<u>Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986</u>

This medicine is dispensed without a doctor's prescription

Softa-Man Viscorub Cutaneous solution

Active ingredients:

Ethanol 45 g/100 ml and propanol 18 g/100 ml For a list of inactive ingredients and allergens see Section 6.

Read the entire leaflet carefully in its entirety before you start using this medicine. This leaflet contains concise information about this medicine. If you have further questions, refer to your doctor or pharmacist.

To use this medicine, follow the instructions in the dosage section of this leaflet. Consult the pharmacist if you need more information.

1. What is this medicine intended for?

Softa-Man Viscorub is an alcoholic hand disinfectant for hygienic and surgical hand disinfection.

Therapeutic group: skin disinfectant.

When used on skin that is not injured, only very small amounts are absorbed through the skin and they have no effect on your body.

The active ingredients in Softa-Man Viscorub are ethanol and propanol. This medicine is very effective against gram-positive and gram-negative bacteria, including antibiotic-resistant strains (such as the methicillin-resistant Staphylococcus aureus [MRSA]) and mycobacteria. Softa-Man Viscorub works well killing fungi and viruses, and quickly neutralizes rota viruses and viruses that have a sheath.

2. Before using this medicine

Do not use this medicine if:

• You are sensitive (allergic) to the active ingredients ethanol and propanol or to any of the other ingredients that this medicine contains (see Section 6 in this leaflet).

Warnings:

- This medicine is for external use only. Avoid all contact with the eyes and mucous membranes.
- Do not use on injured skin.

Flammable. The solution's flash point is 21°C. Keep away from flame and other sources of ignition.

Do not smoke, do not swallow.

Do not light a cigarette or expose to fire until the product has dried completely.

Consult a doctor, pharmacist, or nurse before you start using the medicine.

If you are taking or have recently taken other medicines, including nonprescription medications and nutritional supplements, tell your doctor or pharmacist.

Do not mix this medicine with other medicines.

Pregnancy and breastfeeding

Pregnancy

There is no information about harmful effects of using Softa-Man Viscorub during pregnancy.

Breastfeeding

There is no information about harmful effects of using Softa-Man Viscorub during breastfeeding.

If you are pregnant or breastfeeding, think you may be pregnant, or are trying to get pregnant, consult your doctor or pharmacist before using this medicine.

3. How to use this medicine?

For local treatment.

- Apply about 3 ml of undiluted Softa-Man Viscorub onto dry hands.
- Rub into your hands
 - for 30 seconds at least for hygienic hand disinfection
 - for 90 seconds at least for surgical hand disinfection
- Your skin must stay damp for 30 or 90 seconds, respectively, depending on the type of disinfection.
- · Allow your skin to dry.
- There is no need to rinse.

Softa-Man Viscorub can be used without first cleaning your hands. If your hands are visibly dirty, clean them first with soap and water.

Do not exceed the recommended dose.

If you accidentally used more Softa-Man Viscorub than you should or if you swallowed some, consult your doctor or pharmacist immediately.

Do not swallow. For external use only.

If an adult or child swallows some of this medicine, they may suffer from acute alcohol poisoning. Large quantities of this medicine can cause breathing to stop. Loss of consciousness that associated with a risk of choking after vomiting.

- Go immediately to a hospital emergency room for medical care and bring the medicine package with you.
- Do not induce vomiting unless it is recommended by a doctor.

Do not take medicines in the dark! Check the label and dose <u>each time</u> you take the medicine. Wear glasses if you need them. If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

Like all medicines, using Softa-Man Viscorub may cause side effects in some people. Do not be alarmed by this list of side effects. You may not experience any of them.

In rare cases there may be local irritation caused by the alcohol (such as itching or redness) particularly after repeated uses of Softa-Man Viscorub.

Dry skin may occur in rare cases during seasons with low humidity in the air (mainly in the winter). Applying hand cream is advisable in these cases.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Medication' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link: https://sideeffects.health.gov.il

5. How to store this medicine?

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place out of sight and reach of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) stated on the bottle. The expiry date refers to the last day of that month.
- You can continue using this medicine for 12 months after first opening the bottle, but do not use it after the expiry date stated on the label. Close the package immediately after opening.
- Store below 25°C.
- Flammable substance! Keep away from sources of fire.

6. Additional information

- In addition to the active ingredients, this medicine also contains:

 Purified Water, Butanone, Glycerol, Isopropyl Myristate, Cetearyl Ethylhexanoate,
 Edetol, Octyldodecanol, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Bisabolol.
- What the medicine looks like and what are the contents of the package: Cutaneous solution, clear to slightly turbid, colorless, viscous, with an alcoholic odor.

The cutaneous solution packaged in 100 ml, 500 ml, and 1000 ml bottles. The bottles are closed with a cap or a pump dispenser.

- Registration Holder: Gamida Care Ltd.
 - 32 Shaham St. Petach-Tikva
- Manufacturer: B. Braun Melsungen AG, Melsungen, Germany.
- Revised in November 2022 according to MOH guidelines
- Registration number of the medicine in the Ministry of Health National Drug Registry: 159-59-35073-00.