

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

ASCABIOL, lotion for cutaneous application

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Sulfiram..... 2 g
Benzyl benzoate..... 10 g
per 100 ml of lotion for cutaneous application

Excipient with known effect: 96 percent ethanol.
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lotion for cutaneous application
Pale yellow, milky lotion with a characteristic aromatic odor.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

ASCABIOL is indicated in adults and children aged 1 month and over for the treatment of:

- scabies due to infestation by *Sarcoptes scabiei*
- trombidiosis (red mites or chiggers).

4.2. Posology and method of administration

Posology

Treatment of autumn trombidiosis:

Apply ASCABIOL to the lesions using a cotton swab once or twice.

Treatment for scabies:

The ASCABIOL treatment consists of applying 1 or 2 layers to the entire body.

For adults

- Take a bath or shower in the evening and dry yourself. It is important to use clean linen (clothes, bath towel) after showering and to change the bed linen to avoid re-contamination.
- Apply ASCABIOL with a compress (do not use cotton wool or impregnated wipes) in 2 successive layers at 10-15 minute intervals (corresponding to the drying time) over the entire body surface, paying particular attention to lesions, including skin folds, interdigital spaces, under the breasts, navel, external genitalia, under the nails, scalp, and avoiding the face and mucous membranes.
- A 24-hour contact period must be observed.
- After 24 hours, take a shower and rinse thoroughly. You will need a clean bath towel again. Put on clean clothes and change the bed linens once more.

Treatment of bedding, linen and the environment

- Environmental treatment: the morning following the application of ASCABIOL, proceed with the usual cleaning of the premises and in the case of profuse or hyperkeratotic scabies, disinfect the bedding (mattress, bed base), carpet and other absorbent furniture with an acaricide.
- Treatment of clothing and linen: gather the linen used to date (including towels, sheets, pillowcases, etc.) and wash it in a washing machine at 60°C or disinfect it with an acaricide (store in a closed plastic bag for at least three hours) or by quarantining it for three days (in the case of common scabies) or eight days (in the case of profuse or hyperkeratotic scabies) in a closed plastic bag which will be kept at a temperature above 20°C.
- Don't forget to treat objects that may have been in contact with the body, such as: blood pressure cuff, shoes, stuffed animals...
- Vacuum the carpets and cushions vigorously.

For the pregnant woman

Same procedure as for adults with the application of a single layer and a contact time of 12 hours.

For a child over 2 years old

Same procedure as for adults.

For a child under 2 years old

The same procedure as for adults, with the application of a single layer and a contact time of 12 hours, or even 6 hours in very young children, depending on the extent of the scabies lesions (common, hyperkeratotic or profuse scabies) and on the individual tolerance of the child under 2 years of age.

It is recommended to wrap the hands of young children in mittens to prevent ingestion of ASCABIOL and to limit scratching lesions.

Pediatric population aged less than 1 month

This medicine should not be used in newborns under 1 month of age due to the presence of ethanol (see section 4.4), except where absolutely necessary.

Method of administration

Cutaneous route.

Shake the bottle well before use.

As a guide, in the case of scabies treatment, 1 bottle allows the application of 2 coats for an adult of average height and build (e.g. 175 cm – 77 kg).

If hand washing is necessary, reapply the product to the hands. Repeat this process for any other part of the body.

After the recommended contact time, take a shower and rinse thoroughly. You will need a fresh towel. Put on clean clothes and change the bed linens again.

Do not allow this medication to come into contact with plastic materials during use (bathtub, containers, gloves, and applicator, etc.). This is because there is a risk of significant damage to certain plastics. If necessary, use a glass container to handle this medication.

4.3. Contraindications

Hypersensitivity to any of the active substances or to any of the excipients listed in section 6.1 or to benzyl alcohol or benzoic acid (which are derived from the active substance).

4.4. Special warnings and precautions for use

Warnings

ASCABIOL may contain benzyl alcohol (maximum quantity of 12.5 mg per bottle) and benzoic acid (maximum quantity of 12.5 mg per bottle) both of which come from one of the active substances, benzyl benzoate:

Benzyl alcohol may cause allergic reactions and/or mild local irritation .

