Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

STERILLIUM® Cutaneous Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

100 g of solution contains:

Propan-2-ol	45 g
Propan-1-ol	30 g
Mecetronium etilsulfate	0.2 g

For full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Cutaneous Solution.
Coloured solution with the odour of perfume.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Hygienic and surgical hand disinfection.

Skin disinfection prior to injections and punctures.

4.2 Posology and method of administration

For hygienic hand disinfection:
At least 3 ml of STERILLIUM® should be rubbed onto the dry hands within 30 seconds without rinsing.

For surgical hand disinfection:
STERILLIUM® should be distributed onto dry hands and forearms in order to entirely cover them. As many portions as necessary to keep them wet for at least 1.5 minutes should be rubbed in without rinsing.

Skin disinfection:
STERILLIUM® should be rubbed onto the area of the dry skin for 15 seconds prior to injections and punctures; prior to punctures of joints, body cavities and hollow organs as well as surgical interventions keep wet for 1 minute. Skin containing many sebaceous glands must be kept moist for 10 minutes.

STERILLIUM® is used undiluted.

4.3 Contraindications

STERILLIUM® is not suitable for the disinfection of mucous membranes and must not be used in the immediate proximity of the eyes or open wounds.

Hypersensitivity to the active substances or to any of the excipients.

4.4 Special warnings and precautions for use

- STERILLIUM® should not be used in neonates and premature infants.
- Contact with eyes has to be avoided.
- If the solution gets in contact with the eyes wash them with open palpebral fissure for several minutes under running water.
- Decanting STERILLIUM® from one container to another should be avoided in order to prevent contamination. Should decanting be inevitable, it should be carried out under aseptic conditions (e.g., use of sterile containers under laminar flow).
- Do not use electrical equipment until the preparation has dried.
- Do not bring into contact with naked flames.
- Do not use near to sources of ignition. Flash point 23°C, flammable.
- When the product is used correctly fire and explosion are unlikely.
- In case of spilling the disinfectant the following measures have to be taken: Clean up the solution immediately, dilute with plenty of water, aerate the room, and remove easily ignited sources. Do not smoke.
- In case of fire extinguish with water, a fire extinguisher, foam, or CO_2.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

4.6 Fertility, pregnancy and lactation

No known risk during pregnancy and lactation.

4.7 Effects on ability to drive and use machines

Not relevant.

4.8 Undesirable effects

Slight dryness or irritation of the skin is uncommon. In such a case it is recommended to intensify general skin care. The frequency of allergic reactions is rare.

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

If swallowed by accident the main symptoms of intoxication are similar to those of ethanol intoxication. Danger of respiratory paralysis.
From 3-4 per mill and above: secondary elimination of the poison by means of haemodialysis.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

STERILLIUM® is for topical use only and has no pharmacological properties in man.

ATC-Code: D08A X 53 Antiseptics and Disinfectants

Mechanism of action:
In microorganisms STERILLIUM® modifies the permeability of the cytoplasmic membrane, acts by protein coagulation, and inactivates enzymes.

Antimicrobial properties
In-vitro and *in-vivo* studies have shown that STERILLIUM® is active against a range of common bacteria and fungal pathogens. STERILLIUM® reduces the transient skin flora by more than 99.99 % within 30 seconds for hygienic disinfection and is also active against the resident skin flora within 1.5 minutes in case of surgical disinfection.

The residual effect of STERILLIUM® against microorganisms is, under surgical gloves, at least 3 hours.

5.2 Pharmacokinetic properties

The percutaneous absorption of all constituents of STERILLIUM® was not investigated. Recent studies on percutaneous absorption of Mecetronium etilsulfate in the rats indicate minor substance absorption only.

5.3 Preclinical safety data

The acute (oral, dermal) and subacute (dermal) toxicity of STERILLIUM® is low.

Acute toxicity:

LD_{50} (mouse)	oral, after 14 days	13.0 ml/kg BW
LD_{50} (rat)	oral, after 14 days	15.6 ml/ kg BW
LD_{50} (rabbit)	dermal	> 10.0 ml/ kg BW

Repeated dose toxicity:
A 28-day dermal study in rabbits with 1.0 and 5.0 ml STERILLIUM® per kg body weight revealed no substance related effects on body weight, clinical appearance, organ weights and histopathology of liver and kidneys. Blood levels of Propan-1-ol, Propanol-2-ol and Acetone were not elevated.

Reproductive toxicity:
From *in-vitro* and *in-vivo* data on skin absorption it is calculated that only negligible amounts of the active ingredients of STERILLIUM® may permeate the skin during hygienic and surgical hand disinfection. The alcohols are evaporated within the application time. Mecetroniumetilsulfate is barely absorbed through intact skin. Therefore studies on foetal toxicity and reproductive toxicity may be omitted according to Council Directive 75/318/EEC. Teratogenic effects of lower alcohols in humans and animals after dermal application are not known from literature.

Genotoxicity:
Genotoxicity tests were negative with Propan-1-ol, Propan-2-ol and Mecetroniumetilsulfate.

Local tolerance:
The active ingredients of STERILLIUM® are not irritating to the skin at concentrations used in the product. Propan-1-ol, Propan-2-ol and Mecetroniumetilsulfate have no sensitizing properties. STERILLIUM® causes irritation to mucous membranes.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerol 85%
Tetradecan-1-ol
Perfume
Colour (E131)
Purified water

6.2 Incompatibilities

STERILLIUM® attacks acrylic glass and similar materials.

6.3 Shelf life

The finished product in the unopened packaging: 5 years.
After first opening of the container: 1 year.

6.4 Special precautions for storage

Keep the container tightly closed.
Do not store in the proximity of heating elements or expose to solar radiations of high intensity. Do not store above 40° C.
Water risk class 1: slightly dangerous to water.

6.5 Nature and contents of container

In bottles taking 50 ml, 100 ml, 350 ml, 500 ml or 1000 ml; in containers taking 5 l, 25 l or 500 l; in barrels taking 200 l, all made of HDPE.

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

See section 4.4, Special warnings and precautions for use

Dispensers with adjustable pump system for use of original bottles are offered on request. The standard delivery amount is set at 1.5 ml per pump actuation and can be altered.

Waste disposal: Any unused product or waste material should be disposed of in accordance with local requirements. Medicines should not be disposed of via wastewater.

7 MARKETING AUTHORISATION HOLDER

Bode Chemie GmbH
Melanchthonstrasse 27
D-22525 Hamburg
Germany

8 MARKETING AUTHORISATION NUMBER

PA 0808/001/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 25 July 1997
Date of last renewal: 15 November 2010

10 DATE OF REVISION OF THE TEXT

August 2014