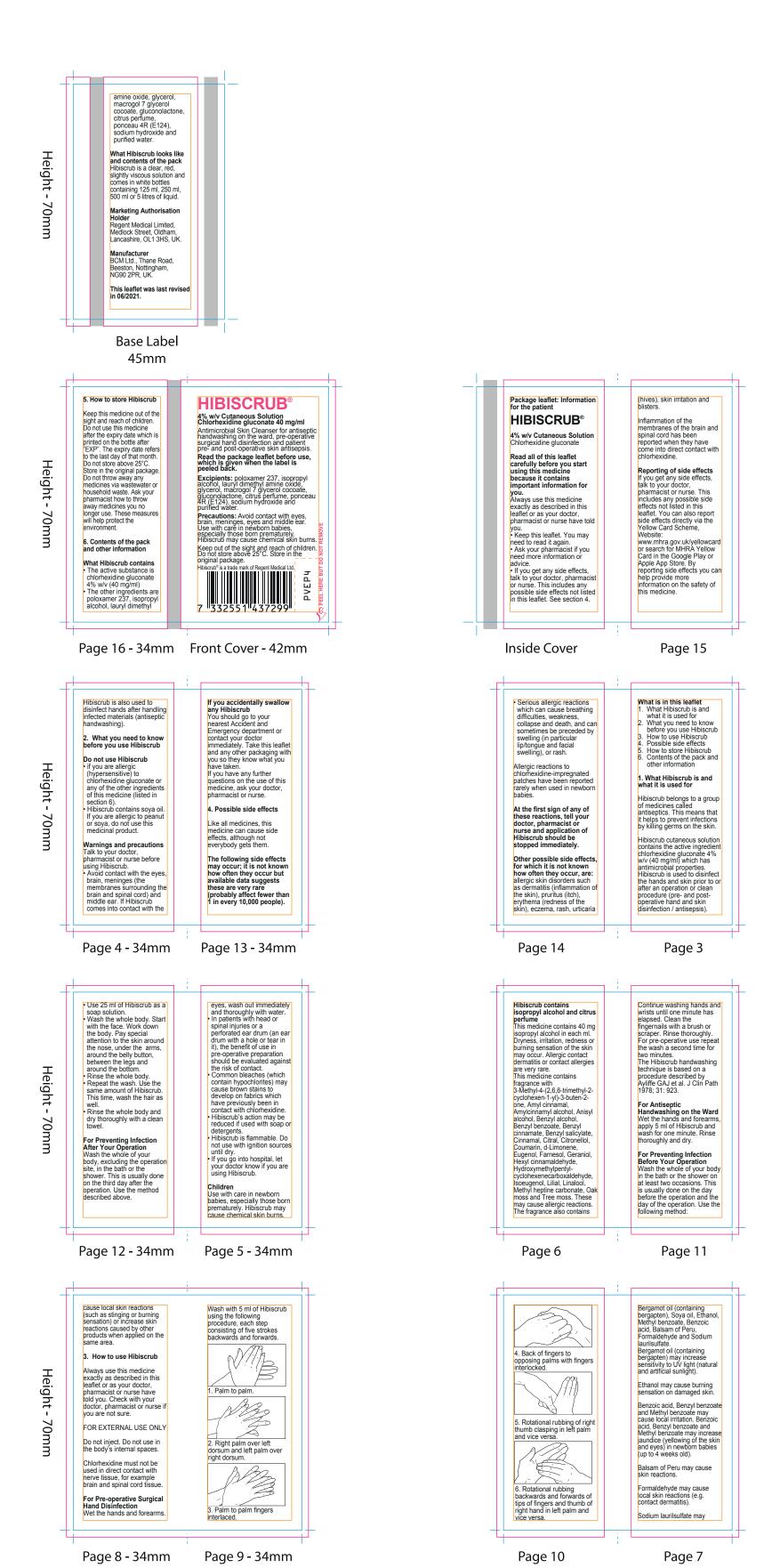
HIBISCRUB

Font: Marburg Medium 28,5 pt. UK Braille





70mm



HIBISCRUB

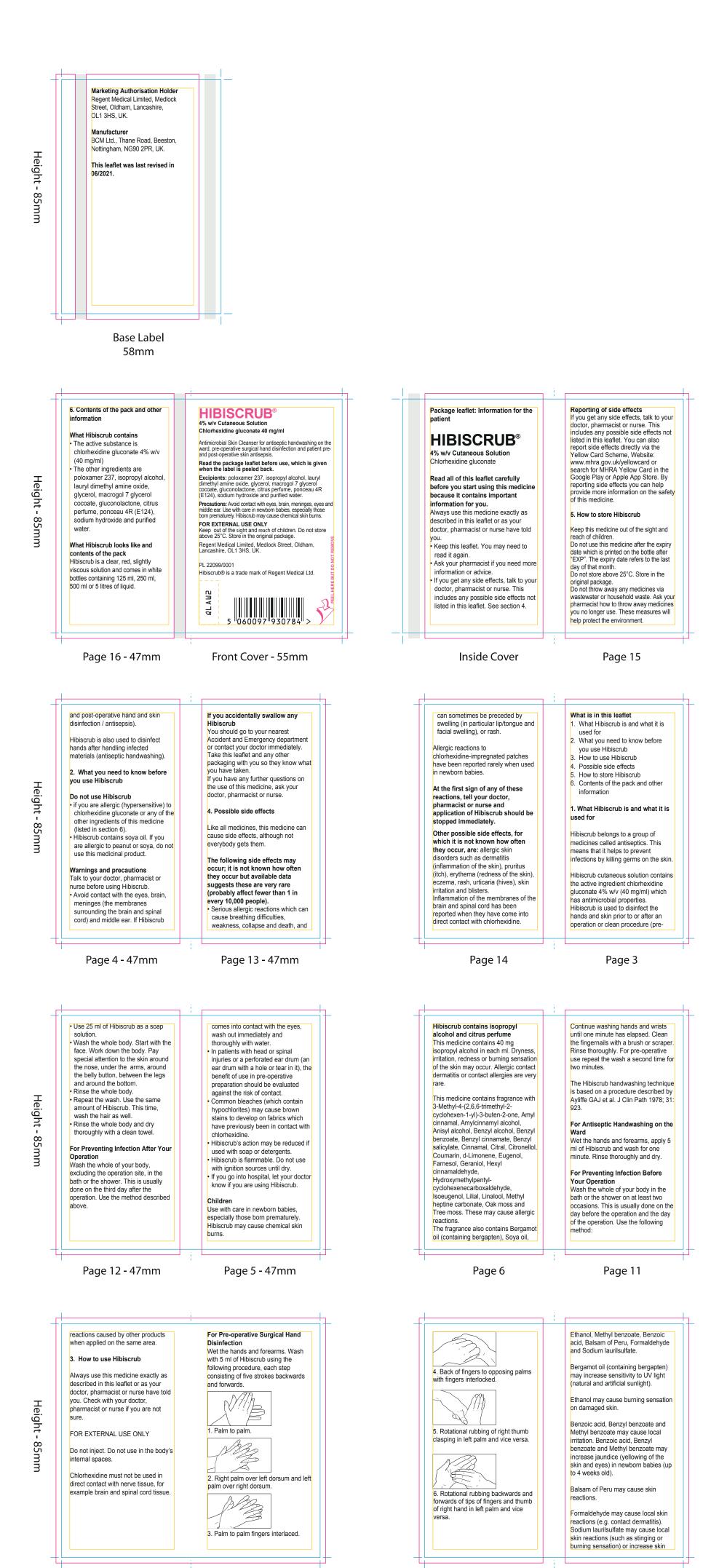
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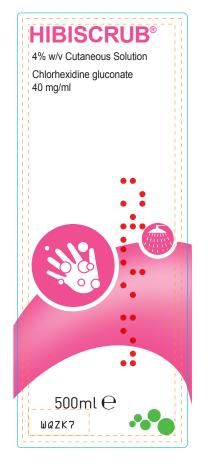
