

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF DRUG

Ascabiol, topical lotion

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Sulfirame.....	2 g
Benzyl benzoate	10 g
Excipient	qs 100 ml.

Bottle of 125 ml

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Topical lotion.

4. CLINICAL

4.1. Therapeutic indications

Treatment of scabies; Also proposed in the fall trombiculosis (mullet or chiggers).

4.2. Dosage and administration

Dosage:

Treatment of scabies. Adult :

In the evening, preferably, to avoid further washing (including hand) for the duration of the application; after bathing, dry, then apply Ascabiol using a flat brush in one or two layers on the entire body surface including genitals, with particular emphasis on the folds, hands, avoiding only face and scalp; after 24 hours, wash to remove the product.

Pruritus may persist for several days (10 to 15 days), sometimes after a momentary initial sedation. This post-scabious pruritus should not lead to iterative applications (see section 4.8).

Treat the environment simultaneously, even in the absence of clinical signs. Disinfect clothes and bedding with insecticide powder.

Children under 2 years:

Same as for adults with the following conditions: it is imperative to be limited to a single application of less than 12 hours; it is advisable to wrap hands to avoid accidental ingestion.

Pregnant woman :

A single application of a duration less than 12 hours.

If an infected scabies:

Treat priority impetiginisation.

Ascabiol may temporarily worsen irritation or eczematization. This can be alleviated by appropriate treatment, including a local corticosteroid, 24 hours after application of Ascabiol.

Treatment offered in the fall trombiculosis:

Apply Ascabiol on lesions using a cotton 1 or 2 times.

Administration mode:

Dermal.

4.3. Contraindications

Not applicable.

4.4. Special warnings and precautions

To avoid local or systemic adverse effects (systemic effect), the user manual must be respected, especially for children under 2 years.

Ascabiol should not be applied on mucous membranes.

4.5. Interactions with other drugs and other forms of interaction

Not applicable.

4.6. Pregnancy and breast feeding

Not applicable.

4.7. Effects on ability to drive and use machines

Not applicable.

4.8. Side effects

Local effects :

Immediate sensation of cooking; Eczematisation possible, especially increased if iterative applications.

General effects :

Seizures: In case of accidental ingestion; For skin pass: this increases systemic risk in case of damaged skin and in children less than 2 years.

4.9. Overdose

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Active on mites, mites scabies and chiggers. Also active on lice.

5.2. pharmacokinetic properties

Not applicable.

5.3. Preclinical safety data

Not applicable.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

List of excipients: Ethyl alcohol 95 °, polysorbate, purified water.

6.2. incompatibility

Not applicable.

6.3. The duration of the conversation

Do not use Ascabiol, topical lotion after the expiry date stated on the box.

The expiry date refers to the last day of the month.

6.4. Special precautions for storage

Store at room temperature.

If the product freezes (low temperature), immerse the vial in warm water.

6.5. Nature and contents of container

Lotion local application.

125 ml.

6.6. Special precautions for disposal and handling

Any unused product or waste material should be disposed of in accordance with regulations.

7. OPERATOR AND MANUFACTURER

HOLDER AND OPERATOR TO INTERNATIONAL:

FRILAB SA

17, rue des Pierres du Niton

1207 Genève SUISSE

Manufacturers:

TERIAK,ZI or ZI El Jebel West Fejja - 1153 El Mornaguia -Tunisia

Alternative site:

POLYMEDIC Amyot d'Inville Street, District Arsalan - Casablanca-Morocco

8. DOSIMETRY

Not applicable.

9. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS

Not applicable.

CONDITIONS OF PRESCRIPTION AND DELIVERY

Medicinal product not subject to medical prescription.
