



Министерство здравоохранения
Российской Федерации

**ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ
В СФЕРЕ ЗДРАВООХРАНЕНИЯ
(РОСЗДРАВНАДЗОР)**

Славянская пл. 4, стр. 1, Москва, 109074
Телефон: (495) 698 45 38; (495) 698 15 74



Субъектам обращения
медицинских изделий

Руководителям
территориальных
органов Росздравнадзора

Медицинским организациям

Органам управления
здравоохранением субъектов
Российской Федерации

04.06.2019 № 014-1390/19

На № _____ от _____

О незарегистрированном
медицинском изделии

Федеральная служба по надзору в сфере здравоохранения сообщает о выявлении в обращении территориальным органом Росздравнадзора по Республике Северная Осетия-Алания незарегистрированного медицинского изделия:

Материал биополимерный для внутрикожной имплантации: «Rejeunesse™ DEEP with Lidocaine Gross Linked Hyaluronic Acid», производства «NEWMEDIC CO., LTD» Korea.

Состав:

- кислота гиалуроновая (24 мг/мл) с лидокаином гидрохлоридом (3 мг/мл) в шприце-инжекторе - 1 шт.,
- игла инъекционная - 2 шт.,
- инструкция по применению - 1 шт. (Инструкция по применению не содержит информации на русском языке).

Федеральная служба по надзору в сфере здравоохранения предлагает субъектам обращения медицинских изделий провести проверку наличия в обращении указанного медицинского изделия, в установленном порядке провести мероприятия по предотвращению обращения на территории Российской Федерации и о результатах проинформировать соответствующий территориальный орган Росздравнадзора.

Территориальным органам Росздравнадзора провести мероприятия в соответствии с порядком, предусмотренным Административным регламентом Федеральной службы по надзору в сфере здравоохранения по исполнению государственной функции по контролю за обращением медицинских изделий, утвержденным приказом Минздрава России от 05.04.2013 № 196н.

Дополнительно информируем, что за нарушения в сфере обращения медицинских изделий предусмотрена административная ответственность согласно статьям 6.28 и 6.33 Кодекса Российской Федерации об административных правонарушениях, а также установлена уголовная ответственность за обращение фальсифицированных, недоброкачественных и незарегистрированных медицинских изделий согласно статье 238.1 Уголовного кодекса Российской Федерации.

Приложение: фотоизображение медицинского изделия на 4 л.

Руководитель

М.А. Мурашко



1.1 mL

COMPOSITION

Cross-linked hyaluronic acid..... 24mg/mL
Lidocaine HCL..... 3mg/mL
Phosphate-buffered saline, pH 7.0..... Q.S

REJEUNESSE™ DEEP with Lidocaine is used for the treatment of
fine lines in the face.
1 Box contains 1 syringe and 2 sterile needles.



Manufacturer: NEWMEDIC CO., LTD
470-1511, 15th, 15th Floor, 15th Building, 15th
Gangnam-gu, Seoul, Korea

Sales: purasac
471-1511, 15th Building, 15th Floor, 15th
Gangnam-gu, Seoul, Korea