Page 8 - 47mm Page 9 - 47mm Page 10 Page 7

HIBISCRUB

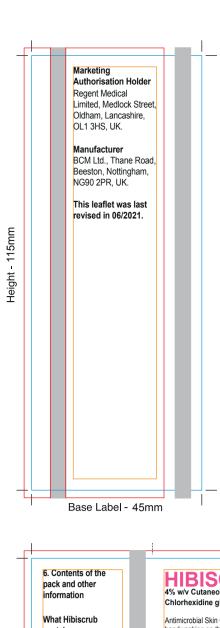
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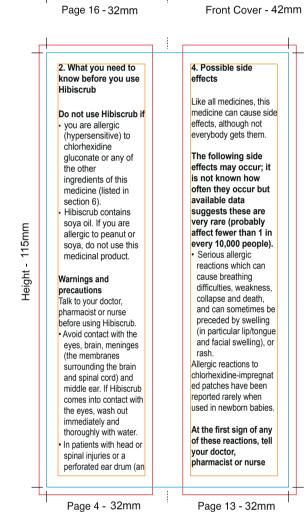
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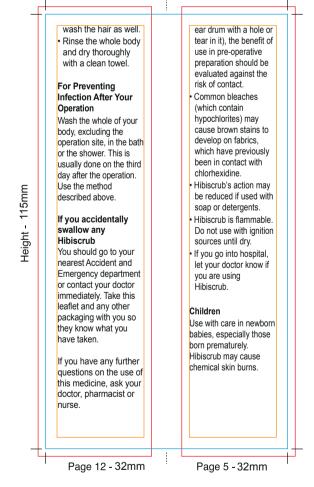


