SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Spirit Salicyl 2% Floris

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Salicylic acid 2.0% w/v

3 PHARMACEUTICAL FORM

Spirit solution

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Topical antiseptic and keratolytic.

4.2 Posology and method of administration

Topical.

Recommended dose and dosage schedule

Rins and dry the skin. Apply to the skin with cotton wool imbibed with the medicine, 1-3 times a day.

This medicine is generally not indicated for children and infants under two years of age.

4.3 Contraindications

Contraindicated in patients displaying salicylate hypersensitivity, or sensitivity to any other ingredient in the preparation.

4.4 Special warnings and precautions for use

For external use only.
Avoid contact with broken or inflamed skin.
Salicylate toxicity may occur if applied to large areas of skin or to the skin of neonates.
Instruct patients not to smoke or go near naked flames – risk of severe burns.
Fabric (clothing, bedding, dressings etc.) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.

4.5 Interaction with other medicinal products and other forms of interaction

There are no known interactions when used as indicated. However, topical salicylic acid may increase the absorption of other topically applied medicines. Concomitant use of Spirit Salicyl 2% Floris and other topical medicines on the same area of skin should therefore be avoided.

4.6 Pregnancy and lactation

Whilst there are no known contra-indications to the use of Spirit Salicyl 2% Floris during pregnancy and lactation, the safety has not been established. Spirit Salicyl 2% Floris should therefore be used with caution or following professional advice.

4.7 Effects on ability to drive and use machines

None likely.

4.8 Undesirable effects

Possible sensitivity reactions, drying and irritation.

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

Symptoms of systemic salicylate poisoning (tinnitus, dizziness and deafness) have been reported after the application of salicylic acid to large areas of skin and for prolonged periods. Salicylism may also occur in the unlikely event of large quantities being ingested. Salicylism is unlikely to occur if Spirit Salicyl 2% Floris is used as indicated.

Salicylate poisoning is usually associated with plasma concentrations >350mg/L (2.5mmol/L). Most adult deaths occur in patients whose concentrations exceed 700mg/L (5.1mmol/L). Single doses less than 100mg/kg are unlikely to cause serious poisoning.

Symptoms

Common features include vomiting, dehydration, tinnitus, vertigo, deafness, sweating, warm extremities with bounding pulses, increased respiratory rate and hyperventilation. Some degree of acid-base disturbance is present in most cases.

A mixed respiratory alkalosis and metabolic acidosis with normal or high arterial pH (normal or reduced hydrogen ion concentration) is usual in adults and children over the age of four years. In children aged four years or less, a dominant metabolic acidosis with low arterial pH (raised hydrogen ion concentration) is common. Acidosis may increase salicylate transfer across the blood brain barrier.

Uncommon features include haematemesis, hyperpyrexia, hypoglycaemia, hypokalaemia, thrombocytopaenia, increased INR/PTR, intravascular coagulation, renal failure and non-cardiac pulmonary oedema.

Central nervous system features including confusion, disorientation, coma and convulsions are less common in adults than in children.

Management

Give activated charcoal if an adult presents within one hour of ingestion of more than 250 mg/kg. The plasma salicylate concentration should be measured, although the severity of poisoning cannot be determined from this alone and the clinical and biochemical features must be taken into account. Elimination is increased by urinary alkalinisation, which is achieved by the administration of 1.26% sodium bicarbonate. The urine pH should be monitored. Correct metabolic acidosis with intravenous 8.4% sodium bicarbonate (first check serum potassium). Forced diuresis should not be used since it does not enhance salicylate excretion and may cause pulmonary oedema.

Haemodialysis is the treatment of choice for severe poisoning and should be considered in patients with plasma salicylate concentrations >700 mg/L (5.1 mmol/L), or lower concentrations associated with severe clinical or metabolic features. Patients under ten years or over 70 have increased risk of salicylate toxicity and may require dialysis at an earlier stage.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Salicylic acid has a keratolytic action.

5.2 Preclinical safety data

No other information relevant to the prescriber other than that already stated in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ethanol 96%
Purified water

6.2 Incompatibilities

None known.

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

125 ml brown HDPE polyethylene bottle with PP polypropylene child proof cap containing 100 ml spirit solution.

6.6 Special precautions for disposal

No special requirements.

7 LICENSE HOLDER AND MANUFACTURER

Ben-Shimon Floris Ltd.,
INDUSTRIAL PARK MISGAV
D.N. Misgav 2017400

8 REGISTRATION NUMBER

060-92-27486-00

This leaflet was revised in January 2025 according to MOH guidelines