Strathmann Antiscabiosum® 25 %

1. NAME OF THE MEDICINAL PRODUKT

Antiscabiosum® 25 %

Affected to Adults

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance
25 g benzyl benzoate/100 g emulsion

Excipients with known effect
Cetostearyl alcohol, propylene glycol
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

White emulsion for application to the skin.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Scabies in adults, as a less toxic agent and as an alternative to adequately investigated anti-scabies drugs.

4.2 Posology and method of administration

Antiscabiosum 25 % is intended exclusively for the treatment of adults. A product with a lower content of active substance is available for children, Antiscabiosum® 10 % for Children.

Posology
Unless otherwise instructed, the emulsion is intended for one daily application to the skin for three consecutive days.

Treatment should then be ended even if the itching continues. Medical follow-up assessment of the success or failure of the scabies treatment is required.

Method of administration
- It is recommended that the body be given a thorough wash (bath, shower) and that the nails be clipped if necessary before treatment. Washing the body is also permitted on the following days before using the emulsion again. The medicinal product should not be applied until the skin has dried and normal body temperature has been reached, therefore after about 60 minutes.
- On 3 consecutive days, rub the product carefully onto the body from the neck to the toes without leaving any gaps. The emulsion is applied as a thin, evenly distributed layer in the same way as a sun protection product would be.
- Treat the visibly affected places with particular thoroughness, e.g. every finger, every toe and the area between the toes, all skin folds, chest, external genitals and the waist and buttock region. These places are particularly affected by scabies mites.
- If an application at the head (hairy-head region and/or face) has been prescribed by the doctor it is absolutely important to leave the area around the eyes, mouth and nose out from treatment.
- If the hands are washed during the day, the emulsion must be applied again immediately afterwards.
- On the fourth day, wash your body thoroughly using soap in a bath or under a shower to remove the emulsion completely.
- Change the clothing worn (underwear and outer clothing) completely and remake the bed, changing the bedclothes.

Follow-up treatment of any itching still present (post-scabies eczema) may be required after consultation with a doctor.

It is important to clean the environment as well to exclude new infection as far as possible. Scabies mites can be reliably destroyed at temperatures above 50 °C or in the absence of air.
For this reason, the bedding, underwear, towels and outer clothing used should be washed at 60 °C at least. This also applies to other objects that have been in contact with the body for some time, e.g. blood pressure cuffs, shoes and cuddly toys.
Objects and clothing which cannot be washed or can only be washed at lower temperatures should be stored in closed plastic bags for 7 days.
Carpets, mattresses and upholstered furniture should be thoroughly cleaned with a vacuum cleaner.

4.3 Contraindications

Antiscabiosum 25 % should not be used:
- in cases of hypersensitivity to benzyl benzoate, benzoic acid and benzyl alcohol or any of the excipients of the medicinal product (see section 6.1)
- during lactation
- for children under 12 years of age

4.4 Special warnings and precautions for use

Antiscabiosum 25 % should not come into contact with the eyes, mucous membranes or highly irritated skin.

Antiscabiosum should be applied with particular caution on persons with epileptic seizure in their medical history, because in such one case a seizure was repeatedly triggered by the emulsion.

The active substance, benzyl benzoate, is not phototoxic itself. Under the effect of sunlight, however, phototoxic substances have formed in laboratory experiments. It is recommended therefore that exposure to intense sunlight be avoided during treatment.

Sensitive surfaces can be affected by Antiscabiosum. Changes in colour may occur for instance. It is recommended that cotton gloves be worn when potentially sensitive surfaces are touched.

Application at the head
In exceptional cases, if the hairy head-region and/or the face is infested with scabies mites the doctor may prescribe an application with Antiscabiosum in this region. This case of application is to be made under medical supervision only. For the method of administration see section 4.2.

Use in children
No adequate investigations are available on use of this medicinal product in children. For this reason, it should not be used in children under 12 years of age. A product with a lower content of active substance is available for children.

Excipients
Cetostearyl alcohol may cause local skin irritations (e.g. contact dermatitis).
Propylene glycol can cause skin irritations.

4.5 Interaction with other medicinal products and other forms of interaction

No interactions are known to date.
To exclude interactions, Antiscabiosum 25 % should not be used with other externally applied anti-scabies agents.

4.6 Pregnancy and lactation

Pregnancy
Insufficient data only are available from animal studies with benzyl benzoate (see section 5.3). No clinical data are available on the use of benzyl benzoate in pregnancy. Therefore, benzyl benzoate should only be used in pregnancy if the indication is compelling.

Lactation
There are no data on whether the active substance benzyl benzoate passes into the mother's milk. Antiscabiosum 25 % should not be used during lactation therefore (see section 4.3).

