

INSTRUCTIONS FOR USE

Softa-Man ViscoRub

Cutaneous solution

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, HIV), and Norovirus.

【Composition:】

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

Excipients: Purified Water, Butanone, Glycerol, Isopropyl Myristate, Cetearyl Ethylhexanoate, Octyldodecanol, Edetol, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Bisabolol

【Indications】

Hygienic and surgical hand disinfection

【Special warnings and precautions for use】

Do not use if you have any of following conditions: Hypersensitivity to any of the ingredients

Other precautions for use:

- Flammable. (Flash point 21°C). Keep away from sources of ignition - No smoking.
- Do not apply on injured skin, eyes or mucous membranes!
- Do not swallow.
- Softa-Man could be used during pregnancy and lactation. (It is applied only locally to intact skin, and the absorption of alcohol is negligible)
- Softa-Man is only applied locally, no overdose can result from regular use.

【Dosage】

| Throughout the period of application the skin must remain wetted with the undiluted preparation. | |
|--|---|
| Intended use | Dosage |
| 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 6 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 1.5 minutes (90 seconds). Allow the hands to dry completely before putting on gloves. |

【Warnings】

1. If there's any below listed adverse reaction occurs, please stop using the preparation, and consult your doctor, pharmacists or assistant pharmacist by this product insert.

| Parts of the body | Symptoms |
|-------------------|--|
| Skin | 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. |

2. If there's any below symptoms occur, please stop using the preparation and go to see a doctor.
 - a. 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.
 - b. When Softa-Man was swallowed inadvertently. (Please note that force-vomiting could only be done under doctor's instruction)

【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, 3 years.

Shelf life of the medicinal product after first opening:

12 months (not beyond the expiry date printed on the label)

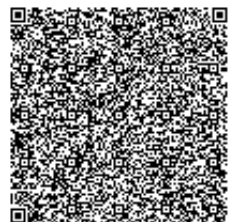
【Pack sizes】

Bottles and containers of polyethylene with contents of 100 ml, 500 ml, 1000 ml, 5 l.

Date of last revision: 03.2018

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



舒膚邁

手部消毒殺菌露

Softa-Man ViscoRub

衛署藥輸字第 025919 號

Softa-Man ViscoRub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。Softa-Man ViscoRub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 HIV、諾羅病毒 Norovirus）和輪狀病毒

【成分】

有效成分及含量

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

其他成分(賦形劑):

Purified Water, Butanone, Glycerol, Isopropyl Myristate, Cetearyl Ethylhexanoate, Octyldodecanol, Edetol, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Bisabolol

【用途 (適應症)】

一般醫護人員之手部殺菌及外科手術之手部殺菌。

【使用上注意事項】

有以下情形者，請勿使用：對本產品任何成分過敏者。

其他使用上注意事項：

1. 本產品為可燃的（閃點21°C），請避開點火開關不可吸菸。
2. 不可使用在受損皮膚、眼睛或黏膜！
3. 不可吞食。
4. 孕婦及哺乳婦可使用。(Softa-Man ViscoRub僅用於局部完整皮膚上，且酒精經由皮膚吸收量低)
5. 本產品為局部使用，故正常使用不會造成用藥過量。

最後修改日期：03. 2018

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

【用法用量】

| | |
|---------------------------|--|
| 整個施用過程中，未稀釋之製劑必須在皮膚上保持濕潤。 | |
| 使用用途 | 用法用量 |
| 一般手部消毒殺菌 | 取至少3ml未稀釋Softa-Man ViscoRub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 (外科手術刷牙) | 摩擦至少6ml未稀釋Softa-Man ViscoRub到乾燥的手和前臂，Softa-Man ViscoRub必須在皮膚上保持濕潤狀態至少1.5分鐘(90秒)。允許手部完全乾燥後再戴上手套。 |

【警語】

一、使用本藥後，若有發生以下副作用，請立即停止使用，並持此說明書諮詢醫師藥師藥劑生。

| 關係部位 | 症狀 |
|------|--|
| 皮膚 | 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。 |

二、使用本藥後，若有發生下列症狀時，請立即停止使用，並接受醫師診治：

1. 當不小心接觸到眼睛，立即使用大量的水沖洗內眼瞼數分鐘後，刺激感仍持續時。
2. 當不小心吞食時。(僅可在醫師指示下催吐)

【包裝】

100ml, 500ml, 1000ml, 5L, 塑膠瓶裝。

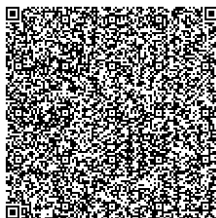
【貯存 和效期】

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3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。



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