Package leaflet: Information for the user

Contractubex® Gel

Active substances: Extr. Cepae, Heparin sodium, Allantoin

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.
- 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® is and what it is used for

Contractubex® is used to treat various types of scars once the lesions have closed.

Contractubex® works to suppress the growth of scar tissue and has a loosening and smoothening effect on scar tissue. It also works to reduce redness, warmth, swelling and pain (anti-inflammatory).

Contractubex® is to be used in patients with movement-restricting, hypertrophic, keloid (scars that are thick, raised, and sometimes differently coloured than your surrounding skin) and cosmetically disfiguring scars after operations, amputations, burns and accidents; after contractures such as Dupuytren's contracture (a constricting of the hand) and traumatic tendon contractures as well as atrophic scars (scars that form a hole or wrinkle in the skin).

Contractubex is indicated in adults and children and adolescents aged 1 to 17 years.

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

Do not use Contractubex®

- If you are allergic (hypersensitive) to Extr. Cepae, heparin sodium, or allantoin, sorbic acid or to any of the other ingredients of this medicine (listed in section 6)

Warnings and precautions
Talk to your doctor or pharmacist before taking Contractubex®.

Other medicines and Contractubex®
Although no interactions have been reported: Please tell your doctor or pharmacist if you are using or have recently used or might use any other medicines.

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.

Contractubex is not recommended during pregnancy. Contractubex should not be used in the breast area if you are breast-feeding.

Contractubex® contains:

- a paraben (methyl-4-hydroxybenzoate) which may cause allergic reaction (possibly delayed),
- sorbic acid which may cause local skin reactions (e.g. contact dermatitis),
- fragrance with citronellol, geraniol, benzyl alcohol, citral and linalool which may cause allergic reactions,
- 13.5 mg alcohol (ethanol) / 1 g gel (1.35% w/w) which may cause burning sensation on damaged skin.

3. How to use Contractubex®

Always use Contractubex® exactly as described in this leaflet. You should check with your doctor or pharmacist if you are not sure.

Unless prescribed otherwise by your doctor apply and gently massage Contractubex® several times daily to the scar tissue. In the case of old, hard scars, allow Contractubex® to take effect overnight under a dressing.

Depending on the extent and thickness of the scar, treatment will be necessary for several weeks or months. Particularly when treating fresh scars, physical irritants such as extreme cold, UV light or heavy massaging should be avoided.

Use in children
In children from 1 year of age the application of the gel once or twice daily to the scar tissue is recommended.

Application in children under 1 year of age cannot be recommended, as there are no data available.

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 commonly reported side effects were local reactions at the treatment site. (see section 2 "Contractubex® contains")

The following undesirable effects were reported from a study in 592 patients treated with Contractubex®:

Common	*may affect up to 1 of 10 people*	Itching (pruritus), redness (erythema), small dilated blood vessels in the surface of the skin (telangiectasis), deepening of the scar (scar atrophy)
Uncommon	*may affect up to 1 of 100 people*	Darkening of the skin (hyperpigmentation), thinning of the skin (skin atrophy)

Beyond clinical trials the following undesirable effects with Contractubex® have been reported:

Frequency not known	*frequency cannot be assessed on the basis of the available data*	Small blisters on the skin filled with pus (pustular rash), allergic reaction (hypersensitivity), abnormal feelings of the skin (paraesthesia), swelling, pain where the gel has been applied, local skin reaction (contact dermatitis), hives (urticaria), rash, itching (pruritus), redness (erythema), skin

		irritation, small solid round bumps (papules), inflammation of the skin, burning sensation in the skin, application site exfoliation, feeling of tightness in the skin.

Contractubex® is generally well tolerated, even on long-term use.

Itching, which is occasionally observed during Contractubex® treatment, can occur as the scar tissue changes and does usually not require discontinuation of treatment.

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 to

Pharmaceutical Services
Minitry of Health
CY-1475 Nicosia
Tel: +357 22608607
Fax: + 357 22608669
Website: www.moh.gov.cy/phs
ADR ReportingWebsite: www.medicinesauthority.gov.mt/adrportal.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Contractubex®

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

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

Do not store above 25 °C.

Use within 6 months after first opening.

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

6. Contents of the pack and other information

What Contractubex® contains

The active substances are Extr. Cepae, heparin sodium and allantoin.

1 g gel contain:

Extr. Cepae	10 0 mg liquid extract from onion (Allium Cepa L., Bulbus (0,16:1)). Extraction solvent: water. Excipient: ethanol.
Heparin sodium	50 IU
Allantoin	1 0 mg

The other ingredients are:
Sorbic acid (E 200), methyl-4-hydroxybenzoate (E 218), xanthan gum, polyethylene glycol 200, fragrance (with citronellol, geraniol, benzyl alcohol, citral and linalool), purified water (see section 2 “Contractubex® contains”).

What Contractubex® looks like and contents of the pack

Contractubex® is an opaque gel of light beige to light brown colour.

It is supplied in tubes containing 10 g, 20 g, and 50 g gel.

Not all pack sizes may be marketed.

Marketing Authorization Holder

Merz Pharmaceuticals GmbH
Eckenheimer Landstraße 100
60318 Frankfurt/Main, Germany

Manufacturer

Merz Pharma GmbH & Co. KGaA
Ludwigstraße 22
64354 Reinheim, Germany

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