

ПОДТВЕРЖДАЮ

Генеральный директор

ООО "Медицинская Эстетика"

Еланский М.В.



20/8г.

Фотографические изображения

**"Гель интрадермальный с гиалуронатом натрия Novacutan, в вариантах
исполнения Novacutan YBio и Novacutan SBio"**

Фото 1. Внешний вид «Геля интрадермального с гиалуронатом натрия Novacutan SBio»

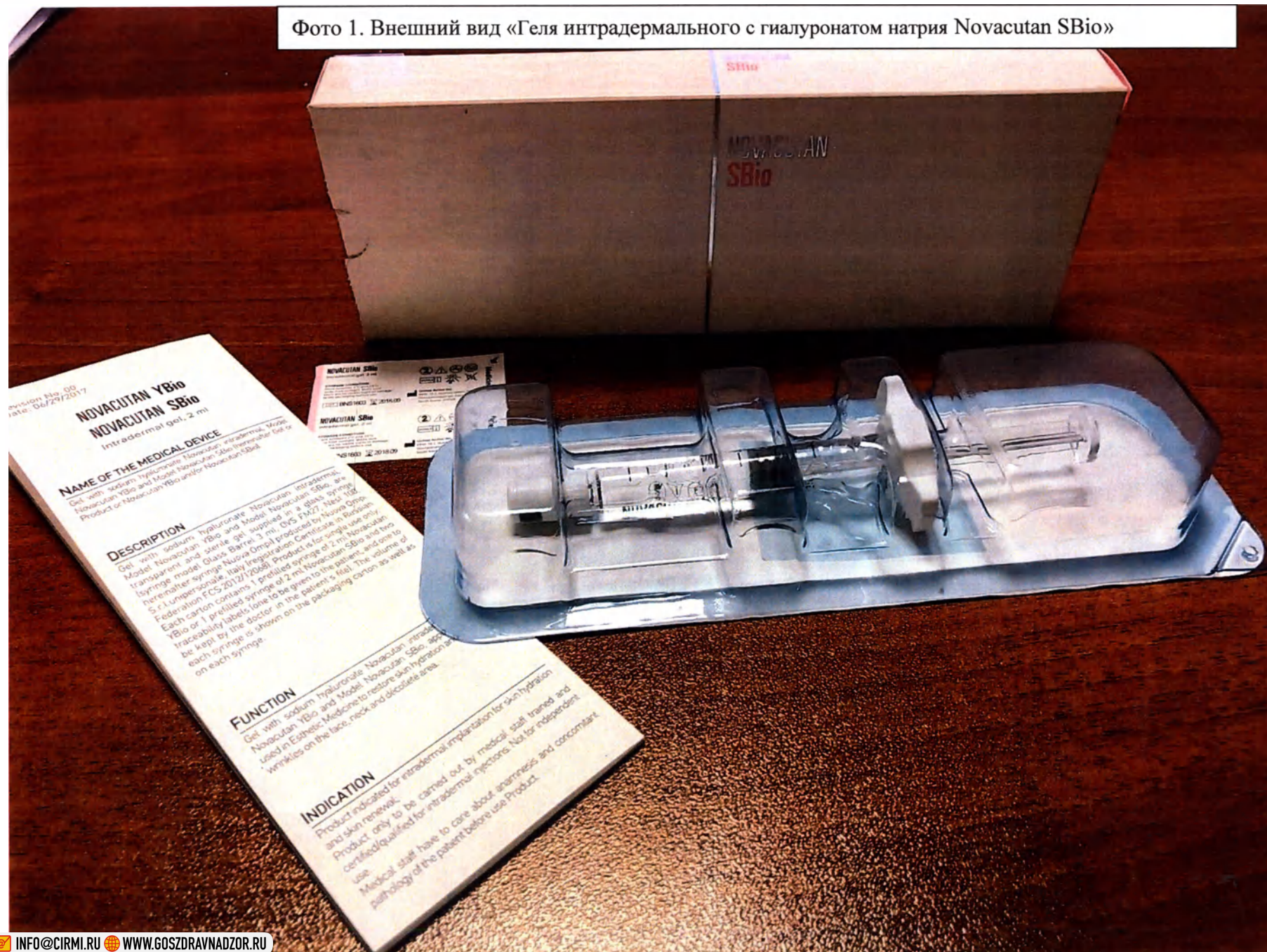


Фото 2. Шприц объемом 3 мл с гелем интрадермальным с гиалуронатом натрия в количестве 2 мл



Фото 5. Внешний вид «Геля интрадермального с гиалуронатом натрия Novacutan YBio»