4.7 Effects on ability to drive and use machines

Antiscabiosum 25 % has no effect on the ability to drive and use machines.

4.8 Undesirable effects

The assessment of undesirable effects is based on the following frequencies:

Very common	(≥ 1/10)
Common	(≥ 1/100 to < 1/10)
Uncommon	(≥ 1/1,000 to < 1/100)
Rare	(≥ 1/10,000 to < 1/1,000)
Very rare	(< 1/10,000)
Unknown	(Frequency cannot be assessed on the basis of the available data.)

Possible undesirable effects

See table on page 2.

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. Healthcare professionals are asked to report any suspected adverse reactions via Bundesinstitut für Arzneimittel und Medizinprodukte, Abt. Pharmakovigilanz, Kurt-Georg-Kiesinger-Allee 3, D-53175 Bonn, Website: www.bfarm.de.

4.9 Overdose

There are no known cases of intoxication after use of Antiscabiosum 25 %.

System organ class	Undesirable effects	Frequencies
Skin and subcutaneous tissue disorders	Irritations of skin and mucous membranes, continued itching (post-scabies eczema) Hypersensitivity reactions which are expressed as malaise, nettle rash (urticaria) and facial oedema (angioedema) as well as touch-sensitive, inflammatory skin reaction (contact dermatitis).	Rare Unknown
Nervous system disorders	Epileptic seizure in children	Unknown

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group:
Agent against ectoparasites including anti-scabies drugs
ATC code: P03AX

According to in vitro studies, there is evidence of acaricidal and ovicidal activity on the part of benzyl benzoate. Experience reports indicate clinical efficacy. The clinical mechanism of this action itself is unknown.

5.2 Pharmacokinetic properties

Benzyl benzoate undergoes rapid hydrolysis to benzoic acid and benzyl alcohol. Benzyl alcohol is oxidised to form benzoic acid and is excreted in the urine after conjugation with glycine as hippuric acid. No findings are available on absorption after epidermal use.
The percutaneous absorption of benzyl benzoate and benzyl alcohol has been studied in monkeys. Dosages each containing 4 µg/cm² of the radio-labelled substance dissolved in acetone were administered. The percutaneous absorption rate was determined by urine collection, accumulated over 4 days and extrapolated to total absorption using correction factors. In the case of benzyl benzoate, 57.0 ± 10.4 % of the administered dose was absorbed. Under plastic film occlusion, absorption increased to 71.2 ± 4.4 %. There are no findings on the absorption of benzyl benzoate by the skin after use of Antiscabiosum 25 %.

5.3 Preclinical safety data

In acute oral toxicity studies, benzyl benzoate was relatively well tolerated in mice, rats and dogs. The toxicity of benzyl benzoate was also low after repeated oral and dermal administration. Cats proved an exception as they reacted with particular sensitivity as even low quantities applied to their skin resulted in fatal effects. Benzyl benzoate causes substantial irritation to mucous membranes and eyes.

The results of in vitro studies on genotoxic potential conducted with benzyl benzoate were negative.

No studies are available on the cancerogenic potential of benzyl benzoate.

Insufficient reproduction toxicity studies have been conducted on benzyl benzoate. An insufficiently documented study on rats yielded no indications of embryotoxic or teratogenic effects. No studies on fertility or peri/postnatal development are available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Emulsifying cetostearyl alcohol (type A) (Eur. Ph.)
Propylene glycol
Purified water
Sorbitol 70 %

6.2 Incompatibilities

None known to date.

6.3 Shelf life

In an unopened, intact pack: 4 years
Do not use the medicinal product after the expiry date given on the label and folding box.

After opening: 3 days
Any residual medicinal product in the bottle after the 3-day period of use is not intended for further use.

6.4 Special precautions for storage

Do not store above 30 °C.

6.5 Nature and contents of container

The emulsion is filled into brown glass bottles which are put into folding boxes.
Pack size: 200 g emulsion N 3

6.6 Special precautions for disposal

No special requirements.

7. MARKETING AUTHORISATION
Marketing authorisation holder

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8. MARKETING AUTHORISATION NUMBER

6380758.01.00

9. DATE OF RENEWAL OF THE AUTHORISATION

19.05.2004

10. DATE OF REVISION OF THE TEXT

February 2021

11. LEGAL CATEGORY

Pharmacy-only medicine

Other information
People who have been in contact with scabies patients must be examined. Because of the latency period of several weeks, small endemics, initially unnoticed, in the family, school classes and kindergartens, residential communities and care institutions are by no means infrequent. Regardless of whether skin changes are present or not, people who have close or long-term physical contact with the patient must be treated simultaneously.

A product with a lower content of active substance is available for children, Antiscabiosum® 10 % for Children.