

INSTRUCTION
for use of medical product
APISARTHON®

Registration number: П N012631/01

Trade name of medical product: Apisarthron®

Dosage form: ointment for external use

Composition

100 gm of medical product contain:

Active substances:

Bee venom – 3.0 mg;

Methyl salicylate – 10.0 gm;

Allylthiocyanate – 1.0 gm.

Excipients: sodium laurylsulfate – 0.7 gm; white vaseline – 6.0 gm; emulgated cetostearyl alcohol – 14.0 gm, which is composed of: sodium cetylstearylsulfate – 1.4 gm, cetostearyl alcohol – 12.6 gm; water – to 100 gm.

Description

White or light yellowish ointment, of uniform consistency with odor of methyl salicylate.

Pharmacotherapeutic group: antiinflammatory remedy for local use

ACT code: M02AC

Pharmacological properties

Combined medical product for external use based on highly purified bee venom.

Bee venom shows pain-killing and antiinflammatory action (stabilizes lysosomal membranes), shows antibacterial effect (suppresses growth of gram-positive bacteria).

Methyl salicylate is related to group of non-steroid antiinflammatory agents, shows significant antiinflammatory action (inhibits production of prostaglandins, inhibits cyclooxygenase).

Allylthiocyanate (purified standardized extract of mustard-seed oil) leads to deep warming of tissues, improves local blood flow, lowers tonic spasm.

Indications for use:

- peripheral nervous system disorders, with feeling of pain: neuralgia, neuritis, radiculitis, low back pain (ischialgia);
- pains in muscle (myalgia) and soft tissue involvement, including caused by trauma;
- warming of muscle before, during and after physical activity and engagement in sports;
- damage/strains, accompanied with pain and edema;
- musculoskeletal diseases (osteoarthritis, rheumatic soft tissue involvement), degenerative-dystrophic damage and pain in joints.

Contraindications

Hypersensitivity to bee venom, salicylates, isothiocyanate; severe chronic renal insufficiency; hepatic insufficiency; dermal diseases; neoplasms; skin damage; acute arthritis; contagious diseases; bone-marrow hemopoiesis inhibition; mental illnesses; children (below 6 years); pregnancy and breast-feeding period.

Precautions: renal insufficiency, children between 6 and 12 years.

Posology and method of administration

External.

Uniformly spread band of ointment with length 3 - 5 cm on skin (layer width is approximately 1 mm) until appearing of redness and feeling of warmth (2-3 minutes). Then slowly and intensively rub ointment into skin. For enhancement of treatment effect it is recommended to keep medicated areas in warmth. Apply 2 - 3 times a day until disappearance of symptoms (not more than 10 days).

Side effects

In rare cases skin allergic reactions, sensation in application site are possible.

Drug-to-drug interaction

Methyl salicylate strengthens action of anticoagulants, methotrexate.

Special warnings

In case of renal failure do not allow long-term application at large surfaces. Do not apply onto damaged and irritated skin. Avoid contact of ointment with eyes, mucous surfaces and open wounds. After application of ointment wash hands thoroughly with soap.

Dosage form

20 or 50 gm of ointment for external use into aluminum tubes, sealed with aluminum foil and closed with plastic cap. Place one tube together with leaflet into carton box.

Storage conditions

Store at the temperature not more than 25°C.

Keep out of reach of children!

Shelf life

3 years

Do not use after expiration of shelf-life!

Prescription status

OTC.

Owner of registration certificate:

Passauer Pharma GmbH,
Eiderstedter Weg 3, 14129 Berlin, Germany.

Manufacturer:

Passauer Pharma GmbH,
Eiderstedter Weg 3, 14129 Berlin, Germany.

Manufactured:

Lichtenheldt GmbH Pharmazeutische Fabrik,
Industriestrasse 7-9, 23812 Wahlstedt, Germany.

Organization that accepts claims from customer:**Representation office of company «Esparma GmbH» (Germany):**

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