

# Contractubex® Gel



## Gel for the treatment of scars

Instructions for use, please read carefully!

### Composition:

100 g gel contains: Extr. Cepae 10.0 g, heparin sodium 5000 I.U., allantoin 1.0 g in water-soluble, fat-free gel base. Excipients: Sorbic acid, p-Methylhydroxybenzoate, Xanthan Gum, Polyethylene glycol 200, Perfume oil, Purified water.

### Properties:

Contractubex exerts a softening and smoothing effect on indurated, hypertrophic, painful and cosmetically disfiguring scar tissue. The water-soluble gel base mediates the deep penetration of the active ingredients into the skin thereby affording an intensive local treatment.

### Indications:

Movement-restricting hypertrophic, keloidal scars and cosmetically disfiguring scars after operations, amputations, burns and accidents; contractures of e.g. the fingers (Dupuytren's contracture) and traumatic tendon contracture; cicatricial strictures.

### Contra-indications:

Contractubex should not be used by patients with hypersensitivity to the active substances cepae extract, heparin sodium or allantoin or to sorbic acid, p-Methylhydroxybenzoate (parabens) or any of the other ingredients.

### Special warnings and precautions:

Contractubex contains p-Methylhydroxybenzoate, which can cause allergic reactions (sometimes delayed). Contractubex contains sorbic acid, which can cause local reactions in the skin, e.g. contact dermatitis.

### Interactions with other medicinal products and other forms of interaction:

No interaction studies have been performed. No interactions have been reported to date.

**Pregnancy and lactation:** No risks during pregnancy or lactation have been reported to date.

### Side-effects:

Assessment of side effects is based on the following frequencies:

Very common	(≥ 10%)
Common	(≥ 1%, < 10%)
Uncommon	(≥ 0.1%, < 1%)
Rare	(≥ 0.01%, < 0.1%)
Very rare	(< 0.01% or unknown)

Not known (Frequency cannot be assessed on the basis of available data.)

The most commonly reported side effects were local reactions at the treatment site.

The following side effects were reported from a pharmacoepidemiological retrospective cohort study in 592 patients treated with Contractubex:

#### *Skin and subcutaneous tissue disorders:*

Common: pruritus, erythema, telangiectasis, scar atrophy

Uncommon: hyperpigmentation of the skin, skin atrophy

Beyond clinical trials the following side effects with Contractubex have been reported; the frequency cannot be assessed on the basis of the available data:

*General disorders and administration site conditions:* Swelling, pain on the application site

#### *Skin and subcutaneous disorders:*

Urticaria, rash, pruritus, erythema, skin irritation, papules, inflammation of the skin, burning sensation in the skin, feeling of tightness in the skin

*Immune system disorders:* Hypersensitivity (allergic reaction)

*Infections and infestations:* Pustular rash

Contractubex is generally well tolerated, even on long-term use. The itching, which is occasionally observed during Contractubex treatment, is a manifestation of cicatricial tissue change and does usually not require discontinuation of treatment.

### Dosage and mode of application:

Unless otherwise prescribed by the physician, slightly massage Contractubex into the scar tissue several times daily until complete penetration of the gel. In the case of hard old scars allow Contractubex to take effect overnight under a dressing. According to the size of the existing scar or contracture treatment will be necessary for several weeks or months. When treating fresh scars physical irritations like e.g. severe cold or UV-light or intensive massage should be avoided.

**Overdosage:** No cases of overdosage have been reported.

**Expiry date:** The expiry date is printed on the outer carton.

Contractubex should not be used after the expiry-date!

**Date of revision of the text:** November 2009.

### Presentation and pack sizes:

Original packs of 10 g, 20 g and 50 g.

**Keep all drugs out of the reach of children!**

**Storage:** Do not store above 25°C.

### Marketing Authorisation Holder:

Merz Pharmaceuticals GmbH  
60318 Frankfurt am Main, Germany.

### Manufacturer:

Merz Pharma GmbH & Co. KGaA  
60318 Frankfurt am Main, Germany.

#### (THIS IS A MEDICAMENT)

Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you. Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.

- Doctor and Pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

Council of Arab Health Ministers  
Union of Arab Pharmacists