

Hydrex Surgical Scrub 4.0% w/v cutaneous solution

Chlorhexidine Gluconate skin cleanser

<What it is and what it is used for>

A cutaneous (relating to the skin) solution also containing Ponceau 4R (E124), Dialkylamine Oxide, Glycerol, Industrial Methylated Spirit, Hydroxyethyl Cellulose, Purified Water and Perfume (Hibetone).

For use as an antiseptic hand wash, a pre-operative hand scrub and a pre-operative skin preparation prior to surgery.

FOR EXTERNAL USE ONLY

Keep out of the sight and reach of children. Do not store above 25°C.

How to use

MEDICAL AND NURSING STAFF: Antiseptic hand wash – wet the hands and forearms, apply 5ml of Hydrex Surgical Scrub and wash for 1 minute. Rinse thoroughly and dry. Pre-operative surgical scrub – wet the hands and forearms, apply 5ml of Hydrex Surgical Scrub and wash for 1 minute, cleaning the fingernails with a brush. Rinse and repeat the procedure using a further 5ml of Hydrex Surgical Scrub and wash for 2 minutes. Rinse thoroughly and dry.

PATIENTS: Pre-operative skin preparation – wash the whole body with 25ml of Hydrex Surgical Scrub on at least two occasions, usually the day before and on the day of the operation. Rinse thoroughly and dry.

What you need to know before you use Hydrex Surgical Scrub
Talk to your doctor, pharmacist or nurse before using Hydrex Surgical Scrub.

Use with care in newborn babies, especially those born prematurely. Hydrex Surgical Scrub may cause chemical burns. Hydrex Surgical Scrub 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 into contact with the eye during surgical procedures, in patients under general anaesthesia (deep painless sleep).

Do not use Hydrex Surgical Scrub

- In body openings (eg nose and ears). Avoid contact with eyes, brain and meninges (skin covering the brain and spinal cord) and middle ear
- if you are allergic to chlorhexidine gluconate or any of the other ingredients of this medicine listed in section 6.

Actions to be taken if swallowed – If you accidentally swallow Hydrex Surgical Scrub you should go to the accident and emergency department of your nearest hospital.

Possible side effects - Chlorhexidine can very rarely cause hypersensitivity, including anaphylactic shock (throat or lip swelling, low blood pressure). Other possible side effects, for which it is not known how often they occur are:

- allergic reactions (e.g. dermatitis, itching, redness, eczema, rash, hives, skin irritation, blisters).
- 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).
- Possibility of chemical burns in neonates and infants.

If any of these reactions occur, stop using the product and seek medical attention.

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 label/leaflet. You can also report side effects directly via HPRAs Pharmacovigilance Earlsfort Terrace, IRL – Dublin 2. Tel +353 1 6764971; Fax: +353 1 6762517; Website: www.hpra.ie. Email: medsafety@hpra.ie.

<Further Information>

Do not store above 25°C.

Keep out of the sight and reach of children. Do not use after the expiry date on the label.

MA Holder & Manufacturer

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Text Revised: July 2024