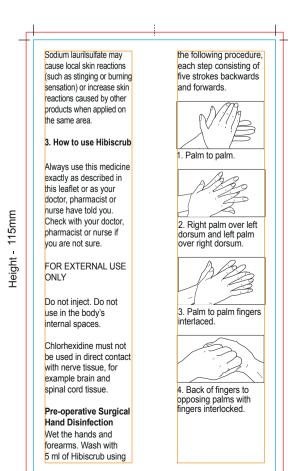
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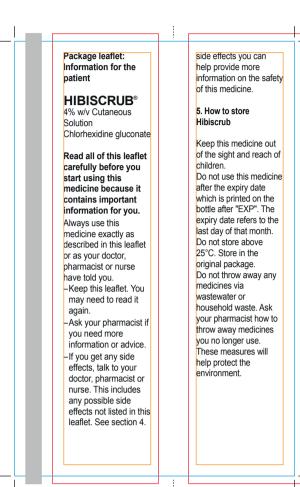






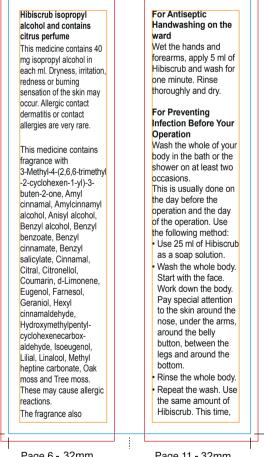
Page 9 - 32mm

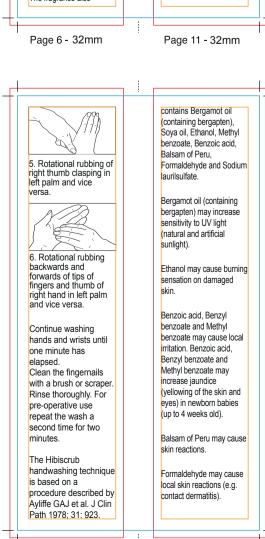
Page 8 - 32mm



Inside Cover - 42mm Page 15 - 32mm What is in this leaflet and application of Hibiscrub should be 1.What Hibiscrub is and stopped immediately. what it is used for ..What you need to effects, for which it is know before you use not known how often Hibiscrub they occur, are: allergic 3.How to use Hibiscrub skin disorders such as 4.Possible side effects dermatitis (inflammation 5.How to store of the skin), pruritus Hibiscrub (itch), erythema (redness 6.Contents of the pack of the skin), eczema, and other information rash, urticaria (hives). skin irritation and blisters 1. What Hibiscrub is Inflammation of the and what it is used for membranes of the brain and spinal cord has been reported when they have Hibiscrub belongs to a come into direct contact group of medicines with chlorhexidine called antiseptics. This means that it helps to Reporting of side prevent infections by effects killing germs on the skin If you get any side effects, talk to your Hibiscrub is used to doctor, pharmacist or disinfect the hands and nurse. This includes any skin prior to or after an possible side effects not operation or a clean listed in this leaflet. You procedure (pre- and can also report side post- operative hand

effects directly via the and skin disinfection/ Yellow Card Scheme. antisepsis). Website: www.mhra.gov.uk/yellow Hibiscrub is also used card or search for MHRA to disinfect hands after Yellow Card in the handling infected Google Play or Apple materials (antiseptic App Store. By reporting handwashing). Page 14 - 32mm Page 3 - 32mm





