

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

SPIRIT WHITFIELD FLORIS

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Benzoic Acid 6% w/v and Salicylic Acid 3% w/v.

3 PHARMACEUTICAL FORM

Spirit solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Antifungal, antiseptic.

4.2 Posology and method of administration

Spirit Whitfield Floris is applied topically and is for external use only.
Apply on the affected skin 1-3 times daily using absorbed cotton wool and let it dry.

Do not exceed the recommended dose.

4.3 Contraindications

Spirit Whitfield Floris is contraindicated in patients with hypersensitivity to the active substances Benzoic Acid and Salicylic Acid or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Spirit Whitfield Floris may cause allergic reactions in some patients.
Do not 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.

Contact with the eyes, mouth and other mucous membranes should be avoided.

4.5 Interaction with other medicinal products and other forms of interactions

There are no known interactions with Spirit Whitfield Floris . However, topical salicylic acid may increase the absorption of other topically applied medicines. Concomitant use of Spirit Whitfield Floris and other topical medicines on the same area of skin should therefore be avoided.

4.6 Fertility, pregnancy and lactation

Spirit Whitfield Floris should not be used in pregnancy without medical supervision.

4.7 Effects on ability to drive and use machines

No adverse effects reported.

4.8 Undesirable effects

Common side effects may include warmth or a burning sensation (may last up to 5 minutes after applying).

Benzoic Acid(E 210): Allergic reactions to Benzoic Acid have been reported. It can be irritant to the eyes, skin and mucous membranes.

Salicylic Acid: Salicylic Acid is a mild irritant, and application of preparations containing salicylic acid to the skin may cause dermatitis. Symptoms of acute salicylate poisoning have been reported after prolonged application of salicylic acid ointments to large areas of the body.

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 Whitfield 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, thrombocytopenia, 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

ATC Code D01AE12 Other antifungals for topical use.

Benzoic Acid has antibacterial and antifungal properties.

Salicylic Acid is bacteriostatic and fungicidal. It also possesses keratolytic properties.

5.2 Pharmacokinetic properties

If systemic absorption occurs, benzoic acid is conjugated with glycine in the liver to form hippuric acid which is rapidly excreted

in the urine. It may also be excreted as benzoglucuronic acid. Salicylic Acid is rapidly distributed to all the body tissues if absorbed, and the rate of excretion in the urine is dependent on the pH.

5.3 Preclinical safety data

No further information available.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Alcohol 70%

6.2 Incompatibilities

Benzoic Acid activity may be reduced in the presence of non-ionic surfactants.

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 of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 LICENSE HOLDER AND MANUFACTURER

Ben-Shimon Floris Ltd.,
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8 REGISTRATION NUMBER

060-91-27485-00

This leaflet was revised in February 2025 according to MOH guidelines