

Package leaflet: Information for the user

Antiscabiosum® 10 % for children
Emulsion with benzyl benzoate

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must talk to a doctor if you do not feel better or if you feel worse.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

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1. What Antiscabiosum 10 % is and what it is used for

What Antiscabiosum 10 % is

Antiscabiosum 10 % is an antiparasitic medicine that is used on the skin.

What it is used for

Antiscabiosum 10 % is used to treat scabies in **children aged over 6 years** as a less toxic medicine and alternative to sufficiently well studied antiscabietic medicines.

Children aged from 1 to 6 years therefore should be treated with Antiscabiosum 10 % only when no additional skin lesions are present that may increase absorption of the active substance, benzyl benzoate, into the body and when treatment is given under careful medical supervision.

2. What you need to know before you use Antiscabiosum 10 %

2.1 Do not use

Do not use Antiscabiosum 10 %,

- in children who are allergic to benzyl benzoate, benzoic acid and benzyl alcohol or any of the other ingredients of the medicine. These other ingredients are listed in section 6.
- in children with extensive skin diseases such as psoriasis, neurodermatitis and eczema
- during breast-feeding
- in infants
Severe, sometimes fatal, side effects may occur particularly in newborns with signs of immaturity that manifest clinically as "gaspings syndrome" (see also section 4 Possible side effects.).

2.2 Warnings and precautions

Take special care with Antiscabiosum 10 %

- Please note that Antiscabiosum 10 % must **not** come into contact with the eyes, mucous membranes and severely irritated skin.
- In children who have epileptic fits and/or have had them in the past, it is **essential** that you talk to your doctor before you use Antiscabiosum.
- The child should avoid intense exposure to the sun during use (including the solarium).
- If symptoms persist after treatment, talk to your doctor. Further therapy should only be given if your doctor agrees.
- Sensitive surfaces can be affected by Antiscabiosum. This may involve colour changes for example. It is therefore recommended that you wear cotton gloves when touching surfaces that may be sensitive.

Use on the head

In exceptional cases, when the scalp and/or face are affected by itch mites, the doctor may prescribe use of Antiscabiosum on the head. It should be used in this way only under medical supervision however. Please read section 3 How to use Antiscabiosum.

Use in pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Pregnancy

Benzyl benzoate has been only insufficiently investigated in animal studies. There is no experience available regarding the use of benzyl benzoate in pregnancy. Therefore you should use Antiscabiosum 10 % during pregnancy only if the doctor treating you considers this to be absolutely necessary after weighing up all the risks.

Breast-feeding

There are no data on whether the active substance benzyl benzoate passes into the mother's milk. Therefore Antiscabiosum 10 % must not be used during breast-feeding (see section 2.1).

Effects on ability to drive and use machines

No special precautions are necessary.

2.3 Interactions

Medicines may influence each other so that their effects are stronger or weaker than usual. Please tell your doctor or pharmacist therefore if other medicines are used, other medicines have been recently used or it is intended to use other medicines for your child.

No interactions between Antiscabiosum 10 % and other medicines are known to date. It should not be used simultaneously with other antiscabietic medicines however to exclude possible interactions.

2.4 Information on other ingredients

The ingredients in Antiscabiosum 10 % include cetyl stearyl alcohol and propylene glycol. Cetyl stearyl alcohol can cause local skin irritation (e.g. contact dermatitis). Propylene glycol can cause skin irritation.

3. How to use Antiscabiosum 10 %

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Antiscabiosum 10 % is intended for use in children. A product with a higher content of active substance is available for adults.

How you should use Antiscabiosum 10 % and how often

Unless otherwise prescribed by your doctor, the normal procedure is as follows:

Apply the emulsion to the skin once daily on 3 consecutive days.

Please stop treatment after that even if itching is still present. Take the child to see a doctor. Follow-up medical examination to assess the success of failure of scabies treatment is necessary in principle.