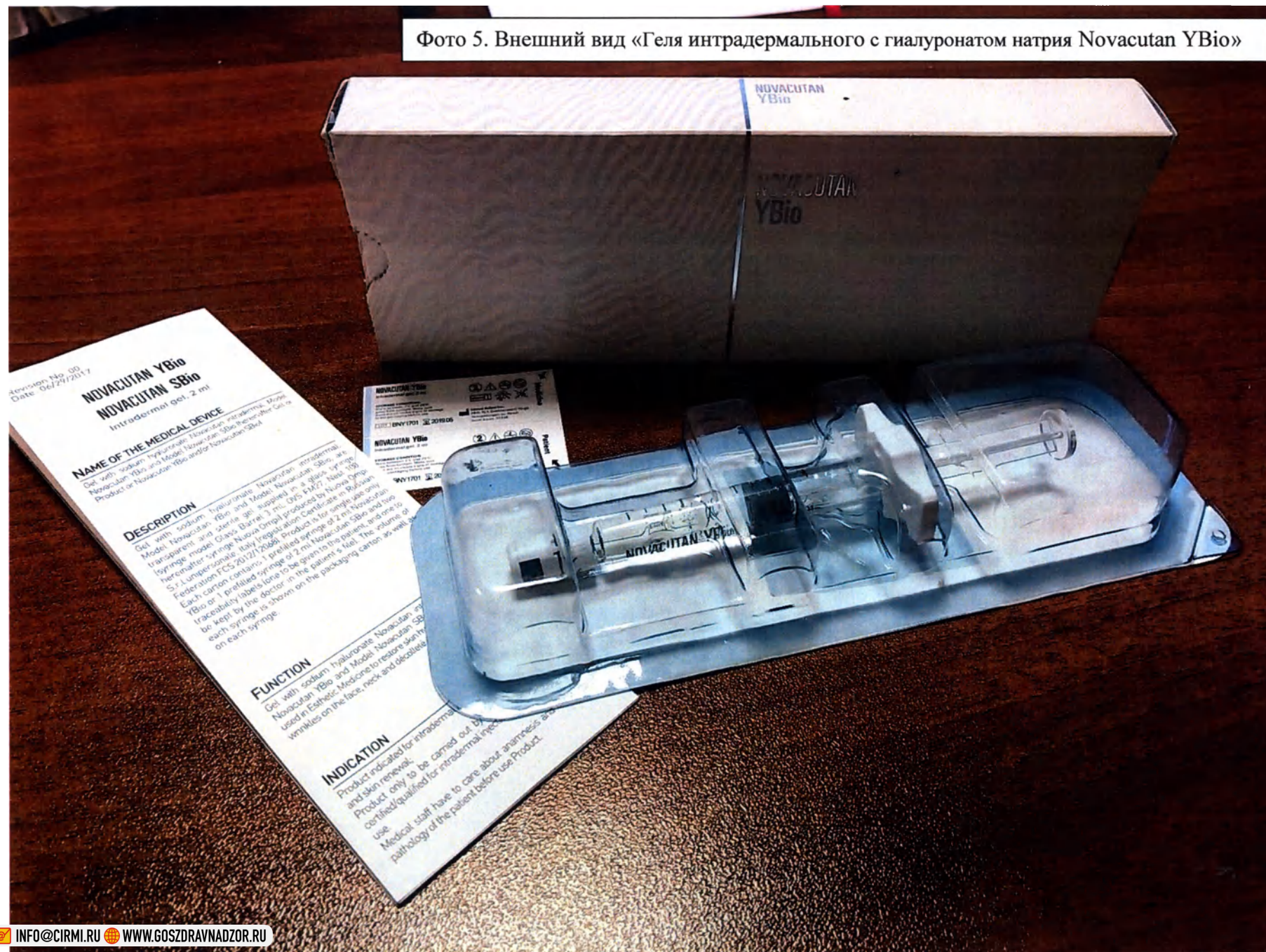


Фото 6. Шприц объемом 3 мл с гелем интрадермальным с гиалуронатом натрия в количестве 2 мл



Revision No. 06
Date: 04/24/2017

NOVACUTAN YBio NOVACUTAN SBio Intradermal gel, 2 ml

NAME OF THE MEDICAL DEVICE

Gel with sodium hyaluronate Novacutan intradermal, Model Novacutan YBio and Model Novacutan SBio, hyaline gel of Product Novacutan YBio and Product Novacutan SBio

DESCRIPTION

Gel with sodium hyaluronate Novacutan intradermal, Model Novacutan YBio and Model Novacutan SBio, are transparent and sterile gel available in a glass syringe (syringe model Glass Ramel 3 ml, QMS PMCT, class 100, hyaline syringe Model Dm) produced by Novacutan GmbH, Germany. Each syringe contains 2 ml of Product Novacutan YBio or 2 ml of Product Novacutan SBio and is sealed with a tamper-evident cap. The product is for single use only. Each syringe is intended for use by the doctor in the patient's face. The volume of each syringe is shown on the packaging carton as well as on each syringe.

FUNCTION

Gel with sodium hyaluronate Novacutan intradermal, Model Novacutan YBio and Model Novacutan SBio, applied to the skin, restores skin hydration and relieves skin wrinkles on the face, neck and décolleté area.

INDICATION

Product indicated for intradermal implantation for skin hydration and skin renewal.
Product only to be carried out by medical staff trained and certified for intradermal injections. Not for independent use.
Medical staff have to care about contraindications and possible side effects of the patient before using Product.

