

INSTRUCTIONS FOR USE

Softa-Man

Cutaneous solution

Composition:

Active substances: 100 ml solution contain 45 g Ethanol (100%) and 18 g Propanol

Excipients: Purified Water, Diisopropyl Adipate, Macrogol 6 Glycerol Caprylocaprate, Dexpanthenol, Bisabolol, Perfume (contains Limonene, Linalool), Allantoin

Pharmaceutical form

Solution for external use;
Clear, colourless, alcoholic solution

Pharmacotherapeutic group

Dermatologicals, other antiseptics and disinfectants, propanol, combinations,
ATC-Code: D08AX53

Softa-Man is an alcoholic solution with skin caring agents for disinfection of the hands.

Indications

Hygienic and surgical hand disinfection

Product efficacy

Softa-Man is 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.

Contraindications

Hypersensitivity to any of the ingredients.

Special warnings and precautions for use

- Flammable. (Flash point 21–22°C). Keep away from sources of ignition – No smoking.
- Do not apply on injured skin, eyes or mucous membranes! Softa-Man is irritant 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.
- Do not swallow. 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.

Pregnancy and lactation

Since it is applied only locally to intact skin and dermal absorption of alcohol is negligible, Softa-Man can be used in the recommended way for hand disinfection during pregnancy and lactation.

Dosage

Recommended dosage schedule and method of administration: Throughout the period of application the skin must remain wetted with the undiluted preparation.

Hygienic hand disinfection: Apply at least 3 ml undiluted Softa-Man onto dry hands and rub into the skin. Proceed until the hands are dry. All parts of the hand including the skin areas between the fingers must remain wetted for at least 30 s.

In case of strong, visible contamination of the hands or after contact with Mycobacteria, perform consecutively two hygienic hand disinfections after cleansing.

Surgical hand disinfection (Surgical hand rub): Rub several portions of 3 ml at least undiluted Softa-Man onto dry hands and forearms. The skin must remain wetted with Softa-Man over a period of at least 1 minute. Allow the hands to dry completely before putting on gloves.

Overdose

Because the preparation is only applied locally, no overdose can result from regular use. Accidental mistakes of concern are oral intake with the possible consequence of acute alcohol poisoning and eye contact with the risk of serious damage to eyes. Please see section **Special warnings and precautions for use** for further advice.

Undesirable effects

Hypersensitive reactions (e.g. contact allergy reactions) occur 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 humidity (such as in winter). The application of skin caring hand creams after work is recommended in such cases.

Storage and shelf life

Keep out of the reach and sight of children.

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

Shelf life of the medicinal product as packaged for sale: < 25°C, 5 years.

Shelf life of the medicinal product after first opening: 12 months (not beyond the expiry date printed on the label)

Pack sizes: Bottles and containers of polyethylene with contents of < 4000 ml.

Date of last revision: 09. 2011

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Manufacturer:

B. Braun Medical AG,
Seesatz 17, CH-6204
Sempach, Switzerland

舒膚邁

Softa-Man Cutaneous solution

衛署藥輸字第 025778 號

主成分

100 ml含45 g Ethanol (100%) 和18 g Propanol

賦型劑：

Purified Water, Diisopropyl Adipate, Macrogol 6 Glycerol Caprylocaprata, Dexpanthenol, Bisabolol, Perfume (contains Limonene, Linalool), Allantoin

劑型

外用液劑；

透明無色的酒精溶液。

藥理分類

皮膚科用藥/抗菌和消毒劑/丙醇/複方

ATC 碼 D08AX53

Softa-Man為一種含有護膚成分之酒精溶液，用來做為手部消毒殺菌劑。

適應症

一般醫護人員之手部殺菌及外科手術之手部殺菌。

說明

Softa-Man可有效的對抗細菌（包含有抗藥性的菌株，如MRSA抗甲氧苄青黴素金黃色葡萄球菌）、分枝桿菌（mycobacteria）（包含結核分枝桿菌 *Mycobacterium tuberculosis*）、真菌、套膜病毒（enveloped viruses）（如B型肝炎病毒 Hepatitis-B Virus、C型肝炎病毒Hepatitis-C Virus、愛滋病毒 HI-Virus）和輪狀病毒（Rotavirus）。

禁忌症

對本產品任何成分過敏者。

警告及注意事項

- 可燃的（閃點21-22°C），避開點火開關-不可吸煙。
- 不可施用在受損皮膚、眼睛或黏膜！Softa-Man會刺激眼睛和黏膜，如不小心接觸到眼睛，張開眼睛並立即用大量的水沖洗內眼瞼數分鐘。若刺激感仍持續著，立即尋求醫療協助。
- 不可吞食。Softa-Man僅供外用，若不小心吞食，可能會導致急性酒精中毒，需要立即的醫療照護，因為大量吞食可能會造成呼吸中止或意識障礙而吸入嘔吐物。僅可在醫師指示下進行催吐。

孕婦及哺乳婦女

Softa-Man僅施用在局部完整皮膚上，且酒精經由皮膚吸收量低，故孕婦及哺乳婦女可使用。

劑量

建議劑量和使用方法

整個施用過程中，未稀釋之製劑必須在皮膚上保持濕潤。

一般手部消毒殺菌

取至少3ml未稀釋Softa-Man到乾燥的手上，摩擦雙手及皮膚至消毒液乾燥為止。手的各部位及指間皮膚必須保持在濕潤狀態下至少30秒。

如果手部可見污染物或手部與分枝桿菌接觸過，請於清洗乾淨後連續使用手部消毒殺菌液2次。

外科手術之手部殺菌（外科手術刷手）

摩擦至少3ml未稀釋Softa-Man到乾燥的手和前臂，Softa-Man必須在皮膚上保持濕潤狀態至少1分鐘。允許手部完全乾燥後再戴上手套。

用藥過量

因為製劑為局部施用，故正常使用不會造成用藥過量。

意外疏失可能為誤食導致急性酒精中毒及眼睛接觸而有嚴重傷害眼睛的危險。更進一步的建議，請參考「警告及注意事項」。

副作用

過敏反應的發生很罕見（例如接觸性過敏反應）。局部酒精引發之刺激症狀（如發癢、紅腫，特別是經常使用Softa-Man）。酒精消毒可能引起皮膚乾燥的症狀，特別是在濕度低的季節（例如冬季）此時建議在工作後使用護手霜。

貯存和效期

貯存於兒童不易見到和取得處。

超過標籤上所標示之有效日期後，請勿使用。

產品效期如包裝所示，儲存於25°C以下，有效期間為5年。

開封產品之效期為開封後12個月，但不可超過標示之保存期限。

包裝

PE材質，4000毫升以下塑膠瓶裝。

最後修改日期：09. 2011

製造廠： B. Braun Medical AG

廠址： Seesatz 17, CH-6204 Sempach, Switzerland

藥商： 台灣柏朗股份有限公司

地址： 台北市松山區健康路152號9樓

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