

Instructions for use - Please read carefully!

Amosept®

(Information for the medical and surgical staff "Fachinformation")

Ready for use

**Simultaneous disinfection and cleaning of hands
Hand decontamination**

Composition

100 g **solution** contains:

Active substances: 1 g Didecyl Dimethyl Ammonium Chloride

Other substances: 1,3-Dimethylurea, Propanol-1-ol, Propylene Glycol, Disodium Cocoamphodiacetate, Dibutyl Adipate, Fragrance, Citric Acid, Purified Water

Dosage form

Solution for application on the skin

Range of application

Hygienic hand washing

Mode of application / dosage

Use externally and **undiluted** only!

Pour 5 ml **Amosept®** of the concentrated product in the palm of the hand, rub during 30 seconds. The hands have to be wet with the product during the complete exposure time recommended by the manufacturer. Then rinse well with water.

Against enveloped viruses* including HBV/HIV/HCV.

Concentrated – 1 min

* Results of *in-vitro* tests against BVDV and vaccinia viruses. On grounds of the current scientific knowledge the results allow the conclusion that this product is also effective against other enveloped viruses for ex. Hepatitis-B and HI-viruses.

There are no adequate studies on the use of Amosept® for children. Consult a doctor or a pharmacist for advice before use.

Contra-indications

Hypersensitiveness against any of the ingredients

Interactions

None known

Pregnancy and lactation

There is no adequate study on the use of Amosept® during pregnancy and lactation. Consult a doctor or pharmacist for advice before using.

Side effects

With hypersensitive people skin-contact irritations or allergic reactions can occur occasionally. If skin irritations become worse get medical aid immediately.

Indication of frequency: "occasionally" (less of 1% but more than 0,1%).

"Reporting side-effects:

The reporting of suspected adverse reactions after approval is of great importance. It allows continuous monitoring of the benefit-risk ratio of the drug. Healthcare professionals are required to report any suspected adverse reactions to the Federal Institute for Drugs and Medical Devices, Department of Pharmacovigilance, Kurt –Georg-Kinskiinger Allee 3, D-53175 Bonn, Website: www.bfarm.de.

Overdose and application errors

Do not apply on open wounds or mucous membranes. If Amosept[®] came in contact with mucous membranes (eyes, throat, stomach, bowels etc.) and open wounds, rinse thoroughly with plenty of water and get medical attention. If it has been swallowed, drink plenty of water to dilute the product and get medical attention.

Pharmacological data

ATC-Code: D08AJ06

Pharmaceutical data**Shelf-life**

Shelf life (also after opening the container): 36 months.
Always observe the labelling of the container!

Special precautions

Do not store medicinal products above 25 °C and keep drugs out of reach of children!
Do not use after expiration date! Do not use beyond expiry date. Any unused product or packagings should be disposed of in accordance with local requirements.

Type of packagings and package sizes

HDPE-containers

Package sizes

500 ml, 1000 ml, 5 litre

Some of the package sizes might not be on the market.

Pharmaceutic company/Manufacturer/Authorisation holder

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