

Ethyl Alcohol + Propyl Alcohol

Softa-Man

45g/18g per 100mL (45%/18% w/v) Topical Solution

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

This product is available without prescription. Nevertheless you still need to use Ethyl Alcohol + Propyl Alcohol (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 Ethyl Alcohol + Propyl Alcohol (Softa-Man) is and what it is used for
2. Before you use Ethyl Alcohol + Propyl Alcohol (Softa-Man)
3. How to use Ethyl Alcohol + Propyl Alcohol (Softa-Man)
4. Possible side effects
5. Storing Ethyl Alcohol + Propyl Alcohol (Softa-Man)
6. Further information

Ethyl Alcohol + Propyl Alcohol (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 ETHYL ALCOHOL + PROPYL ALCOHOL (SOFTA-MAN) IS AND WHAT IT IS USED FOR

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

Ethyl Alcohol + Propyl Alcohol (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).

Ethyl Alcohol + Propyl Alcohol (Softa-Man) is available in bottles of 100 mL, 500 mL, 1 L and in containers of 5 L

2. BEFORE YOU USE ETHYL ALCOHOL + PROPYL ALCOHOL (SOFTA-MAN)

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

Take special care with Ethyl Alcohol + Propyl Alcohol (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.

Ethyl Alcohol + Propyl Alcohol (Softa-Man) is for external use only. If Ethyl Alcohol + Propyl Alcohol (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 Ethyl Alcohol + Propyl Alcohol (Softa-Man) is applied only locally to the hands no precautions are necessary.

Driving and using machines: Ethyl Alcohol + Propyl Alcohol (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 ETHYL ALCOHOL + PROPYL ALCOHOL (SOFTA-MAN)

The recommended dosage is:

Hygienic hand disinfection:

Rub 3 mL undiluted Ethyl Alcohol + Propyl Alcohol (Softa-Man) into the hands for 30 seconds until the hands are dry.

Surgical hand disinfection:

Rub at least 2 x 5 mL undiluted Ethyl Alcohol + Propyl Alcohol (Softa-Man) into the hands and forearms. The skin has to be wetted with Ethyl Alcohol + Propyl Alcohol (Softa-Man) over a period of 3 minutes

Hepatitis-B-prophylaxis:

Rub at least 10 mL undiluted Ethyl Alcohol + Propyl Alcohol (Softa-Man) into the hands into dry hands. The skin has to be wetted with Ethyl Alcohol + Propyl Alcohol (Softa-Man) over a period of 2 minutes.

4. POSSIBLE SIDE EFFECTS

Ethyl Alcohol + Propyl Alcohol (Softa-Man) can have side effects. Sensitivity (allergy) to Ethyl Alcohol + Propyl Alcohol (Softa-Man) occurs very rarely.

Cases of local alcohol-induced irritation symptoms (e.g. itching, redness, especially after frequent application of Ethyl Alcohol + Propyl Alcohol (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 ETHYL ALCOHOL + PROPYL ALCOHOL (SOFTA-MAN)

Keep out of the reach and sight of children. Do not use after the expiry date stated on the label. Store at temperatures not exceeding 30 °C.

6. FURTHER INFORMATION

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

DRHR-1693

AVAILABILITY: Green HDPE Plastic Bottle x 100mL with white screw cap, Green HDPE Plastic Bottle x 500mL and 1L with white hand pump dispenser and in containers of 5 L.

Manufactured by:

**B.Braun Medical AG, Seesatz 17
6204 Sempach, Switzerland**

For:

**B.Braun Melsungen AG, Carl-Braun-Strasse 1
34212 Melsungen, Germany**

Imported by:

**B. Braun Medical Supplies, Inc.
15th Floor Sun Life Centre, 5th Avenue, corner Rizal Drive,
Bonifacio Global City, Taguig City, Philippines**

This leaflet is revised in December 2014