

Package leaflet: Information for the user

Tenutex 20 mg/g + 225 mg/g cutaneous emulsion

disulfiram/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, pharmacist or nurse have told you.

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

What is in this leaflet

1. What Tenutex is and what it is used for
2. What you need to know before you use Tenutex
3. How to use Tenutex
4. Possible side effects
5. How to store Tenutex
6. Contents of the pack and other information

1. What Tenutex is and what it is used for

Tenutex is indicated in adults and children ~~as-~~ against head lice, crab lice and scabies. Tenutex has an antiparasitic effect.

2. What you need to know before you use Tenutex

Do not use Tenutex

- if you are allergic to disulfiram, benzyl benzoate or any of the other ingredients of this medicine (listed in section 6).
- if you are allergic to organic sulfur compounds in vulcanized rubber.

Warnings and precautions

Talk to your doctor or nurse before using Tenutex when treating crab lice or scabies. It is important that a diagnosis is made before treatment is started, as itching may have other causes that require different treatment.

Consider the following before using Tenutex:

- Avoid contact with the eyes.
- Before treating, first apply Tenutex on a small area of the skin on the forearm, to ensure that you or your child is not allergic to Tenutex. If you or your child is not feeling any skin irritation or burning sensation Tenutex can be used as described in the section How to use Tenutex. The treatment should be discontinued immediately if you or your child gets skin irritation or burning sensation.
- Tenutex can cause yellowing or a certain lingering smell in some textiles. Therefore, always use appropriate clothing and textiles during treatment. Also protect carpets, floors etc.
Stain removal advice: The stains should be treated as soon as possible, which can be done in the following way:
 1. Use stain remover, if the material allows it.
 2. Wash with detergent in the usual way, preferably in a machine

Children

Before treating children under the age of 2 years, a doctor should always be consulted.

Pregnancy, breast-feeding and fertility

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

There are only limited experience from the use of Tenutex during pregnancy. It is not recommended to use Tenutex during pregnancy or by women who can become pregnant and are not using contraception.

It is unknown if Tenutex passes into breast milk.

If you are breast-feeding, and are using Tenutex, make sure to protect the child from getting Tenutex into the mouth, from your skin or hair, during breast-feeding.

Driving and using machines

Tenutex has no or negligible influence on the ability to drive and use machines.

Tenutex contains cetostearyl alcohol

which can cause local skin reactions (e.g. contact dermatitis).

3. How to use Tenutex

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

Accurate diagnostics, contact tracing and well-executed treatment are of great importance for a successful outcome.

HEAD LICE

In the case of head lice, the whole family should be examined, but treat only the people who have lice or eggs near the scalp. The examination requires a louse comb and magnifying glass. As the agent is potent, "just in case" treatment should be avoided to reduce the risk of developing resistance.

Part the towel-dried hair in the middle and place a strand of Tenutex in the parting. Massage out towards the sides. Keep parting the hair to the right and left and soak the hair (required amount depends on hair length, 25-75g) from the start of the root towards the tip of the hair - it is at the scalp that the lice live and lay eggs. Avoid getting Tenutex near the eyes. After 24 hours, wash and comb your hair carefully.

To get rid of the lice, treatment is usually required twice with Tenutex cutaneous emulsion, 8 days apart, in combination with daily, careful combing of the hair. Thoroughly comb and inspect the hair daily for 14 days after treatment.

If desired, you can wear a knitted cap or similar over your hair during the treatment period - but definitely not an airtight one, such as a swimming cap or plastic bag. Since infection mainly occurs through head-to-head contact, there is no need for extensive cleaning and cleaning of objects. However, cleaning of combs, brushes and caps is recommended.

Lack of effect may be due to incorrect treatment, re-infection or resistance. Children who have recently been infected and adults with lice often have no symptoms, and can therefore be an important source of infection. Note that it takes a while for the lice to die, which is why finding live lice immediately after treatment is not necessarily a sign of resistance.

Seek medical advice if repeated treatment attempts fail.

CRAB LICE

Talk to a doctor or nurse before using Tenutex to treat crab lice.

Massage groin, armpits and other hairy areas of the body (e.g. legs) with Tenutex. As a rule, the head hair does not need to be treated, but should the lice appear there, it is treated as for head lice. Tenutex must not be used around the eyes. In the case of crab lice in eyelashes, a doctor should therefore be contacted. Wait with all body wash for 2 days (48 hours) after the Tenutex treatment.

SCABIES

Talk to a doctor or nurse before using Tenutex to treat scabies.

1. Thorough body wash. Dry well.
2. Carefully massage the whole body - except the head - with Tenutex (50-60 g). Avoid excessive rubbing. **ATTENTION!** Don't forget to lubricate the soles of your feet and between your toes and fingers. Every square millimeter of the body must be covered by the ointment for 24 hours.
3. Hold off all body washing for 24 hours. Use rubber gloves, which are then thrown away, when doing dishes and other wet tasks. Lubricate your hands again with Tenutex after work and also after each hand wash.
4. Wash the body thoroughly 1 day (24 hours) after the treatment. Change all clothing closest to the body, change bed linen, all towels, bath towels, etc. All textiles and shoes that have been in close contact with the body must be washed or aired for 3-5 days.
5. In severe cases of scabies, the treatment (according to points 1-4) is repeated after a week.

If you have any further questions about this medicine, ask your doctor, pharmacist or nurse.

Use in children

First make sure that the child ~~under 12 years~~ is not allergic to any of the ingredients in Tenutex as described in section Warnings and precautions. After that, you can treat the child according to the treatment instructions above.

A child under 2 years should be properly diagnosed by a doctor, before you start treating the child with Tenutex.

If treating a baby against scabies also the head needs to be treated, because scalp and face are common sites for scabies on babies.

Avoid getting Tenutex near the baby's eyes or mouth.

If you use more Tenutex than you should

If you have used too much medicine or if, for example, you or a child has ingested the medicine by mistake, contact a doctor, hospital or the Poisons Information Center (tel. <to be completed nationally>) for an assessment of the risk and advice.

4. Possible side effects

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

Seek medical advice immediately if you experience the following side effects:

Severe allergic reaction with symptoms such as fever, rash, swelling and drop in blood pressure (anaphylactic reaction). This side effect has been reported (affects an unknown number of people).

Other side effects

Uncommon (affects more than 1 in 1,000 people): Hypersensitivity reactions eg skin redness, skin rash, burning, hair loss. Discoloration of blond hair has been reported.

Rare (affects less than 1 in 1,000 people): Allergic skin reactions to organic sulfur compounds.

Not known (cannot be estimated from the available data): Burning sensation

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

[To be completed Nationally]

5. How to store Tenutex

Do not store above 25°C.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton after EXP and on the tube. The expiry date refers to the last day of the given month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Tenutex contains

1 g of cutaneous emulsion:

- The active substances are disulfiram 20 mg and benzyl benzoate 225 mg.
- The other ingredients are cocoa fat, stearic acid, trolamine, cetostearyl alcohol, eucalyptus oil and water.

What Tenutex looks like and contents of the pack

White to yellow-white cutaneous emulsion.

Laminate tube 100 g

Marketing Authorisation Holder and Manufacturer

Bioglan AB
Box 503 10
202 13 Malmö

This leaflet was last revised in 2025-07-03