Benzoic acid and benzyl benzoate can cause local irritation and immediate non-immunological contact reactions, possibly through a cholinergic mechanism. Furthermore, because absorption through the immature skin of newborns is

significant, benzoic acid and benzyl benzoate may increase the risk of jaundice (yellowing of the skin and eyes) in newborns (up to 4 weeks old).

ASCABIOL contains 12.5 g of alcohol (96% ethanol) per bottle. This may cause a burning sensation on damaged skin. Furthermore, in newborns (premature and full-term), high concentrations of ethanol can cause severe local reactions and systemic toxicity due to significant absorption through immature skin (especially under occlusion).

Ethanol is flammable. Do not use this medicine near an open flame, a lit cigarette, or certain appliances (e.g., a hair dryer).

Precautions for use

- ASCABIOL should not be applied to mucous membranes.
- In case of infected scabies: treat impetiginization as a priority.
- In cases of irritated or eczematous scabies: ASCABIOL may temporarily worsen the irritation or eczematization caused by scabies. These symptoms can be relieved by appropriate treatment, including a topical corticosteroid, 24 hours after applying ASCABIOL.
- After treatment, the itching usually subsides within two to three days. However, itching may persist for a few weeks without necessarily indicating that the treatment has failed.
- Do not swallow to avoid the risk of neurotoxic effects such as convulsions due to benzyl benzoate.
- Scabies is a contagious parasitic disease. To avoid the risk of re-infestation and spread, it is important to take appropriate hygiene measures and treat those in close contact with the infected person. Hygiene measures and treatment depend on the clinical form of the disease (common, hyperkeratotic, or profuse scabies) and the degree of proximity to the index case.
- People who have come into contact with someone who has scabies, especially family members and partners, should be examined by a doctor as soon as possible and, if necessary, treated for scabies. In cases of close contact with infected individuals or widespread outbreaks, it may be helpful to also treat asymptomatic contacts to prevent further infestations.
- In addition, patients must:
- Keep your nails short and clean.
- After applying ASCABIOL, change clothes, sheets and towels and wash them at at least 60°C. This effectively decontaminates the laundry.
- Disinfect at the same time the clothing and bed linen of all people living under the same roof, used for less than 72 hours in case of common scabies.
- If laundry cannot be machine-washed at this temperature, an acaricide can be used to disinfect it relatively quickly. Alternatively, laundry can be left in a bag for at least 72 hours at room temperature (above 20°C) (see section 4.2).
- Vacuum the carpets and cushions vigorously.

Pediatric population

See Warnings

4.5. Interactions with other medicinal products and other forms of interaction

No interaction is known to date.

4.6. Fertility, pregnancy and breastfeeding

Pregnancy

A moderate amount of data from pregnant women (between 300 and 1000 pregnancies) has not shown any malformative or toxic effects on the fetus or newborn of benzyl benzoate.

Animal studies have not shown any reproductive toxicity (see section 5.3).

ASCABIOL may be prescribed during pregnancy if necessary.

Breastfeeding

It is not known whether benzyl benzoate and/or its metabolites are excreted in breast milk. A risk to newborns/infants cannot be excluded.

Breastfeeding should be interrupted during treatment with ASCABIOL to avoid contamination of the child.

Fertility

No fertility studies were conducted.

4.7. Effects on the ability to drive vehicles and use machinery

The effects on the ability to drive or operate machinery have not been studied. Under normal conditions of use, it is unlikely that ASCABIOL will affect the ability to drive or operate machinery.

4.8. Undesirable effects

Local demonstrations :

- Possible sensation of immediate cooking.
- Eczema may occur, particularly with repeated applications.
- Rare skin reactions such as acute generalized pustulosis may occur.
- Possibility of hypersensitivity reactions.

Post-scabies itching can persist for up to four weeks after the end of treatment, which is generally considered an allergic reaction to dead parasites and not necessarily an indicator of treatment failure.

