

This leaflet format has been determined by the Ministry of Health and the content thereof has been checked and approved in November 2017

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF MEDICINE

Softa-Man ViscoRub

Ethanol 45 % w/v ; Propanol 18 % w/v

Cutaneous solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

100 grams of gel contains 55.70 g of ethanol (96% v/v); 21.00 g of propanol

For full list of excipients, see *section 6.1*.

3. PHARMACEUTICAL FORM

Viscous non-sterile aqueous solution

4. CLINICAL INFORMATION

4.1 Therapeutic indications

Softa-Man ViscoRub is indicated for hygienic and surgical hand disinfection.

4.2 Dosage and route of administration

Topical.

At least 3 ml of undiluted Softa-Man ViscoRub should be applied on the dry palms of the hands and rubbed for:

- at least 30 seconds for hygienic hand disinfection

- at least 90 seconds for surgical hand disinfection

The skin must remain moist for 30 or 90 seconds, accordingly.

the skin should be left to dry and no rinse is needed.

Softa-Man ViscoRub can be used without prior cleansing of the hands. Visibly dirty hands should be washed with soap and water first.

4.3 Contraindications

Hypersensitivity to the active ingredient or to any of the excipients listed in *section 6.1*.

4.4 Special warnings and precautions for use

Avoid any contact with eyes and mucous membranes.

Apply only to intact skin.

Flammable (flash point: 21° C). Keep away from any flame or source of ignition.

No smoking. Do not ingest. For external use only

4.5 Interactions with other medicines and other forms of interactions

No interaction study was performed.

4.6 Fertility, pregnancy and breastfeeding

Pregnancy

Given that the product is only applied locally to intact skin and that the absorption of alcohol by the skin is negligible, Softa-Man ViscoRub can be used in the recommended manner for hand disinfection during pregnancy.

Alcohol is a known teratogenic agent in case of systemic absorption during the use of the product. In alcohol-dependent mothers, foetal alcohol syndrome was observed in which babies had specific characteristics and abnormalities such as microcephaly, low body weight, and facial abnormalities, with certain characteristics resembling an animal's snout.

Breastfeeding

Given that the product is only applied locally to intact skin and that the absorption of alcohol by the skin is negligible, Softa-Man ViscoRub can be used in the recommended manner for hand disinfection during breastfeeding.

4.7 Effects on the ability to drive and use machines

Not applicable.

4.8 Side effects

In rare cases, local irritation attributable to the alcohol (e.g. itching, redness), especially after repeated applications of Softa-Man ViscoRub, may occur. Skin dryness can be experienced in rare cases, during seasons with low humidity (mainly winter). In such cases, the use of a hand cream is recommended. If any of the side effects become serious, or if you experience any side effects not listed in this leaflet, contact your doctor or pharmacist.

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. Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form:

<https://sideeffects.health.gov.il/>

4.9 Overdose

In the event of accidental ingestion of a large quantity, perform gastric lavage or administer emetics. Treat respiratory depression if necessary. Keep the patient warm.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic class: Other antiseptics and disinfectants

ATC Code: Propanol, combinations: D08AX53

Softa-Man ViscoRub is an alcohol-based hand sanitiser solution containing skincare products.

Mechanism of action:

The active ingredients, namely the ethanol and propanol alcohols, have an inhibitory and lethal effect on Gram-positive and Gram-negative bacteria, including mycobacteria. They are also powerful virucides and fungicides. Their sporicidal action is not reliable.

The antimicrobial activity of alcohols is obtained by the rapid coagulation of proteins. The effect of blood, proteins, serum and other organic substances on this action is negligible.

Ethanol and propanol, alone or in combination, have an antimicrobial action that is almost negligible if they are not diluted with water. Depending on their concentration and type of combination, they have an optimal effect in concentrations between 60 and 90%.

Pharmacodynamic effect:

The active ingredients of Softa-Man ViscoRub are ethanol and propanol. It is extremely effective against the Gram-positive and the Gram-negative bacteria, including antibiotic-resistant bacterial strains [for example, Methicillin-resistant *Staphylococcus aureus* (MRSA)] and mycobacteria. Softa-Man ViscoRub has a good fungicidal and virucidal action and quickly inactivates enveloped viruses and rotaviruses. The effectiveness of Softa-Man ViscoRub against spores has not been tested.

The effect of Softa-Man ViscoRub in hand disinfection procedures has been successfully tested according to international standards EN 1500 (hygienic hand disinfection) and EN 12791 (surgical hand disinfection). A decrease of more than 99.99% (4 log₁₀) in temporary hand contamination was observed in 30 seconds (hygienic hand disinfection). A 90-second contact time (surgical hand disinfection) results in an immediate effective reduction of the natural bacterial flora on the skin that persists for more than 3 hours.

Softa-Man ViscoRub has been shown to inactivate viruses in a variety of approved *in vitro* test models with a 15-second contact time:

| Virus | Inactivation time |
|--|--------------------------|
| Enveloped viruses | 15 s |
| <i>Hepatitis C virus (tested substitute: BVD virus)</i> | 15 s |
| <i>Vaccinia virus</i> | 15 s |
| <i>Avian influenza type A virus (substitute of the strain of influenza virus tested: H7N1)</i> | 15 s |
| Non-enveloped viruses | |
| <i>Rotavirus</i> | 15 s |

5.2 Pharmacokinetic properties

The absorption of ethanol and propanol by the skin is negligible.

There is no preclinical data available that may be of importance to the prescriber other than those already included in the other sections of the "Summary of Product Characteristics".

5.3 Preclinical safety data

The preclinical data does not indicate a specific risk to human use if the product is applied according to the approved indications and in the recommended dosage.

In animals, systemic absorption of ethanol induces hepatotoxicity, teratogenicity, an increased percentage of miscarriages and, in male rats, decreased fertility.

Systemic absorption of propanol induces hepatic toxicity and hyperplasia of the hematopoietic parenchyma. Ethanol is known for its clastogenic activity and it can act as a tumour promoter in combination with known carcinogens. Propanol has not been tested for carcinogenicity but, theoretically, it can act as a tumour promoter just like ethanol.

6. PHARMACEUTICAL DATA

6.1 List of excipients

Butanone; glycerol; isopropyl myristate; cetearyl ethylhexanoate; Edetol; octyldodecanol; acrylates / C10-30 alkyl acrylate crosspolymer; bisabolol; purified water

6.2 Incompatibilities

This medicine must not be mixed with other medicines.

6.3 Shelf life

The expiry date of the product is indicated on the packaging materials.

Shelf life after first opening: 12 months but not beyond the expiry date.

Close the packaging immediately after each use.

6.4 Special precautions for storage

Flammable (flash point: 21° C). Store below 25°C, away from any flame or source of ignition.

For the storage conditions of the medicinal product after the first opening, see *section 6.3*.

6.5 Type and content of the outer package

500 ml bottle with a screw cap or a pump

100 ml bottle with a screw cap or a pump

1000 ml bottle with a screw cap or a pump

6.6 Special precautions for disposal

Any unused product or waste must be disposed of in accordance with the local regulations.

7. Manufacturer

B. Braun Melsungen AG

Carl-Braun-Strasse 1

34212 Melsungen

Germany

8. Marketing Authorisation Holder and Importer

C.W.T - CHRONIC WOUND TREATMENT LTD.,

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9. Marketing Authorization Number

159-59-35073-00