

SUMMARY OF PRODUCT CHARACTERISTICS

ALCOHOL 70% FLORIS

1. NAME OF THE MEDICINAL PRODUCT

Alcohol 70% FLORIS

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Alcohol 70% v/v

3. PHARMACEUTICAL FORM

Solution

Clear colorless solution.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Antiseptic.

4.2 Posology and method of administration

This product is applied topically.

4.3 Contraindications

Do not use in patients with a known hypersensitivity to the product or any of its components listed in section 6.1 (see section 4.8).

Do not use in contact with eyes, brain, meninges, middle ear or external ear with a perforated tympanic membrane.

Do not inject.

Do not use in body cavities.

When use is to be followed by diathermy do not allow pooling of the fluid to occur and ensure that the skin and surrounding drapes are dry.

4.4 Special warnings and precautions for use

Accidental intravenous infusion – blood transfusion may be necessary to counteract hemolysis.

Remove any soaked materials, drapes or gowns before proceeding with the intervention. Do not use excessive quantities and do not allow the solution to pool in skin folds or under the patient or drip of sheets or other material in direct contact with the patient. Where occlusive dressing are to be applied to areas previously exposed to Alcohol 70% Floris, care must be taken to ensure no excess product is present prior to application of the dressing.

4.5 .Interactions with other medicinal products and other forms of interaction

None stated.

4.6 Pregnancy and lactation

None stated.

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

Skin disorders

Frequency not known:

- Allergic skin reactions such as dermatitis, pruritus, erythema, eczema, rash, urticarial, skin irritation, and blisters.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form <https://sideeffects.health.gov.il>

4.9 Overdose

None stated.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

None stated.

5.2 Pharmacokinetic properties

None stated.

5.3 Preclinical safety data

None stated.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The expiry date of the product is indicated on the packaging materials.

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and contents of container

Alcohol 70% Floris is packaged in a 100 ml, 200 ml and 1000 ml bottle.

6.6 Special precautions for disposal

Not applicable.

7. LICENCE HOLDER AND MANUFACTURER:

Ben Shimon Floris Ltd, Industrial Park Misgav, DN Misgav, 2017400, Israel.

8. REGISTRATION NUMBER(S)

057-39-27018-00

Revised in 12/2024 according to the MOH guidelines.