General events :

- Anaphylactoid reactions (frequency not known)
- Convulsions:
 - in case of accidental ingestion.
 - In case of skin penetration: the systemic risk increases according to the extent of skin lesions and in children under 2 years of age.

Due to the presence of benzyl alcohol, this medicine may cause allergic reactions and/or slight local irritation (see section 4.4).

Due to the presence of benzoic acid and benzyl benzoate, this medication may cause local irritation and immediate non-immunological contact reactions, possibly through a cholinergic mechanism. Furthermore, because absorption through the immature skin of newborns is significant, benzoic acid and benzyl benzoate may increase the risk of jaundice (yellowing of the skin and eyes) in newborns (up to 4 weeks old). (see section 4.4).

Due to the presence of ethanol, this medication may cause a burning sensation on damaged skin. Furthermore, in newborns (premature and full-term), high concentrations of ethanol can cause severe local reactions and systemic toxicity due to significant absorption through immature skin (especially under occlusion). (see section 4.4).

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals report any suspected adverse reactions using the FRILAB reporting form available under the pharmacovigilance tab of the website: www.frilab.ch.

4.9. Overdose

Cases of eczema have been reported during repeated applications.

In case of accidental ingestion, gastric lavage may be helpful if performed within a few hours of ingestion. If necessary, symptomatic treatment will be administered in a hospital setting.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic class: EXTERNAL ANTIPARASITICS, INCLUDING SCABICIDS, ATC code: P03AA
Sulphur derivatives

Mechanism of action

Sulfiram is an acaricide which, combined with benzyl benzoate, is active against mites, scabies mites and chiggers, and also against lice.

5.2. Pharmacokinetic properties

The risk of systemic absorption of ASCABIOL (active substances and excipients) increases with the severity of skin lesions and in children under 2 years of age.

Benzyl benzoate is rapidly hydrolyzed to benzoic acid and benzyl alcohol, which, after conjugation with glycine, are excreted as hippuric acid. No data are available on absorption after topical application in humans.

The percutaneous absorption of benzyl benzoate and benzyl alcohol was studied in monkeys (10 mg/cm²). Dermal absorption under occlusion was approximately 70% after a 24-hour application and 57% without occlusion.

5.3. Preclinical safety data

Benzyl benzoate has also shown moderate toxicity following oral administration and repeated topical application. Benzyl benzoate is irritating to mucous membranes and eyes.

In vitro studies of the Ames test on the genotoxic potential of benzyl benzoate have given negative results.

There are no studies on the carcinogenic potential of benzyl benzoate.

The reproductive toxicity of benzyl benzoate has not been sufficiently studied. No studies are available on fertility or on peri- and postnatal development.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

96 percent ethanol, polysorbate 80, purified water.

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

60 months.

6.4. Special precautions for storage

Store at a temperature not exceeding 25°C.

6.5. Nature and contents of container

125 ml in a bottle (polyethylene) with a cap (polyethylene).

6.6. Special precautions for disposal and handling

Do not allow ASCABIOL to come into contact with plastic materials during use (bathtub, containers, gloves, and applicator). This is because there is a risk of significant damage to certain plastics. If necessary, use a glass container to handle ASCABIOL.

Do not use ASCABIOL near an open flame, a lit cigarette or certain appliances (e.g., hair dryer).

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

7. MARKETING AUTHORISATION HOLDER AND OPERATOR

FRILAB SA

17 RUE DES PIERRES DU NITON
1207 GENEVA - SWITZERLAND

8. MANUFACTURER

TERIAK

INDUSTRIAL ZONE 1111, DJEBEL WEST
ZAGHOUAN – TUNISIA

9. DATE OF REVISION OF THE TEXT

15.07.2025

10. DOSIMETRY

Not applicable.

11. INSTRUCTIONS FOR THE PREPARATION OF RADIOPHARMACEUTICALS

Not applicable.

CONDITIONS FOR PRESCRIPTION AND DISPENSING

This medication is not subject to medical prescription.