- Before starting treatment, you should wash the child's body thoroughly (in a bath or shower) and cut his or her nails if necessary. The child should also bath or shower before the medicine is used again on the following two days. Always wait until the skin is completely dry and the body temperature has returned to normal before applying Antiscabiosum 10 %. Leave about 60 minutes after the shower therefore. On 3 consecutive days, rub Antiscabiosum 10 % carefully over the child's whole body from neck to toes. Apply a thin layer of emulsion and spread it evenly as you would with a sun screen. There should be about 24 hours between applications.
- Treat visibly affected places with particular thoroughness. Carefully rub the emulsion into every finger, toe and between the fingers and toes, all body folds, the chest, external genitals (**not** the mucous membranes) and waist and buttock region. These places are particularly affected by itch mites.
- If your doctor has prescribed that Antiscabiosum should be used on the head as well, it is essential to make sure that you carefully avoid the areas around the eyes, mouth and nose.
- If the child washes his or her hands during the day, the emulsion must be re-applied directly afterwards.
- On day 4, you must make sure you give the child a shower or bath to wash the medicine off the entire skin.
- Change all the child's clothing (underwear and outer clothing) daily and change his or her bed.

How long you should use Antiscabiosum 10 % for

Three consecutive days.

Do not use Antiscabiosum 10 % for longer than 3 days without medical advice. If the itching is still present, it is essential that you take the child to see the doctor. Follow-up treatment may be necessary.

Please talk to your doctor or pharmacist if you think that the effects of Antiscabiosum 10 % are too strong or too weak.

If you apply more Antiscabiosum 10 % than you should, remove the excess from the skin with a cloth. Overdose has not been reported. If you suspect overdose please inform a doctor immediately. Wash the emulsion off the child's skin and stop further use or intake of medicines.

If you forget to use Antiscabiosum 10 %, do not use it twice on the following day and do not use a double dose but talk to your doctor immediately. He will decide whether you should continue treatment.

If you stop using Antiscabiosum 10 %, the itch mites will recover and the original symptoms will recur again.

What to do about textiles and objects

It is important that you clean the environment as well to exclude another infection as far as possible. Itch mites can be killed at temperatures above 50 °C or in the absence of air.

For this reason, the bed clothes, underwear and outer clothing used should be washed at 60 °C at least. This also applies to objects that have come into contact with the body for a long period such as soft toys, blood pressure sleeve and shoes. Objects and clothing that must be washed at lower temperatures only or not washed at all should be stored in closed plastic bags for 7 days.

Carpets, mattresses and upholstered furniture should be thoroughly vacuum cleaned.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Possible side effects

Rare (1 to 10 patients treated in 10,000): irritation of skin and mucous membranes occur or itching continues.

Not known (frequency cannot be estimated from the available data): The following side effects have been reported post marketing:

- Hypersensitivity reactions that manifest as feeling unwell, nettle rash (urticaria) and vascular oedema (angiooedema) as well as touch-sensitive inflammatory skin reactions (contact dermatitis)
- Epileptic fits in children

Because absorption of the active substance through the skin has not been studied, it must be assumed that benzyl alcohol is available for the whole organism after topical application of Antiscabiosum 10 %. Severe, sometimes fatal, side effects (gasping syndrome) can be caused particularly in immature newborn or premature infants.

Reporting of side effects

If you notice side effects in your child, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly to the Federal Institute for Drugs and Medical Devices, Pharmacovigilance Department, Kurt-Georg-Kiesinger-Allee 3, D-53175 Bonn, website: www.bfarm.de. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Antiscabiosum 10 %

Storage conditions

- Keep out of the sight and reach of children.
- Do not store above 30 °C.

Shelf life

Do not use this medicine after the expiry date. This date is stated on the label and folding box after "EXP". The expiry date refers to the last day of that month.

If there is anything left in the bottle after the 3-day application, please do not keep this. It is not intended for further use.

6. Contents of the pack and other information

What Antiscabiosum 10 % contains

- The active substance is benzyl benzoate. 100 g emulsion contains 10 g benzyl benzoate.
- The other ingredients are: Purified water, sorbitol 70 %, emulsifying cetyl stearyl alcohol (type A) (Ph. Eur.), propylene glycol

What Antiscabiosum 10 % looks like and contents of the pack

Antiscabiosum is a white emulsion. It is contained in brown glass bottles which are put into folding boxes. There is a pack size containing 200 g emulsion.

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Important information

It is essential that persons coming into contact with scabies patients are examined. Because itching does not occur until about 3 to 5 weeks after infection, the infection can spread, initially unnoticed, in the family, schools and kindergartens, in shared accommodation and healthcare institutions. Regardless of whether or not skin changes are present, it is essential to treat people in the close environment as well. By doing so, potential as yet undetected infections can be cured and transmission of scabies or new infection can be prevented.

A product with a higher content of active substance is available for adults.