

Softa-Man

45% Ethanol w/v
18% n-Propanol w/v

Consumer Medication Information Leaflet(RiMUP)

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription. Nevertheless you still need to use Softa-Man carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.

In this leaflet:

1. What Softa-Man is and what it is used for
2. Before you use Softa-Man
3. How to use Softa-Man
4. Possible side effects
5. How to store Softa-Man
6. Further information

Softa-Man, cutaneous solution

The active substances are Ethanol (45 %) and n-Propanol (18 %). The other ingredients are Diisopropyl Adipate, PEG-6 Caprylic/Capric Glycerides, Dexpanthenol, Bisabolol, Allantoin, Perfume and Purified Water.

1. WHAT SOFTA-MAN IS AND WHAT IT IS USED FOR

Softa-Man is an alcoholic hand disinfectant with skin caring agents. It is a clear colourless solution for application on the skin (cutaneous solution).

Softa-Man is intended for hygienic and surgical hand disinfection. The active ingredients, ethanol and n-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 many viruses (e.g. Hepatitis-B Virus and Hepatitis-C Virus, HI-Virus, Rota-, Vaccinia-, Herpes-Viruses).

Softa-Man is available in bottles of 100 ml, 500 ml, and 1000 ml.

2. BEFORE YOU USE SOFTA-MAN

Do not use Softa-Man if: you are allergic to ethanol or n-propanol or any of the other ingredients of Softa-Man listed above.

Take special care with Softa-Man if: you develop sensitivity (allergy) to the product. In this case you should stop using it immediately.

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

Softa-Man is for external use only. If Softa-Man is accidentally or deliberately swallowed, seek immediate medical attention.

The solution is flammable (Flash point 21 - 22°C). Keep away from sources of ignition - No smoking.

Pregnancy and breast-feeding: Since Softa-Man is applied only locally to the hands no precautions are necessary.

Driving and using machines: Softa-Man does not affect the ability to drive or operate machinery.

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

3. HOW TO USE SOFTA-MAN

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 has to be wetted with Softa-Man over a period of 3 minutes.

Hepatitis-B-prophylaxis:

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Softa-Man can have side effects. 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 you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

5. STORING SOFTA-MAN

Keep out of the reach and sight of children

Do not store above 30°C.

Do not use after the expiry date stated on the label.

Discard 12 months after first opening of the container.

This leaflet is revised in Jun 2016

6. FURTHER INFORMATION

For any information about this medicinal product, please contact the local representative of the Marketing Authorisation Holder:

Manufactured by:
B.Braun Medical AG
6204 Sempach
Switzerland

Released by:
B.Braun Melsungen AG
34209 Melsungen
Germany

Licence Holder in Malaysia:
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