DEEP with Lidocaine

(Model Name) - Rejeunesse Deep with Lidocaine
(Product License No) - 17-251



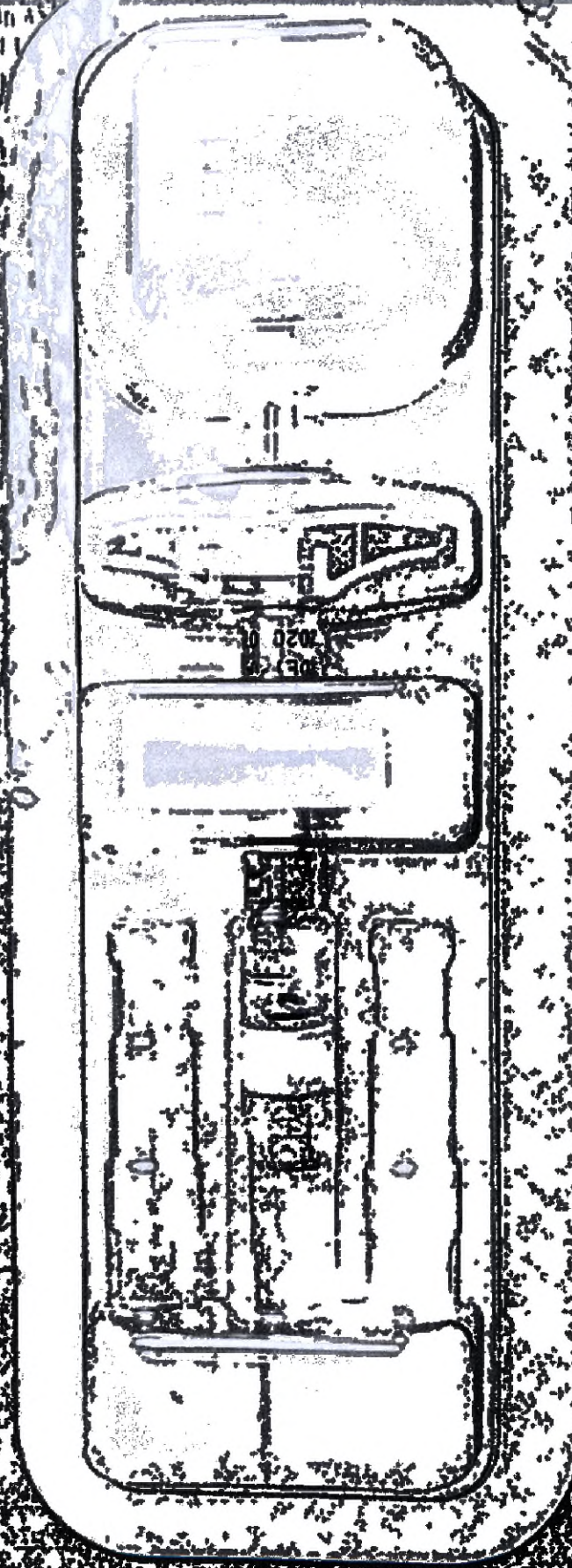
25°C



2+276

STERILE

CE



Rejuvenesse

COMPOSITION

Rejuvenesse is a powerful natural product that contains a unique blend of vitamins, minerals, and herbs. It is designed to help you feel younger, more energetic, and more confident. The ingredients are carefully selected to provide the best possible results.

DESCRIPTION

Rejuvenesse is a natural product that is easy to take and does not have any side effects. It is suitable for both men and women of all ages. The product is available in a convenient, easy-to-swallow capsule form.

INDICATIONS

Rejuvenesse is indicated for the treatment of various conditions, including:

- Fatigue and exhaustion
- Low energy and lack of motivation
- Poor memory and concentration
- Hair loss and thinning
- Skin problems and aging signs

CONTRAINDICATIONS

Rejuvenesse is contraindicated for individuals who are pregnant or breastfeeding. It should also be avoided by those with known allergies to any of the ingredients. Consult your doctor before taking this product.

PREPARATION

Rejuvenesse should be taken orally, with water, after a meal. The recommended dosage is one capsule per day. Do not exceed this dosage. The product should be stored in a cool, dry place.

CAUTIONS

Rejuvenesse is a natural product and should be used as directed. Do not take it with alcohol or other medications without consulting your doctor. If you experience any adverse effects, stop taking the product immediately.

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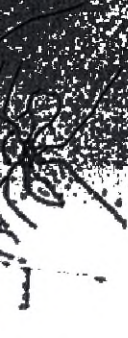
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STEP 1



STEP 2



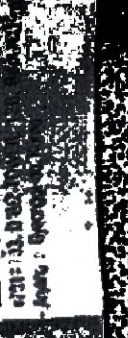
STEP 3



STEP 4



STEP 5



STEP 6

