Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Hydrex Surgical Scrub 4.0% w/v Cutaneous Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Chlorhexidine gluconate 4% w/v (equivalent to 40mg/ml)

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cutaneous Solution.
Red-coloured antiseptic solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

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

4.2 Posology and method of administration

Antiseptic hand wash - wet the hands and forearms, apply 5 ml of skin cleanser and wash for one minute. Rinse thoroughly and dry.

Pre-operative Surgical Scrub - wet hands and forearms, apply 5 ml of skin cleanser and wash for one minute, cleaning the finger nails with a brush. Rinse and repeat the procedure using a further 5 ml of skin cleanser and wash for 2 minutes. Rinse thoroughly and dry.

Pre-operative Skin Preparation - the patient should wash his whole body with 25 ml of the cleanser on at least two occasions, usually the day before and on the day of the operation.

4.3 Contraindications

Avoid contact with eyes, middle ear, brain and meninges.
Known hypersensitivityto the product or any of its components, especially in those with a history of possible chlorhexidine-related allergic reactions (see sections 4.4 and 4.8).

4.4 Special warnings and precautions for use

For external use only.
Keep out of the reach and sight of children.
Do not use in body cavities.

Hydrex Surgical Scrub contains chlorhexidine. Chlorhexidine is known to induce hypersensitivity, including generalised allergic reactions and anaphylactic shock. The prevalence of chlorhexidine hypersensitivity is not known, but available literature suggests this is likely to be very rare. Hydrex Surgical Scrub should not be administered to anyone with a potential history of an allergic reaction to a chlorhexidine-containing compound (see sections 4.3 and 4.8).

The use of chlorhexidine solutions, both alcohol based and aqueous, for skin antisepsis prior to invasive procedures has been associated with chemical burns in neonates. Based on available case reports and the published literature, this risk appears to be higher in preterm infants, especially those born before 32 weeks of gestation and within the first 2 weeks of life.

Remove any soaked materials, drapes or gowns before proceeding with the intervention. Do not use excessive quantities and do not allow the solution to pool in skin folds or under the patient or drips sheets or other material in direct contact with the patient. Where occlusive dressings are to be applied to areas previously exposed to Hydrex Surgical Scrub, care must be taken to ensure no excess product is present prior to application of the dressing.

4.5 Interaction with other medicinal products and other forms of interactions

None known.

4.6 Fertility, pregnancy and lactation

No special precautions need to be taken when used in pregnancy and lactation.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Immune disorders
Frequency not known
- Hypersensitivity including anaphylactic shock (see sections 4.3 and 4.4) to chlorhexidine gluconate or amine oxide, particularly on repeated use.

Skin disorders
Frequency not known:
- Allergic skin reactions such as dermatitis, pruritus, erythema, eczema, rash, urticarial, skin irritation, and blisters.
- Chemical burns in neonates and infants.

System Organ Class	Very Common (≥1/10)	Common (≥1/100 < 1/10)	Uncommon (≥1/1,000 < 1/100)	Rare (≥1/10,000 < 1/1,000)	Very Rare (< 1/10,000)	Not known (cannot be estimated from available data)
Immune System Disorders						**Hypersensitivity** **Anaphylactic shock**
Skin and Subcutaneous Tissue Disorders						**Allergic skin reactions** **Chemical Burns (Neonates and infants)**

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie .

4.9 Overdose

Chlorhexidine is poorly absorbed. If swallowed treat with gastric lavage. Employ supportive measures as appropriate.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC Code D08AC02.
Chlorhexidine is a bisbiguanide disinfectant which is active against a wide range of Gram-positive and Gram-negative vegetative bacteria. It is also active against some viruses and some fungi. It is most active at neutral or slightly acid pH.

5.2 Pharmacokinetic properties

Percutaneous absorption of chlorhexidine gluconate is negligible and leads to clinically insignificant plasma concentrations.

5.3 Preclinical safety data

Preclinical data reveal no special hazard for humans based on conventional studies of repeated dose toxicity, carcinogenic potential and toxicity to reproduction.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ponceau 4R (E124)
Dialkylamine oxide
Glycerol
Industrial methylated spirits
Hydroxyethyl cellulose
Perfume (Hibitone)
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Hydrex Surgical Scrub is packaged in HDPE containers with a flip-top cap or screw cap with EPE wad, in the following sizes: 100ml, 250ml, 500ml, 2000ml and 5000ml.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Ecolab Deutschland GmbH
Ecolab-Allee 1
D-40789 Monheim am Rhein
Germany

8 MARKETING AUTHORISATION NUMBER

PA1843/001/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 16 October 1995

Date of last renewal: 16 October 2010

10 DATE OF REVISION OF THE TEXT

March 2019 CRN008WP5