CONTRAINDICATIONS

Use with cautions

- Do not inject into blood vessels;
- Do not inject into the eyelids;

Do not use

- In combination with peeling, laser and/or ultrasonic skin treatment;
- If the patient has cutaneous disorder, inflammation or infection at the treatment site or near to this site;
- In case of patient has known hypersensitivity to hyaluronic acid and/or with a history of severe allergy or anaphylactic shock;
- In case of patient with autoimmune diseases;
- In pregnancy, breastfeeding mother, or in children.

POSOLGY AND PRECAUTIONS

Gel with sodium hyaluronate Novacutan intradermal, Model Novacutan YBio and Model Novacutan SBio, are packaged for single patient use. Sterile (do not re-sterilize). Do not use if package is opened or damaged.

As with all transcutaneous procedures, Novacutan YBio and Novacutan SBio implantation carries risk of infection. Standard precautions associated with sterile injectable materials should be followed.

The safety of hyaluronic acid filler for use during pregnancy in breastfeeding females or in patients under 18 years has not been established.

Hyaluronic acid filler injection may cause hyperpigmentation at the injection site if standard precautions are not followed.

Product should be used with caution in patients on immunosuppressive therapy.

POSSIBLE SIDE EFFECTS

After implantation of the Product, typical post-injection reactions may appear: redness, swelling, itching, easy bleeding, pain and discoloration of the skin at the injection site. Inflammatory papules after use of the Product can occur extremely rare - appearance of them are short-term, usually, revert independent.

Theoretically possible heavy defects after the introduction of Product, such as the formation of granulomas, necrotic tissue damage, anaphylactic reaction were not observed.

Conditions of use

Product only to be used by medical staff trained and certified qualified for intradermal injection.

OPERATING CONDITIONS

Product implantable and intended for use in the internal media of the human body.

MEDICAL DEVICE CLASSIFICATION

Medical Device potential risk - Class I

TREATMENT PROCEDURE

Pre-treatment Guidelines

Product only to be carried out by medical staff trained and certified for intradermal injections.
Before applying the skin of treating area has to be disinfected by sterile application of antiseptic solution: 0.05% solution of chlorhexidine and/or miramistin® are suitable. In case of significant pain reaction to injections the prior application of anesthetic cream is possible.

Novacutan YBio and Novacutan SBio intradermal to be injected in the form of a series of multiple small puncture with micro needle injector (needle per each puncture: needle with the size 0.23 x 0.25 mm) to be inserted into the skin at 45° to the skin surface, penetration depth 2-4 mm. It is suitable to use alternative needles with size from 0.20 x 0.33 (1) to 0.26 x 0.31 (1).

Intradermal area injections on the mobile part of eyelids there is possible to use technique of "micro papules". The diameter of the papules should not exceed 0.5 mm.

The single usage volume of 2.0 ml is designed to complete handle of face: forehead, neck and décolleté. If you process only one of the treated zones, the flow rate of the product should not exceed 1 ml. The cure consists of 3-6 sessions with interval of 2 weeks in between two sessions. However, depending on the age and skin conditions it is possible to follow treatments once every 3 weeks or even 1 week. The optimal amount of Product per session is 2 ml with allocation of it on the area of face, neck and décolleté. After 3-6 treatments - once every 1.5-2 months.

Syringe/Needle assembling

For implanting of Gel with sodium hyaluronate Novacutan intradermal it is recommended to use sterile needles for intradermal injections with the size 0.23x0.32 (1). It is possible to use needles with other sizes from 0.20x0.33 (1) to 0.26x0.31 (1).

The carton is not equipped with a needle for injection. The doctor must pick up a needle of the required size in compliance to manufacturer's recommendations and patient's skin condition.



Carefully break the cap covering the Luer adapter of the syringe in vertical direction.



Align the needle connector and a Luer adapter of the syringe, push the needle and quarter turn clockwise.



Ensure that the needle is securely fixed in the adaptor. Remove the protective cap from the needle. Syringe is ready for use.

COMPOSITION

Gel with sodium hyaluronate Novacutan intradermal, Model Novacutan YBio
Biopolymeric Sodium Hyaluronate

Active substance 2.5
Excipients 4.0
Total 6.5

Intradermal gel, 2 ml

NOVACUTAN
YBio
SBio

Фото 4. Этикетки самоклеющиеся

NOVACUTAN YBio

Intradermal gel, 2 ml

STORAGE CONDITION:

Store between 2°C and 25°C,
away from sunlight. Make sure
there are no visible signs of damage
to the packaging before use

LOT BNY1603 ⏳ 2018.09



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Medicine

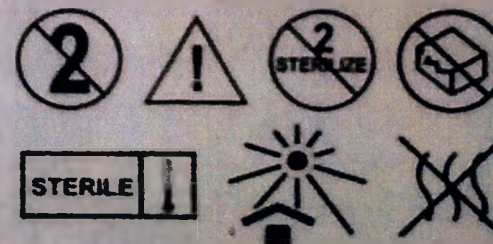
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Patient



Всего пронумеровано,
прошнуровано и
скреплено печатью
9 листа (ов)