

Softa-Man®

Cutaneous Solution

Ethanol-absolute 57.0 % v/v and Propan-1-ol 22.5 % v/v

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.
- 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.

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

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

Softa-Man® is an antiseptic handrub for hygienic hand disinfection and surgical hand preparation.

2. BEFORE YOU USE SOFTA-MAN®

Do not use Softa-Man® if: you are allergic to ethanol or propan-1-ol or any of the other ingredients of Softa-Man®.

Take special care with Softa-Man®: 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. In case of accidental release of larger amounts, take special care of the risk of ignition. Soak up with inert absorbent material or dilute with plenty of water. Ensure adequate ventilation and remove sources of ignition.

Do not swallow. Softa-Man® is for external use only. If somebody swallows Softa-Man® inadvertently, they 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.

Do not apply on injured skin, eyes or mucous membranes! Softa-Man® is irritating to the eyes and to mucous membranes. 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.

If you develop sensitivity (allergy) to Softa-Man®, you should stop using it immediately.

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

Pregnancy and breast-feeding: Softa-Man® can be used in the recommended way for hand disinfection during pregnancy and breast-feeding.

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

3. HOW TO USE SOFTA-MAN®

Recommended dosage : *Hygienic hand disinfection (Hygienic hand rub according to EN 1500):*

Apply about 3 mL undiluted Softa-Man® onto clean, dry hands and rub into the skin. All parts of the hand including the skin areas between the fingers must remain wetted for at least 15 s. Proceed until the hands are dry.

Surgical hand preparation:

Prior to commencing the antiseptic rub procedure.

- Wash hands and forearms with soap and running water.
- Clean the subungual areas of both hands under running water using a nail cleaner.
- Rinse hands and forearms under running water.

Dry hands and forearms with a paper towel prior to commencing antiseptic rub procedure.

Rub several portions of about 3 mL undiluted Softa-Man® onto dry hands and forearms. The skin must remain completely wetted with Softa-Man® over a period of at least 60 s. At completion allow to air dry thoroughly before donning sterile gloves.

If you use more Softa-Man® than you should: Allow excess product to run-off from your hands, then let dry. Pay attention to the flammability of Softa-Man® (see section 2).

4. POSSIBLE SIDE 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.

5. HOW TO STORE SOFTA-MAN®

Keep out of the reach and sight of children

Store below 25°C.

Do not use after the expiry date stated on the label. Discard 12 months after the first opening of the container.

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.

What Softa-Man® contains: The active substances are Ethanol-absolute and Propan-1-ol. 100 mL solution contain 45 g Ethanol-absolute and 18 g Propan-1-ol.

The other ingredients are Purified Water, Diisopropyl Adipate, Macrogol 6 Glycerol Caprylocaprate, Dexpanthenol, Bisabolol, Perfume (contains Limonene and Linalool), Allantoin.

What Softa-Man® looks like and contents of the pack: Clear, colourless solution with spirituous odour. The cutaneous solution is available in bottles and containers of 100 mL, 500 mL, 1000 mL, 5 L.

This leaflet was last prepared in 08/2018

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

Distributed by:
B. Braun Australia Pty Ltd
Level 5, 7-9 Irvine Place
Bella Vista NSW 2153
Australia, Toll Free Number 1800 251 705