



## Fine Lines

### Content

Stabilized hyaluronic acid = 24 mg/ml ; sodium chloride physiological solution q.s;ph7

### Description

Reyoungel Derm Fine Lines is a purified viscous and transparent gel, presented in a glass syringe jointly with a 30G needle. It is a single use product. Reyoungel Derm Fine Lines is a unique stabilized hyaluronic acid of non animal origin.

The hyaluronic acid is a natural polysaccharide present in the skin, in the subcutaneous and in the connective tissues acting as important structuring element, and equally in the synovial tissue and synovial fluid. The hyaluronic acid is one of the few substances having an identical form in all living organisms.

### Mode of action

Reyoungel Derm Fine Lines allows the increment of the skin and lips volume. It restores the contour of the former and accentuates the shape of the latter so that the desired level of correction can be attained. The implant is naturally integrated in the tissues and as time goes by it will undergo an isovolemic degradation.

### Sterilization

The syringe containing Reyoungel Derm Fine Lines is sterilized by steam. The needle is sterilized by means of gamma radiation.

### Indication

Reyoungel Derm Fine Lines is indicated for facial tissue augmentation. It is recommended for fine lines. It should be injected into superficial layer of the dermis. Better results regarding the deformities of the cutaneous contour will be obtained if its defects can be manually stretched until their complete elimination. The duration of the correction will last depending on the type of defect treated, stress at the graft implant spot, depth of implant within the tissue and the adopted injection technique. More serious defects may be hard to correct.

### Warning

Reyoungel Derm Fine Lines must be used only by intradermal. Do not resterilize Reyoungel Derm Fine Lines. Do not inject intravascularly. Do not mix with other products.

### Precaution

Normal precaution measures associated with intradermic injections must be observed. Like any kind of product, implants are associated with a risk of infection. Reyoungel Derm Fine Lines must not be used close or in anatomic locations where there are active pathologies of the skin, inflammations or related conditions. Do not use Reyoungel Derm Fine Lines in association to any other injectable implant.

The product must not be injected in areas where a permanent implant was inserted or in patients having unreal expectations.

Patients must be informed that they must not expose the treated region to intense heat (as sun bathing) or extreme cold, at least until the initial light edema and erythema disappear.

If a chemical "peeling" or other procedure based on a dermal active response is to be effected after the implant with Reyoungel Derm Fine Lines there is a theoretical risk of reaction at the implant spot. The same can occur if Reyoungel Derm Fine Lines is applied before the skin completely recovers from this type of procedure.

There is a potential risk of accidental injection of materials in blood vessels of the dermis which might generate vascular occlusion in a terminal artery, with the correspondent consequences. There are no reported cases of this occurrence with Reyoungel Derm Fine Lines. The product has not been tested neither on pregnant or nursing women, nor on children.

### Foreseeable collateral effects

Following a Reyoungel Derm Fine Lines injection some common reactions to injections may occur. These include erythema, swelling, pain, itching, discoloration or sensibility at the spot. The typical healing is spontaneous, occurring one or two days after the injection is effected into the skin, and within a week if effected into the lips.

The composition of the Reyoungel Derm Fine Lines is to equilibrate the normal pressure of the tissues. However, as the pressure of the tissues is sometimes altered upwards, as in the case of edemas, or downwards, as in dehydration, a small but significant modification may occur (swelling or wrinkling).

### Adverse reactions

Hypersensitivity character were reported in about 1 in every 2000 patients treated with Reyoungel Derm Fine Line. These were swelling and hardening at the implant spot, sometimes with edemas at the adjacent tissues. Sometimes erythemas, sensitivity and more rarely, acne papulae, may occur. These reactions may start right after the injection or after 2 - 4 weeks, It has been described as benign to moderate, and spontaneously healing within 2 weeks. Patients having presented this kind of reactions must not be treated again with Reyoungel Derm Fine Line. Any adverse occurrence must be informed to the Bioha Biological Products representative.



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### Interactions

The Reyoungel Derm Fine Lines combined with other medicines and devices, has not yet been tested.

### The fitting of the needle

For a safe and uncomplicated use of Reyoungel Derm Fine Lines it is important to fit in the needle correctly.

- Carefully unscrew the syringe needle cap.
- Carefully hold the needle sheath by its narrowest part and fit in the needle screwing it into the luer-lock until you start feeling some counter-pressure.
- Hold securely the needle sheath by its widest part. Press and rotate 90° (a quarter of a turn).
- Remove the needle sheath.

### Posology and administration procedure

Before starting the treatment, a study of the patient's compatibility and his threshold to pain must be carried out. Normally, no anesthesia for wrinkle treatment is needed. For lips volume increase, a never blockading anesthesia can be applied.

The patient must be informed about the indications, expected outcomes, counter-indications, warnings, precautions and potentially adverse reactions.

The spot to be treated must be cleaned with an adequate antiseptic solution. The Reyoungel Derm Fine Lines is applied using a fine small caliber needle (30G), injecting the product into the dermis. In case Reyoungel Derm Fine Lines must be deeply injected into the dermis or intra-muscularly, the implant duration will be shorter in view of the higher uptake of hyaluronic acid. A very superficial injection may cause discoloration; or, in other words, if the subjacent skin becomes whitish, the injection must be immediately stopped and the area must be massaged until the skin resumes its normal color. Prior to injecting, the embolus must be pushed until a drop shows up at the needle end.

The injection technique regarding its depth and the quantity to be administered may vary. The "tack" technique can be used to carefully raise a wrinkle or a fold, although some doctors favor a series of punctual injections or a combination of both. During the injection, it is recommended that the top of the needle be directed upward. The needle contour must be visible without its color being visible. Inject Reyoungel Derm Fine Lines graft while pulling the needle slowly backward. The injection must be stopped immediately before the needle is withdrawn from the skin to avoid spilling of the product on the injected spot.

If it is to be applied to the lips, an enhanced contour or a volume increase can be achieved.

The defects can be completely corrected at each application, but they must not be overcorrected. If the skin is quite loose, it is recommended that Reyoungel Derm Fine Lines be administered in two separate applications. The area to be corrected must be then massaged to fit the adjacent tissues contour. For each treated area, it is recommended a maximum dose of 2ml per application. If the treated area swells right after the injection, apply melted ice on it for a short time. After the first treatment, additional Fine Lines of Reyoungel Derm Fine Lines may be necessary to achieve the desired correction. Periodical injections for finishing touches may be necessary to achieve the desired correction.

**Remark:** The right injection technique is crucial for the final result of the treatment. Reyoungel Derm Fine Lines graft must only be administered by authorized personnel, according to the local regulations.

THE SYRINGE, NEEDLE AND ALL OTHER MATERIAL USED MUST BE DISCARDED RIGHT AFTER TREATMENT.

Manufactured by: Bioha Biological Products  
Symbols on packing:



Refer to instructions for use



For single use



Lot number



Use until date



Storage temperature



Sterile. The contents of the syringe have been sterilized by using moist heat.



Sterile. The contents of the syringe have been sterilized by using irradiation.



Sterile. The products are sterilized according to the European Standards.