

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Skinman 96% (v/v) Cutaneous Solution

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 100 g of cutaneous solution contains 95.7 g denatured Ethanol 96 % v/v (complies to 89.0 g Ethanol)  
Denaturing agent: Ethyl Methyl Ketone (1 % v/v)

For a full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Cutaneous solution  
Skinman is a clear and colourless liquid with an alcoholic scent.

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic Indications

This medicinal product is an alcoholic ready-to-use hand disinfectant for hygienic and surgical hand disinfection.

### 4.2 Posology and method of administration

#### Adults and adolescents aged above 12 years

The product must be used in accordance with the following instructions:

- Hygienic hand disinfection:  
Rub undiluted Skinman into dry hands, keeping the skin moist for at least 30 seconds.
- Surgical hand disinfection:  
Rub undiluted Skinman into dry hands and forearms, keeping the skin moist for at least 90 seconds.
- For full virucidal efficacy, you must allow an application time of at least 120 seconds, during which time the hands must be kept moist with Skinman.

Then allow hands to air dry.

Skinman is not recommended for use in children under 12 years due to a lack of data on safety.

### 4.3 Contraindications

Hypersensitivity to the active substance denatured Ethanol 96 % or to any of the excipients.

### 4.4 Special warnings and precautions for use

Attention has to be paid if large amounts of Skinman are spilt, as Skinman is highly inflammable (fire and explosion hazard!). If this happens, precautionary measures have to be taken immediately: Clearing up the liquid, dilution with lots of water, airing the room, removal of any ignition sources.

The product must be allowed to dry before using electrical equipment. Attention has to be paid when using Skinman near alcohol-sensitive surfaces.

Skinman is an eye and mucosal irritant. It may not be used in the eye area, on broken skin or mucous membranes. In case of accidental contact with eyes or mucous membranes, immediate flushing with plenty of water (also under the eyelids in the case of the eyes) is recommended. In case of persistent irritation, a doctor must be consulted.

Skinman should only be used externally. In case of accidental swallowing, medical assistance must be sought immediately.

In case of minor skin irritations (e.g. dryness) due to frequent use of Skinman skin care should be intensified.

The content of pack sizes > 1 L may be refilled into smaller original dispenser units under appropriate hygienic conditions (e.g., laminar flow) by healthcare professionals.

#### **4.5 Interaction with other medicinal products and other forms of interaction**

There are no known interactions with other medicinal products.

#### **4.6 Fertility, pregnancy and lactation**

Provided that it is used properly, Skinman can be used during pregnancy and lactation.

#### **4.7 Effects on ability to drive and use machines**

Skinman has no influence on the ability to drive and use machines.

#### **4.8 Undesirable effects**

Within each frequency grouping, undesirable effects are presented in order of decreasing seriousness.

very common ( $\geq 1/10$ )

common ( $\geq 1/100$  to  $< 1/10$ )

uncommon ( $\geq 1/1,000$  to  $< 1/100$ )

rare ( $\geq 1/10,000$  to  $< 1/1,000$ )

very rare ( $< 1/10,000$ )

*Skin and subcutaneous tissue disorders*

Rare: Skin irritations such as redness and burning, contact allergies

Disinfecting agents containing alcohol can dry the skin and may cause skin irritations, particularly if air humidity is low (e.g. in winter).

#### **4.9 Overdose**

No case of overdose has been reported.

### **5 PHARMACOLOGICAL PROPERTIES**

#### **5.1 Pharmacodynamic properties**

Pharmacotherapeutic group: Other antiseptics and disinfectants

ATC code: D08AX08

Skinman is for topical use only and has in this application no systemic or pharmacologic efficacy.

Ethanol is effective against gram-negative and gram-positive bacteria incl. mycobacteria, yeasts and viruses. Ethanol is also effective against antibiotic resistant bacteria strains (e.g. MRSA).

The antimicrobial effect of Ethanol is very probably based on the denaturation of proteins.

No specific clinical data in atopic subjects are available for Skinman.

## Information on the Efficacy of Skinman

- Range of efficacy: Bacteria (including mycobacteria), yeasts and enveloped and non-enveloped viruses (classification: “virucidal”)\*.
- Transient skin flora (hygienic hand disinfection): Using the hand rub method, Skinman achieves the reduction in germs on artificially contaminated skin after 30 seconds, as specified by DIN EN 1500.
- Resident skin flora (surgical hand disinfection): Skinman fulfils the requirements of EN 12791 after 90 seconds. After this contact time the resident (natural) skin flora is significantly reduced for a period of 3 hours.
- Efficacy against viruses: Skinman has been tested against various test viruses. In vitro efficacy in accordance with test standards was achieved after a contact time of 15 – 120 seconds:
  - Vaccinia virus (DVV 2008): 15 seconds
  - BVDV (Surrogate virus for Hepatitis C virus, DVV 2008): 15 seconds
  - Adenovirus (DVV 2008): 60 seconds
  - Adenovirus (EN 14476): 120 seconds
  - Polyoma virus SV 40 (DVV 2008): 120 seconds
  - Poliovirus (DVV 2008): 120 seconds
  - Poliovirus (EN 14476): 60 seconds

According to current knowledge\*, the results show evidence of efficacy against other enveloped and against non-enveloped viruses, e.g. Noro virus, Hepatitis B and C viruses and HI virus.

\*Mielke M et al.; Position of the Virucide Study Group of the Robert Koch Institute (RKI) and the “Virus Disinfection” Professional Committee of the German Society for Control of “Virus Infections” and the Disinfectant Committee of the German Society of Public Health and Microbiology “Evaluation and declaration of effectiveness of disinfectants against viruses” (Bundesgesundheitsbl - Gesundheitsforsch - Gesundheitsschutz 2004 • 47:62–66)

## 5.2 Pharmacokinetic properties

Skinman should be used undiluted. The dose for each indication has been determined based on results of antimicrobial efficacy studies.

The absorption of Skinman has not been tested. The active substance Ethanol shows negligible skin penetration. Bioavailability, distribution, biotransformation and elimination are therefore not relevant.

## 5.3 Preclinical safety data

Ethanol is a well known active substance for topical antiseptics and disinfectants. Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential and toxicity to reproduction and development

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Denaturing agent: Ethyl Methyl Ketone (1 % v/v)  
 Macrogol-6-glycerolcaprylocaprate (Ph. Eur.)  
 Lactic acid (90 %)  
 Fragrance (containing orange oil with more than 90 % limonene)  
 Purified water

## 6.2 Incompatibilities

Not applicable.

## 6.3 Shelf life

4 years

After first opening the container:

1 year

## 6.4 Special precautions for storage

Do not store above 25 °C.

Store in a cool dry place, away from direct sunlight.

Flammable contents. Flash point 13° C.

Product should be kept away from a naked flame.

## 6.5 Nature and contents of container

Skinman is marketed in the following pack sizes:

- HDPE-bottles with a capacity of 100 ml
- HDPE-wall dispenser bottles with a capacity of 500 ml and 1 l
- HDPE-dispenser containers with a capacity of 5 l

Not all pack sizes may be marketed.

## 6.6 Special precautions for disposal and other handling

Any unused solution and the containers should be adequately disposed of, in accordance with local requirements.

## 7 MARKETING AUTHORISATION HOLDER

Ecolab Limited  
Lotherton Way  
Garforth  
Leeds, LS25 2YJ  
United Kingdom

## 8 MARKETING AUTHORISATION NUMBER

PA1110/12/1

## 9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 10th February 2012

## 10 DATE OF REVISION OF THE TEXT