

**PATIENT LEAFLET IN ACCORDANCE WITH
THE PHARMACISTS' REGULATIONS
(PREPARATIONS) – 1986**

This medicine is dispensed without a doctor's prescription

Calamine Lotion Floris

Lotion

The active ingredients and their concentration:

Calamine 15% W/V

Zinc oxide 5% W/V

For a list of inactive ingredients – 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.

The medicine is intended for adults, children and the elderly. Use the preparation according to the instructions in the dosage section of this leaflet. Consult the pharmacist if you need further information.

Refer to the doctor if symptoms of the ailment worsen or do not improve after 7 days.

1. What is the medicine intended for?

The medicine is intended for the relief of skin irritations.

Therapeutic group: astringes the skin and relieves irritation.

2. Before using the medicine

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredients or any of the additional components the medicine contains. For a list of inactive ingredients – see section 6 "Additional information".
- Your skin is wounded.

Special warnings regarding the use of the medicine

Before treatment with Calamine Lotion Floris, tell the doctor if:

- You are sensitive to any type of food or medicine.

- You are going to have an X-ray, the medicine may change X-ray imaging results under certain circumstances.

Avoid contact with the eyes, mucous membranes. In case of such contact, wash thoroughly with water.

Do not use this medicine frequently or for a prolonged period of time without consulting the doctor.

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.

Pregnancy, breastfeeding and fertility:

No evidence has been found regarding the safety of the preparation when used in pregnant or breastfeeding women. However, the preparation has been used for many years, with no harmful effects.

Driving and operating machinery:

The effect of the medicine on driving and operating machinery is not known.

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 preparation.

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

Shake the bottle before use and apply a thin layer on the affected area several times a day (or according to the doctor's instructions) and leave the preparation on the skin until it dries.

Do not swallow. This medicine is intended for external use only!

Duration of treatment – if there is no improvement in your condition within a week, refer to the doctor.

Do not exceed the recommended dose.

Overdose is considered unlikely with this medicine. However, if you accidentally apply a higher dosage, you may experience vomiting, inflammation in the mucosa of the mouth and bowel, weakness, mental confusion, cold sweat, slowed heartbeat and leg cramps.

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 use of the medicine, consult the doctor or the pharmacist.

4. Side effects

As with any medicine, using Calamine Lotion 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.

- Side effects such as rash may occur.
- **Discontinue use and contact a doctor immediately** if you experience side effects such as: irritation, rash or local inflammation that were not present before using the preparation.
- **Side effects and drug interactions in children and infants:** parents should inform the doctor about any side effect and any other medicine given to the child.

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

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 via 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.
- Store in a cool place, at a temperature below 25°C.

- After opening for the first time, the medicine can be used up to the expiry date appearing on the package.

6. Additional information

In addition to the active ingredients, the medicine also contains:

Purified Water, Glycerol, Bentonite, Sodium Citrate, Liquefied Phenol.

What does the medicine look like and what are the contents of the package? A light pink lotion in a 100 ml bottle.

Manufacturer and license holder: Ben Shimon Floris Ltd., Industrial Park Misgav, D.N. Misgav 2017400.

This leaflet was revised in 12/2025 in accordance with the Ministry of Health guidelines.

Registration number of the medicine in the national drug registry of the Ministry of Health: 125-47-28879-00