

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Aquasept Skin Cleanser 20mg/ml Cutaneous Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains 20mg Triclosan

Excipients: also contains chlorocresol 0.25% w/v, and Propylene glycol 5% w/v.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cutaneous solution

A clear blue aqueous solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

This product has an antibacterial effect and is intended for the following uses:

For skin disinfection prior to surgery and for routine skin cleansing to reduce the risk of cross-infection.

4.2 Posology and method of administration

For pre-operative hand disinfection (100ml, 250ml, 500ml, 5l):

Wet area to be cleansed. Apply about 5ml of Aquasept and wash for one minute, paying particular attention to the area around the fingernails and cuticles and between the fingers. Rinse and repeat for two minutes. Rinse thoroughly and dry hands with a sterile towel.

Antiseptic skin cleanser (100ml, 250ml, 500ml, 5l):

Wet area to be cleansed and use Aquasept as a liquid soap, washing thoroughly for one minute. Rinse and dry thoroughly.

4.3 Contraindications

Hypersensitivity to triclosan or to any of the excipients.

4.4 Special warnings and precautions for use

For external use only.

Avoid contact with eyes or mucous membranes.

Keep out of reach of children.

Do not apply to broken skin.

Some product excipients may give rise to allergic reactions in some people. In this instance, discontinue use and seek medical advice.

4.5 Interaction with other medicinal products and other forms of interactions

None stated.

4.6 Fertility, pregnancy and lactation

None stated.

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

There have been isolated reports of contact dermatitis reported with the use of Triclosan.

4.9 Overdose

Gastric lavage and symptomatic treatment.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC code: D08AE04-Antiseptics and disinfectants.
Triclosan is a bactericide.

5.2 Pharmacokinetic properties

None stated.

5.3 Preclinical safety data

None stated.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Monoethanolamine lauryl Sulphate (30 % solution)
Cocamide diethanolamine
Cocamidopropyl betaine (30 % solution)
Isopropyl alcohol
Propylene glycol
Tetrasodium edetate
Chlorocresol
Perfume
Triethanolamine
Patent Blue V (E131)
Purified Water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Unopened: 3 years.

6.4 Special precautions for storage

Do not store above 25 °C.

6.5 Nature and contents of container

HDPE or HDPP container.

Polypropylene wadless screw cap or compression moulded screw caps with steran faced pulpboard liner.

Sizes: 28.5 ml, 100 ml, 250 ml, 500 ml, 5000 ml.

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

Ayrton Saunders (Ireland) Limited
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Blackthorn Avenue
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8 MARKETING AUTHORISATION NUMBER

PA22906/003/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 22 April 1992

Date of last renewal: 22 April 2007

10 DATE OF REVISION OF THE TEXT

November 2019