

1. NAME OF THE MEDICINAL PRODUCT

Galways Hand Sanitizer

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredient: Alcohol 70%

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Gel for cutaneous administration.

Clear, colourless gel.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

For hand disinfection.

4.2 Posology and method of administration

For external use only.

Squeeze desired amount unto the palms and rub over palms, back of hands, finger tips and wrists until dry.

4.3 Contraindications

Hypersensitivity to alcohol or to any of the excipients listed in section 6.1.

Do not apply on broken skin because of the risk of increased absorption and toxicity.

Do not use under occlusive dressings.

4.4 Special warnings and precautions for use

For external use only.

Do not apply to broken skin or irritated skin, or under occlusive dressings to prevent unwanted systemic effects. Do not use on the genital area.

Avoid contact with eyes and sensitive areas of the skin. In case of contact with eyes, flush with plenty of water. If swallowed seek immediate medical help and show container or label.

Discontinue use if excessive irritation occurs.

Keep all medicines out of the reach of Children.

The use of alcohol-based hand sanitizers is associated with a small but measurable risk of fires and burns. Alcohol vapor may be easily flammable, and care must be taken to use away from fire.

Additionally, personnel applying hand alcohol-based sanitizer should keep a safe distance from fires application as there is a risk of skin burning.

4.5 Interaction with other medicinal products and other forms of interaction

Not applicable.

4.6 Fertility, pregnancy and lactation

Pregnancy

Systemic absorption after topical administration is negligible and thus not likely to be excreted through the placenta.

Breast-feeding

Systemic absorption after topical administration is negligible and thus not likely to be excreted in breast milk. Application of the product to the breast is not recommended during breast feeding.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

Frequent application of alcohol to the skin produces irritation and dry skin.

Skin necrosis has been reported after application of alcohol-containing preparations on preterm neonates.

4.9 Overdose

Symptoms

Alcohol-based hand sanitizers can cause alcohol poisoning if a person swallows more than a couple of mouthfuls.

Management

Over dosage is unlikely to occur with topical application but in case of accidental ingestion, treatment of acute poisoning should include hydration with intravenous fluids, control of nausea and vomiting, and correction of electrolyte imbalance, such as hypomagnesaemia. Protection of the airway is crucial and ventilation may be required in cases of respiratory depression. Glucose is indicated for patients with hypoglycaemia. Hypothermia and hypotension should be corrected. Convulsions may be controlled with intravenous benzodiazepines or phenytoin. Haemodialysis is of value in severe alcohol poisoning.

Gut decontamination and activated charcoal are unlikely to be of benefit due to the rapid absorption of alcohol through intestinal mucosa.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Other Antiseptics and disinfectants; Ethanol; **ATC Code:** D08AX08.

Alcohol is bacteriostatic at low concentrations but has bactericidal activity at higher concentrations; it does not however destroy bacterial spores. The antimicrobial activity of alcohol is attributed to its ability to denature and coagulate proteins. This causes microbes to lose their protective coatings and become non-functional. In the total absence of water, proteins are not denatured as rapidly as when water is present.

Its bactericidal activity drops sharply when diluted below a 50% concentration and optimal bactericidal concentration is 60 to 90% by volume. Alcohol has some fungicidal and virucidal activity. It is used to disinfect the skin before injection, venepuncture or surgical procedures. It is also used to disinfect hands and clean surfaces.

Alcohol also has anhidrotic, rubefacient and astringent and haemostatic properties. It is sometimes used for its skin cooling properties and to harden the skin. It is an ingredient of several topical preparations used for skin disorders.

5.2 Pharmacokinetic properties

Absorption through intact skin is negligible and results in low plasma concentration. Its usefulness is limited to its local effects.

5.3 Preclinical safety data

No preclinical findings of relevance have been reported.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerol
Carbomer
Triethanolamine
Deionised Water

6.2 Incompatibilities

Not applicable to a topical formulation.

6.3 Shelf life

Three years.

6.4 Special precautions for storage

Store below 30°C. Protect from light.
Highly inflammable. Keep away from fire and sources of ignition.

6.5 Nature and contents of container

Plastic bottle made of polyethylene with plastic Dispenser Pumps with transparent dip tube.
Pack sizes: 60, 100ml, 250 ml, 500 ml

6.6 Special precautions for disposal and other handling

For external use only.

7. APPLICANT/MANUFACTURER

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