

FERMENCOL®
(High Tech JSC, Russia)

COMPOSITION

The basic material for **Fermencol®** production is the organs of digestive systems of sea hydrobionts. **Fermencol®** is an enzymatic agent, made from collagenase of hydrobionts, representing a complex of 9 collagenolytic protease with the molecular weight from 20 to 100kDa, 36 kDa, 35(I)kDa, 35(II)kDa, 32kDa, 28kDa, 25(I)kDa, 25(II)kDa, 25(III)kDa and 23kDa.

SCARREDUCTION MECHANISM

Fermencol® shows an apparent collagenolytic activity against the excessive collagen in scar tissue, providing deep collagen peptide bond hydrolysis. Collagen is hydrolyzed until it splits into single amino acids.

Fermencol® shows high selective activity in relation to the branched molecules of pathological collagen with knotted and vortex folding patterns specific for keloid and hypertrophic cicatrices; shows less activity to

native collagen fibrils of a healthy connective tissue. Scar reduction occurs due to dissolution of excessive collagen.

When **Fermencol®** is used for elimination of acne and its consequences, it causes dissolution of a scar capsule around an inflamed gland, facilitating gland cleaning, reduction in scar volume and skin smoothing.

In addition to collagenolytic activity, **Fermencol®** shows general proteolytic activity and ability to hydrolyze polysaccharides, which has an integral effect on all components of a scar extracellular matrix. As a result of **Fermencol®** application, the scars are reduced and scar tissue hydration comes to normal.

FIELD OF APPLICATION

Fermencol® is applied to scar tissue resulting from surgery, wounds, burns, and acne.



PHARMACEUTICAL DOSAGE FORM

Fermencol® enzymatic correction set

Fermencol® enzymatic agent, dry active substance, 4 mg
Solaktin® agent for enzymatic solution, 40ml

Fermencol® gel

Fermencol® gel 0.01 %, 30g

METHODS OF APPLICATION

Different production forms allow for choosing the most appropriate method of application. **Fermencol®** can be delivered into a scar tissue through application, electrophoresis, and phonophoresis. Electrophoresis and phonophoresis help to deliver the enzymes of collagenase from hydrobionts deep into a scar tissue.

Electrophoresis treatment in a physiotherapy office

Given the production form, age, area and a scar thickness, the **Fermencol®** solutions of different concentration are applied. The **Solaktin®** agent is used for making a solution. The recommended concentration for the keloid scars is 0.5-1mg/ml, for the hypertrophic scars 0.1-0.2mg/ml. Refer to Table 1 for a required concentration of a solution.

In order to treat 1cm² of a scar tissue, 0.1-0.2 ml of the **Fermencol®** solution are required.

Table #1

Type of cicatrix	Solution concentration recommended mg/ml	Required qty of Solaktin® per 4mg of dry agent, ml
Hypertrophic "new"	0.1	40
Hypertrophic "mature"	0.2	20
Keloid "new"	0.5	8
Keloid "mature"	1	4

Moisten a piece of a filter paper or a gauze pad with the **Fermencol®** solution and apply to a scar. Apply on top a water moistened tissue with an electrode. To prevent burns the tissue must extend beyond the perimeter of the electrode.

Application must be done from a positive pole (anode)!

Mode of application: the current density is to be no more than 0.1 mA/cm² for scars located on body and limbs; and no more than 0.05 mA/cm² when electrophoresis treatment is applied on a facial area. For children under 5 years old, when electrophoresis treatment is applied on a facial area, the current density must be no more than 0.01 mA/cm².

The duration of exposure is 20 – 25 min. It is required to stay indoors for 30 min after treatment.

Duration of treatment is 12 – 15 applications.

Frequency of application: recommended at the same time daily, no less than once a day.

Treatment interval is 7 – 10 days.

1. Remove a bottle from a pack. Read carefully the instructions.

2. Open the bottles.

3. Pour a little quantity of Solaktin® into a bottle of FERMENCOL®.

4. Pour the bottle content into a measuring jar.

5. Add a required quantity of Solaktin® according to the Table 1.

6. Fill the syringe with a required quantity of the solution based on a scar area (0.1-0.2 ml for 1 cm² of a scar tissue).

7. Moisten the gauze with the solution.

8. Apply the gauze to the cicatrix. Begin electrophoresis treatment.

Phonophoresis treatment in a physiotherapy office

Prior to the treatment procedure it is required to clean the scar area using an appropriate cleanser. Apply a thin layer of the gel.

Mode of application: the current density is to be no more than 400 mW/cm² for scars located on body and limbs, and no more than 200 mW/cm² when located on facial area.

The duration of exposure is 3 – 5 min for one area. It is required to stay indoors for 30 min after treatment.

Duration of treatment is 10 – 12 applications.

Frequency of application: recommended at the same time daily.

Treatment interval is 10 – 14 days.

1. Remove the FERMENCOL® gel from a pack. Read carefully the instructions.

2. Clean the skin with a cotton pad.

3. Open a gel tube.

4. Apply the gel to a scar using light movements.

5. Phonophoresis treatment

Home application

Prior to gel application it is required to clean the scar area using an appropriate cleanser. Apply the FERMENCOL® gel to the scar using light movements, do not rub.

Frequency of application: 2-3 times a day.

Duration of treatment is 30-40 days.

Treatment interval is 10 – 14 days.

1. Remove the FERMENCOL® gel from a pack. Read carefully the instructions.

2. Clean the skin with a cotton pad.

3. Open a gel tube.

4. Apply the gel to a scar using light movements.

CONTRA-INDICATION

Individual collagenase intolerance, hypotrophic and atrophic scars.

SPECIAL WARNINGS

Can be applied not earlier than 3-4 weeks after injury, burning or surgery.

SAFETY CONDITIONS

FERMENCOL® consists of active enzymes. When applied to a sensitive skin, redness can occur, which is gone soon after the course of use has been terminated. In case of eye contact, rinse with plenty of water.

STORAGE CONDITIONS

Store in a dry, dark, cool place, do not freeze or heat above 40 °C.

The FERMENCOL® solution shelf life is 7 days at a temperature from 2° C to 6 °C.

USE BY DATE

3 years from the production date

MANUFACTURER

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ADDITIONAL INFORMATION

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