

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Hydrogen Peroxide Solution 3% Floris

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Hydrogen peroxide aqueous solution 3% w/v as the active ingredient.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

A clear, colourless solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Antiseptic

4.2 Posology and method of administration

Topical.

Recommended dose and dosage schedule

1. As a disinfectant use as required. Dress the wound with cotton wool soaked in the peroxide.

As a disinfectant this product is suitable for use by adults, children and the elderly.

4.3 Contraindications

Hypersensitivity to any of the ingredients

Not for use in closed body cavities or on surgical wounds due to the risk of oxygen released into the circulation causing gas embolism.

Not for use as a disinfection agent for surgical instruments (particularly endoscopes) and as an enema.

4.4 Special warnings and special precautions for use

For external use only.

Keep all medicines away from children.

Not for use in closed body cavities or on surgical wounds due to risk of oxygen released into the circulation causing gas embolism.

Avoid normal skin.

Product bleaches fabric.

4.5 Interactions with other Medicaments and other forms of Interaction

None known.

4.6 Pregnancy and Lactation

All medicines should be avoided if possible during pregnancy and lactation. No evidence is available as to the safety of use of this product in these conditions.

4.7 Effects on Ability to Drive and Use Machines

None known.

4.8 Undesirable effects

Cases of gas embolism, sometimes resulting in cardiac arrest, have been reported when hydrogen peroxide has been instilled in closed body cavities or deep surgical wounds.

Strong solutions of hydrogen peroxide produce irritating burns on the skin and mucous membranes with a white eschar. The pain disappears after about 1 hour.

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

Accidental ingestion may cause sore throat, gastric disturbances and vomiting. Sudden evolution of oxygen may cause injury by acute distension of the stomach and internal bleeding. Water may be given to drink. Ingestion of large volumes can lead to gas embolism following evolution of oxygen in the stomach.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Hydrogen peroxide is used as a disinfectant and deodorant. It releases oxygen when applied to tissues, the effect lasts only as long as the oxygen is being released and is of short duration. The antimicrobial effect of the liberated oxygen is reduced in the presence of organic matter. It is used to cleanse wounds and ulcers in concentrations of up to 6%. Adhering and blood-soaked dressings may be released by the application of a solution of hydrogen peroxide.

5.2. Pharmacokinetic Properties

No further information available.

5.3. Preclinical safety data

No data of relevance which is additional to that already included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Purified water
Dibasic sodium phosphate
Phosphoric acid

6.2. Incompatibilities

Incompatible with reducing agents including organic matter and oxidisable substances and with alkalis, iodides, permanganates and other stronger oxidising agents. Its decomposition is increased by metallic salts, light, agitation, heat and metals.

6.3 Shelf life

24 months unopened.
Use within 24 months of first opening

6.4. Special Precautions for Storage

Store in a cool place and not above 25°C.

6.5 Nature and contents of container

A clear colorless solution inside of brown/white plastic bottles.
Approved sizes: 50 ml, 100 ml, 1000 ml.
Not all pack sizes may be marketed.

6.6. Instruction for Use/Handling and Disposal

None.

7. MANUFACTURER AND LICENCE HOLDER

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Industrial park Misgav,
DN Misgav,
2017400,
Israel

8. MARKETING AUTHORIZATION NUMBER(S)

057-38-27020-00

Revised in 07/2024 according to MOH guidelines.