

Package leaflet: Information for the user

Contractubex gel, 100 mg+50 IU+10 mg/g
onion extract (*Extr. Cepae*), heparin sodium, allantoin

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

Although this medicine can be obtained without a prescription, you still need to use Contractubex gel according to the instructions to achieve the best results.

- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse.

What is in this leaflet

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

1. What Contractubex gel is and what it is used for

Contractubex gel is used for the treatment of various types of scars after the wounds have healed. Contractubex gel inhibits the growth of scar tissue and softens scar tissue. The gel also reduces redness, swelling and pain (anti-inflammatory).

Contractubex gel is suitable for use in patients with movement-inhibiting, hypertrophic, keloid (thick scars higher than the skin surface and sometimes with a different colour than the surrounding skin) and cosmetically disfiguring scars resulting from an operation, amputation, burn or accident. Suitable in case of contractures, such as Dupuytren's contracture (persistently bent fingers) and traumatic tendon contractures, as well as atrophic scars (scars lower or higher than the skin surface).

2. What you need to know before you use Contractubex gel

Do not use Contractubex gel:

- if you are allergic to onion extract, heparin sodium, allantoin, methyl-4-hydroxy benzoates (parabens), sorbic acid, citronellol, geraniol, benzyl alcohol, citral, linalol, or other ingredients of Contractubex gel (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before using Contractubex gel.

Children

Special instructions apply to children (see section 3).

Other medicines and Contractubex gel

No interactions have been reported. Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Pregnancy and breast-feeding

No risks concerning use during pregnancy and breast-feeding are currently known. If you are pregnant or breast-feeding or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Not applicable.

Contractubex gel contains methyl 4-hydroxybenzoate, sorbic acid, ethanol and allergenic fragrance

Methyl 4-hydroxybenzoate may cause allergic reactions (including delayed type).

Sorbic acid can trigger local skin reactions such as contact dermatitis.

Contractubex contains 13.4 mg of ethanol (alcohol) per gram of gel (1.34% by volume). Alcohol can cause burns to the affected skin.

Contractubex contains a fragrance that contains citronellol, geraniol, benzyl alcohol, citral and linalol, which can cause allergic reactions.

3. How to use Contractubex gel

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

Apply Contractubex gel onto the skin several times per day and gently massage into the scar tissue until the gel is completely absorbed. In case of old hard scars, Contractubex gel can also be applied overnight and covered with a bandage.

The treatment can last for several weeks or months, depending on the size of the scar or contracture. In case of fresh wounds, avoid physical irritants, such as extreme cold, UV radiation, or intense massage.

Use in children

When used in children aged 1 *or older*, it is recommended to apply the gel on scar tissue once or twice per day.

Using this medicine in children *under* 1 year of age is not recommended due to insufficient data.

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.

The most often reported side effects are application site reactions.

The following side effects were reported in a study where Contractubex gel was used for treating 592 patients:

Common (might affect up to 1 user in 10): pruritus, redness (erythema), visible dilation of blood vessels (telangiectasia), scar lower than skin surface (scar atrophy).

Uncommon (might affect up to 1 user in 100): darkened skin (hyperpigmentation), thinned skin (skin atrophy).

Unknown (the following side effects have been reported post marketing; incidence cannot be estimated from available data):

small pustules on the skin (pustular rash), allergic reaction (hypersensitivity), skin crawling (paraesthesia), swelling, pain in the application site, local skin reactions (contact dermatitis), hives (urticaria), rash, itching (pruritus), redness (erythema), skin irritations, small bumps (papules), skin inflammation, burning sensation on the skin, separation of skin layers in the application site, tight skin sensation.

Contractubex gel is generally well-tolerated, even in case of extended use.

The itchiness occasionally reported during treatment with Contractubex gel indicates changes in scar tissue and generally does not require terminating the treatment.

Side effects are classified based on incidence:

Very common	Occurs in more than 1 user in 10
Common	Occurs in up to 1 user in 10
Uncommon	Occurs in up to 1 user in 100
Rare	Occurs in up to 1 user in 1,000
Very rare	Occurs in up to 1 user in 10,000
Unknown	Incidence cannot be estimated from available data

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via www.ravimiamet.ee. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Contractubex gel

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

Do not use Contractubex gel after the expiry date which is stated on the carton and tube.

Do not store at a temperature higher than 25 °C.

The expiry date after the initial opening of the pack is 6 months.

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 Contractubex gel contains

The active substances are onion extract (Extr. Cepae), heparin sodium, and allantoin
1 g of gel contains:

onion liquid extract	100 mg
(Allium Cepa L., Bulbus (0,16:1); extractant: water, excipient: ethanol)	
heparin sodium	50 IU
allantoin	10 mg

The other ingredients are sorbic acid (E200), methyl-4-hydroxy benzoate (E218), macrogol 200, xanthan gum, purified water, fragrance containing citronellol, geraniol, benzyl alcohol, citral, linalol.

What Contractubex gel looks like and contents of the pack

Contractubex gel is opaque, light beige to light brown in colour.

Contractubex gel is packaged inside a 20 g tube.

Marketing Authorisation Holder

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Manufacturer

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