PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS

(PREPARATIONS) – 1986
This medicine is dispensed without a doctor's prescription

Spirit Whitfield Floris

Composition:

Benzoic acid 6% w/v, salicylic acid 3% w/v For inactive ingredients and allergens in the medicine – see section 6 "Additional information". Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have any other questions, refer to the doctor or the pharmacist.

This medicine is dispensed without requiring a doctor's prescription and is usually not intended for children and infants under two years of age. Use the medicine according to the instructions in section 3 "How should you use the medicine?" in this leaflet. Consult the pharmacist if you need more information. Refer to the doctor if symptoms of the ailment worsen or do not improve.

1. What is the medicine intended for?

The medicine is intended for treatment of fungal infection.

Therapeutic class: antifungal preparations.

2. Before using the medicine Do not use this medicine:

 If you are sensitive (allergic) to the active ingredients or to any of the additional components the medicine contains. For a list of inactive ingredients – see section 6 "Additional information".

Special warnings regarding the use of the medicine:

- Spirit Whitfield Floris may cause allergic reactions in some patients.
- Do not light a cigarette or go near an open flame there is a risk of severe burns. Fabric (clothes, bed linen, dressings etc.) that comes in contact with the medicine will burn more easily and is a

- serious fire hazard. Washing clothes and bed linen can decrease the accumulation of the medicine, but not remove it completely.
- Avoid contact with the eyes and mucous membranes.

Drug interactions:

If you are taking, or have recently taken, other medicines including non-prescription medicines and nutritional supplements, tell the doctor or the pharmacist.

Spirit Whitfield Floris has no known interactions with other preparations. However, topical salicylic acid may increase the absorption of other topical medicines. Therefore, avoid concomitant use of Spirit Whitfield Floris with other topical medicines on the same area of skin.

Pregnancy, breastfeeding and fertility:

If you are pregnant, you should consult the doctor or pharmacist before using the medicine.

Driving and operating machinery:

The medicine has no effect on the ability to drive and operate machinery.

Important information about some of the ingredients of the medicine:

The medicine contains alcohol which may cause a burning sensation on damaged skin.

This medicine contains 70 mg of alcohol in each 100 ml, a concentration equivalent to 0.7 mg/ml.

3. How should you use the medicine?

Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the medicine.

The accepted dosage when no other instruction from the doctor is given is:

Apply on the affected skin using a cotton wool ball soaked with the substance, 1-3 times a day, and allow the substance to dry.

Do not exceed the recommended dose.

Method of administration

Do not swallow, this medicine is intended for external use only.

If you accidentally took a higher dosage

If you took an overdose or if a child accidentally swallowed this medicine, refer to the doctor or to a hospital emergency room immediately and take the package of the medicine with you.

Do not take medicines in the dark! Check the label and the dose every time you take a medicine. Wear glasses if you need them. If you have any other questions regarding the use of the medicine, consult the doctor or the pharmacist.

4. Side effects

As with any medicine, using Spirit Whitfield Floris may cause side effects in some users.

Do not be alarmed when reading the list of side effects. You may not experience any of them.

Common side effects – effects that occur in 1-10 users out of 100:

Sensation of warmth or burning (which may last for up to 5 minutes after use).

- Benzoic acid (E210) allergic reactions to benzoic acid have been reported. This substance may irritate the eyes, skin and mucosa.
- Salicylic acid salicylic acid causes mild irritation.
 Using preparations containing salicylic acid on the
 skin may cause skin inflammation (dermatitis).
 There have been reports of symptoms of acute
 salicylate poisoning following prolonged use of
 preparations containing salicylic acid on extensive
 areas of skin.

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult your doctor.

Reporting side effects

Side effects may be reported to the Ministry of Health by clicking on the link "Report side effects due to medicinal treatment" found on the Ministry of Health website homepage (www.health.gov.il), which will direct you to the online form for reporting side effects, or by clicking on the following link: https://sideeffects.health.gov.il

5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.
- Do not use the medicine after the expiry date (exp. date) appearing on the package.
 The expiry date refers to the last day of that month

Storage conditions:

- Store at room temperature, below 25°C.
- Caution! Flammable substance, keep away from fire.
- After opening, the product can be used until it expires.

6. Additional information

In addition to the active ingredients the medicine also contains:

Alcohol 70%

What does the medicine look like and what are the contents of the package?

A brown bottle containing a clear, colorless liquid. Package content: 100 ml

Manufacturer and license holder:

Ben Shimon Floris Ltd., Industrial Park Misgav, D.N. Misgav 2017400, Israel.

This leaflet was revised in 02/2025 in accordance with the Ministry of Health guidelines.

Registration number of the medicine in the national drug registry of the Ministry of Health: 609127485