

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 g of cutaneous emulsion contains: Disulfiram 20 mg and benzyl benzoate 225 mg.

Excipient with known effect

Cetostearyl alcohol

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Cutaneous emulsion

White to yellowish white (oil/water).

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Tenutex is indicated in adults and children against pediculosis capitis (head lice), pediculosis pubis (crab lice), scabies.

4.2 Posology and method of administration

Method of administration

Pediculosis capitis: Depending on hair length, 25-75 g of Tenutex is worked into the scalp, from the start of the root towards the tip of the hair. After a day (24 hours), the hair is washed and finely combed for inspection. As a rule, 2 treatments with Tenutex are required 8 days apart in combination with thorough combing of the hair. The inspection is repeated daily for 14 days after the treatment.

Pediculosis pubis: About 50 g of Tenutex is massaged into the groin, armpits and other hairy places of the body. Body washing may only take place after two days (48 hours). Any lice in the hair of the head are treated as in the case of head lice.

Scabies: After thorough body washing and drying, the whole body is carefully massaged in with 50-60 g of Tenutex - but not the head. In infants and young children, scalp and face involvement are common sites for scabies, compared to older children and adults. Therefore, treatment should be applied to the whole-body including the head and neck on children below 2 years, and after properly diagnosed by a physician. Avoid excessive rubbing. After a day (24 hours), body washing can take place. In severe cases of scabies, the treatment is repeated after a week. Hydrocortisone ointment can be used if the skin becomes irritated by the treatment.

4.3 Contraindications

Hypersensitivity to the active substances or to any of the excipients listed in section 6.1. Tenutex should not be used by those who are allergic to organic sulfur compounds in vulcanized rubber.

4.4 Special warnings and precautions for use

Contact with the eyes must be avoided. Crab lice in eyelashes or eyebrows should therefore not be treated with Tenutex.

Tenutex contains cetostearyl alcohol which can cause local skin reactions (e.g. contact dermatitis).

Before treatment Tenutex should be applied on a small area of the skin in the forearm one (1) hour before use, and if no skin irritation or burning sensation are detected, Tenutex can be administered as described in the section Method of administration. This action is proposed to avoid/minimize local skin reaction.

If signs of an allergic reaction or severe burning occur the treatment should immediately be discontinued.

Paediatric population

Use on children below 2 years should only be performed if he/she has been properly diagnosed by a physician. This action is proposed mainly to avoid possible accidental toxicity by oral intake in children below 2 years, although the likelihood of such risk is low if the product is used in the recommended therapeutic margins and the optimum recommendations of use.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

4.6 Fertility, pregnancy and lactation

Fertility

There are no data on effects of disulfiram and benzyl benzoate on female or male fertility.

Pregnancy

There are no or limited amount of data from the use of disulfiram and benzyl benzoate in pregnant women. Animal studies are insufficient with respect to reproductive toxicity.

Tenutex is not recommended during pregnancy and in women of childbearing potential not using contraception.

Lactation

It is unknown whether disulfiram/metabolites of disulfiram and benzyl benzoate/metabolites of benzyl benzoate are excreted in human milk.

A risk to the newborns/infants cannot be excluded.

A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from Tenutex therapy taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman.

A lactating woman in treatment with disulfiram and benzyl benzoate should make sure that no disulfiram and benzyl benzoate are transferred orally, from skin or hair, to the child during breastfeeding.

4.7 Effects on ability to drive and use machines

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

4.8 Undesirable effects

The list below shows side effects per organ class. Within each organ class, the side effects are structured under frequency headings as follows:

Very common ($\geq 1/10$), common ($\geq 1/100$, $< 1/10$), uncommon ($\geq 1/1,000$, $< 1/100$), rare ($\geq 1/10,000$ to $< 1/1,000$), very rare ($< 1/10,000$), not known (cannot be estimated from the available data).

Skin and subcutaneous tissue disorders

Uncommon: Contact dermatitis, urticaria, alopecia, hair discoloration.

Not known: Burning sensation.

General disorders and administration site conditions

Rare: Allergic skin reactions to organic sulfur compounds.

Not known: Anaphylaxis

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 the national reporting system.

[To be completed Nationally]

4.9 Overdose

In case of overdose or accidental ingestion, a doctor, hospital or the Poisons Information Center (telephone <to be completed nationally>) should always be contacted.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Parasiticides, ATC code: P03AA54

Tenutex is an antiparasitic agent effective against eggs and both early and adult stages of head lice, crab lice and scabies.

5.2 Pharmacokinetic properties

Not studied.

5.3 Preclinical safety data

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6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cocoa butter, stearic acid, trolamine, cetostearyl alcohol, eucalyptus oil and water.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

30 months.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Laminate tube of 100 g. Instructions for use included in each package.

6.6 Special precautions for disposal and other handling

No special requirements.

7. MARKETING AUTHORISATION HOLDER

Bioglan AB
Box 503 10
202 13 Malmö

8. MARKETING AUTHORISATION NUMBER

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 22 October 1982

Date of latest renewal: 01 January 2010

10. DATE OF REVISION OF THE TEXT

2025-11-07