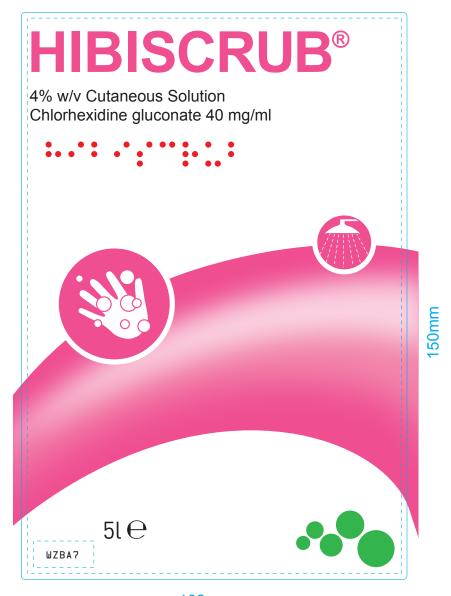
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Page 10 - 32mm

HIBISCRUB

Font: Marburg Medium 28,5 pt. UK Braille





102mm

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

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) ma/ml)

The other ingredients are poloxamer 237, isopropyl alcohol, lauryl dimethyl amine oxide, glycerol, macrogol 7 glycerol cocoate, gluconolactone, citrus perfume, 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

Marketing Authorisation Holder

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

Manufacturer

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

This leaflet was last revised in 06/2021.

Base Label - 102mm

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 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

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).
- Hibiscrub contains soya oil. If you are allergic to peanut or soya, do not use this medicinal product.

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.
- Hibiscrub is flammable. Do not use with ignition sources until dry. • 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 isopropyl alcohol and citrus perfume

This medicine contains 40 mg isopropyl alcohol in each ml. Dryness, irritation, redness or burning sensation of the skin may occur. Allergic contact dermatitis or contact allergies are very rare.

This medicine contains fragrance with $3\hbox{-Methyl-4-} (2,6,6\hbox{-trimethyl-2-cyclohexen-1-yl})\hbox{-} 3\hbox{-buten-2-one, Amyl}$ 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. The fragrance also contains Bergamot oil (containing bergapten), Soya

oil, Ethanol, Methyl benzoate, Benzoic acid, Balsam of Peru, Formaldehyde and Sodium laurilsulfate.

Bergamot oil (containing bergapten) may increase sensitivity to UV light (natural and artificial sunlight).

Ethanol may cause burning sensation on damaged skin.

Benzoic acid, Benzyl benzoate and Methyl benzoate may cause local irritation. Benzoic acid, Benzyl benzoate and Methyl benzoate may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).

Balsam of Peru may cause skin reactions Formaldehyde may cause local skin reactions (e.g. contact

Sodium laurilsulfate may cause local skin reactions (such as stinging or burning sensation) or increase skin reactions caused by other products when applied on the same area.

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.

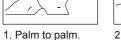
Inside Cover Page 3 Page 4

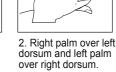


4. Back of fingers to

opposing palms with fingers interlocked.

Height - 150 mm





5. Rotational rubbing

of right thumb clasping 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.

Wet the hands and forearms, apply 5 ml of Hibiscrub and wash for

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

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.

· Repeat the wash. Use the same amount of Hibiscrub. This time,

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

Use 25 ml of Hibiscrub as a soap solution.

Rinse the whole body.

wash the hair as well.

For Preventing Infection Before Your Operation

and the day of the operation. Use the following method:

one minute. Rinse thoroughly and dry.



3. Palm to palm

6. Rotational rubbing

of tips of fingers and

thumb of right hand in

left palm and vice versa

backwards and forwards

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

For Preventing Infection After Your Operation

the operation. Use the method described above

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

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

4. Possible side effects

swelling), or rash.

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

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 dematitis (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 the Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

HIBISCRUB®

4% w/v Cutaneous Solution Chlorhexidine gluconate 40 mg/ml

Antimicrobial skin cleanser for antiseptic handwashing on the ward, pre-operative surgical hand disinfection, and patient pre- and post-operative skin antisepsis.

Read the package leaflet before use, which is given when the label is peeled back.

Excipients: poloxamer 237, isopropyl alcohol, lauryl dimethyl amine oxide, glycerol, macrogol 7 glycerol cocoate, gluconolactone, citrus perfume, ponceau 4R (E124), sodium hydroxide and purified water.

Precautions: Avoid contact with eyes, brain, meninges and middle ear. Use with care in newborn babies, especially those born prematurely. Hibiscrub may cause chemical skin burns. Keep out of the sight and reach of children.

FOR EXTERNAL USE ONLY

Do not store above 25°C. Store in the original package.

Regent Medical Limited Medlock Street, Oldham, Lancashire, OL1 3HS, UK

PL 22099/0001

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KSQB9



Page 5 - 91mm

· Rinse the whole body and dry thoroughly with a clean towel.