CONTRACTUBEX® GEL

COMPOSITION

Each gram of Contractubex® Gel contains 100 mg Extractum Cepae, 50 IU Heparin and 10 mg Allantoin. It also contains Sorbic acid, p- Methylhydroxybenzoate, Xanthine gum, Polyethylen glycol 200, Parfume and Distilled water as excipients.

PHARMACOLOGICAL PROPERTIES

Pharmacodynamic properties

Contractubex® has antiproliferative, antiphlogistic, relaxing and ameliorating effects on the scar tissue.

Extractum cepae

Extractum cepae shows antiphlogistic effects through inhibition of inflammation mediators secretion and antiallergenic effect. Extractum cepae inhibits growth of fibroblast of different origin, particularly kelloidal fibroblasts.

Extractum cepae has also bactericidal effect. While these properties stimulate primary wound healing, it prevents non physiological scar formation.

Exractum cepae is derived from Allium cepae (onion membrane). This substance has dermatologic effect and posses peptides containing sulphur. These peptides correspond to glutathione and it show a special role in cell metabolism. Peptides along with carbohydrates (glucose, fructose) provide cellular regeneration. By means of containing different types of components (such as Flavonoids) it provides anti-inflammatory and anti-proliferative properties. This extract also contains vitamin A, B1, B2, C, Pantotenic acid, minerals (i.e cobalt and iron) and trace elements. Epitel protecting effect of Vitamine A is well known.

Heparin

In case of local application, it shows inhibitory effect on fibroblast proliferation. While heparin increases tissue hydration, it reduces irritation resulted from induration and inflammation.
Anti-inflammatory effect and activities on connective tissue matrix of Heparin are more considerable than its antithrombotic effect in the scar treatment.

Allantoin

Allantoin is a final product of purine metabolism in animal and plant tissues. While it stimulates cellular proliferation, it also supports the development of healthy cells. Allantoin is convenient substance for the treatment of scar through its properties of stimulating epitelization, providing elastic surface formation and support of physiological scar formation.

Allantoin accelerates wound healing, achieves epitelization and has an increasing effect on water binding capacity of tissues. In addition, keratolytic and facilitating penetration activities of allantoin are essential for other substances in Contractubex gel to show their effects on skin. Allantoin has an effect to relieve the pruritus, which is frequently present in scars.

Synergic combination of these active substances provides additional supports on fibroblast proliferation and especially inhibition of pathologically increased collagen synthesis.

Pharmacokinetic properties

Contractubex is a topically applied product. Penetration of Heparin through human skin is controversial. However that is used with convenient vehicles (oil, water emulsion or gel) and applied with material which facilitates penetration (such as allantoin), heparin can be detected upper layer of skin and in capillary microcirculation. Clinical and experimental studies demonstrated that even if when it applies with allantoin which facilitates penetration, the highest concentration that is detectable in tissues found as 0.1IU/ml. Local administration of a preparation containing heparin at a dose of 150 IU, 3 IU/ml maximum heparin concentration is obtained in circulation. This blood level is much lower than level that is necessary for heparin to exert minimum anticoagulant effect.
In addition, the amount of heparin in Contractubex is 50 IU/g, so that maximum blood concentration is much lower than the lowets blood levels mentioned above.
Therefore, it is accepted that heparin penetrating particularly the horny layer of the skin, by support of allantoin, practically cannot get into systemic circulation and it doesn't cause any significant clinical effect.
Extractum cepae and allantoin, as the other ingredients of Contractubex, do not get into systemic circulation following topical applications.

INDICATIONS
Contractubex is indicated for hypertrophic and colloidal scars, movement restricting and cosmetically disfiguring scars that occur after surgery, amputation, burns and trauma. It is also indicated for Dupuytren's contracture and traumatic tendon contracture as well as for cicatrical scars.

CONTRAINDICATIONS
Contractubex® gel should not be used in patients with known hypersensitivity to any of its ingredients or Alkyl -4 hydroxybenzoates (parabens).

WARNINGS/PRECAUTIONS
Treatment may take several weeks or months depending on size of existing scars and contractures. During treatment of fresh scars physical irritation such as excess cold, UV lights and abrupt massage should be avoided.
KEEP IT OUT OF REACH AND SIGHT OF CHILDREN IN ORIGINAL PACKAGE

USE IN PREGNANCY AND LACTATION
Pregnancy category: A
There are no studies conducted during pregnancy and lactation periods. Like with all other drugs, in these periods use of Contractubex® is not recommended. Usage of Contractubex® depends on the doctor decision and assessment of potential benefits/risks ratio.

UNDESIRABLE EFFECTS
Contractubex® Gel is generally well tolerated even on long term use. In rare cases some local irritations are reported such as slight erythema and itching. These side effects do not require discontinuation of the treatment.
IN CASE UNDESIRABLE EFFECTS, PLEASE CONSULT YOUR DOCTOR.

DRUG INTERACTIONS
There is no known and reported drug interaction.

METHOD OF ADMINISTRATION AND DOSES
Unless indicated otherwise by doctor, Contractubex® gel is applied few times a day on scar tissue by massage in order to achive better penetration. In the case of old, hard scars, Contractubex® Gel can be applied during night with occlusion. Treatment may take several weeks or months depending on size of existing scars and contracture.

Treatment results are more satisfying especially in children and in wide scar areas.
To prevent scar development and get best result, therapy should be initiated immediately after epitelization of the skin damage. In this case, keloid development can be prevented even in predisposing patients to keloid formation.

OVERDOSE
There is no knowledge about overdose of Contractubex®.

STORAGE CONDITIONS
Keep it at room temperature under 25 °C.
Keep out of the reach and sight of children and store in its original package.

PRESENTATION AND CONTENTS OF CONTAINER
Contractubex is presented in 100 g of aluminium tubes and in its carton box.

OWNER OF REGISTRATION AND IMPORTER
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Available only with prescription