

Directions for Use

B. Braun Melsungen AG, 34209 Melsungen, Germany

Softa-Man

Propan-1-ol 18 g + Ethanol (100%) 45 g
Cutaneous Solution

Composition

100 ml of solution contain

Active substances:

Propan-1-ol 18 g

Ethanol (100%) 45 g

Excipients:

Diisopropyl Adipate, PEG-6 Caprylic/Capric Glycerides, Dexpanthenol, Bisabolol, Allantoin, Perfume (contains Limonene and Linalool) and Purified Water

Pharmaceutical Form

Cutaneous solution

Softa-Man is a clear colourless solution for application on the skin (cutaneous solution).

It is available in plastic bottles and containers of 100 ml, 500 ml, 1000 ml, 5 l and 25 l.

Pharmaco-Therapeutic Group

Antiseptics and disinfectants with propanol combinations
Softa-Man is an alcoholic hand disinfectant with skin caring agents.

The active ingredients, ethanol and propanol are effective against bacteria [incl. strains which are resistant against antibiotics, e.g. MRSA (Methicillin Resistant Staphylococcus Aureus)], mycobacteria (incl. mycobacterium tuberculosis), fungi and enveloped viruses (e.g. Hepatitis-B Virus and Hepatitis-C Virus, HI-Virus), and Rotavirus.

Indications

Softa-Man is intended for hygienic and surgical hand disinfection.

Contraindications

Softa-Man must not be used if you are allergic to ethanol or propanol or any of the other ingredients of Softa-Man listed above.

Special Warnings and Precautions for Use

Take special care with Softa-Man if:

you develop sensitivity (allergy) to the product. In this case you should stop using it immediately.

Softa-Man is flammable. The flash point of the solution is 21 – 22 °C. That means that at 21 to 22°C and higher, Softa-Man may be ignited by sparks, burning cigarettes, open flames and other sources of ignition.

Do not swallow. Do not apply on injured skin, eyes or mucous membranes!

Softa-Man is for external use only. If somebody swallows Softa-Man inadvertently, he may suffer from acute alcohol poisoning. Immediate emergency medical care is needed because large doses could stop breathing or impair consciousness with a danger of inhaling vomit. Initiate vomiting under medical advice only.

In case of accidental eye contact, the open eye and the inner side of the eyelid has to be rinsed with plenty of water immediately for several minutes. If irritation continues please seek immediate medical advice.

Effects on ability to drive and use machines:

Softa-Man does not affect the ability to drive or operate machinery.

Pregnancy and Lactation

Since Softa-Man is applied only locally to the hands no precautions are necessary.

Interactions

Using other medicines:

Because the product is applied locally on intact skin, no special restrictions are to be observed.

Dosage

The recommended dosage is

Hygienic hand disinfection:

Rub 3 ml undiluted Softa-Man into the hands for 30 seconds until the hands are dry.

Surgical hand disinfection:

Rub at least 2 x 5 ml undiluted Softa-Man into the hands and forearms. The skin must remain wetted with Softa-Man over a period of 3 minutes.

Inactivation of Hepatitis-B-Virus:

Rub at least 10 ml undiluted Softa-Man in portions into dry hands. The skin must remain wetted with Softa-Man over a period of 2 minutes.

Throughout the period of application the skin must remain wetted with the undiluted preparation.

Undesirable Effects

Like all medicines, Softa-Man can cause side effects, although not everybody gets them.

Sensitivity (allergy) to Softa-Man occurs very rarely.

Cases of local alcohol-induced irritation symptoms (e.g. itching, redness, especially after frequent application of Softa-Man) are uncommon. Symptoms of dry skin may occur uncommonly in seasons of low air humidity (especially in winter). The application of skin caring hand creams after work is recommended in such cases.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Expiry Date

The product must not be used beyond the expiry date stated on the labelling. After the first opening of the container, Softa-Man will maintain its quality for 12 months, but not beyond the expiry date.

Instructions for Storage/Use/Handling

Keep out of the reach and sight of children.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to maintain the environment.

Date of last revision: 08/2010

B | BRAUN