



## For rehydration and elasticity of the facial dermis.

### Presentation:

R-fine® is a clear solution of sterile 1.5% sodium hyaluronate in a phosphate buffered saline contained in a pre-filled syringe for intradermal injection to supplement the hyaluronan of the skin.



R-fine® sterilised by filtration is enclosed within a glass ready to use, disposable syringe. The syringe is packed within a blister pack and an outer cardboard carton. The outer surfaces of the pre-filled syringe have been sterilised by ethylene oxide.



Two 30G needles sterilised by ethylene oxide are included.

### Dosage and Administration:

Remove from cold storage approximately one hour before treatment to allow equilibrium to room temperature. The healthcare professional should ensure that the area for treatment is clearly identified and that the patient is fully informed about the method of administration, the intended purpose of R-fine®, contraindications, undesirable effects and potential adverse reactions.

The area to be treated should be disinfected before injection.

R-fine® is implanted through the 30G needle into the mid-dermis. The linear tracking technique is recommended. It is necessary to attach the needle firmly to the pre-filled syringe. If the needle becomes blocked remove it and replace it with the second needle provided. The quantity injected will depend on the effect required. Do not over correct. Initial treatment can be supplemented with touch-up injections.

After implantation the treated area should be lightly massaged to shape R-fine® into the desired facial contours.

Patients should be advised not to apply make-up for 12 hours after the injection and to avoid prolonged exposure to harsh environmental conditions such as sunlight, UV light or saunas for two weeks after treatment.

### Uses:

R-fine® is intended to rehydrate and give elasticity to the dermis which has become depleted through age and/or exposure to extreme environmental conditions. Sodium hyaluronate is naturally present in the intercellular matrix of the skin. Through time the turgidity of the sodium hyaluronate decreases and this can result in wrinkle formation. R-fine® is intended to supplement the diminished sodium hyaluronate.

### Contra-indications:

Patients with known sensitivity to hyaluronan.

### Warnings and Precautions:

R-fine® must not be injected into blood vessels because the viscoelastic has the potential to occlude the vessels, which could result in embolism or infraction.

Do not inject into the facial dermis of patients if the area of the injection site is infected or where there is evidence of acute or chronic skin disease.

Do not use in areas of the face that are not readily distensible.

Do not inject into the eyelid, muscle tissue, bone, tendon or ligament.

Sodium hyaluronate is manufactured by fermentation of *Streptococcus equi* and rigorously purified. However, the healthcare professional should consider the immunological and other potential risks that can be associated with the injection of any biological material.

There is a risk of infection at the injection site as with any percutaneous procedure.

The safety of R-fine® has not been established in pregnant or lactating women or in children under 18 years of age.

Bleeding or bruising has been rarely associated with percutaneous implantation of viscoelastic materials. Therefore patients with known bleeding and/or coagulation disorders or who are on anticoagulation therapy should only be treated with appropriate caution.

Needles should not be reused because R-fine® may become turbid due to precipitation in the presence of cationic agents such as benzalkonium chloride or detergents residual in the needle following re-sterilisation. Do not use if packaging has been damaged.

**Undesirable effects:**

Patients should be informed of the possibility of undesirable effects following injection of R-fine®. The following effects have been reported by patients receiving sodium hyaluronate implants by injection to the facial dermis.

Pinpoint bleeding at the injection site that resolves spontaneously soon after injection.

Transient pain or discolouration at the site of injection.

Inflammation that may be associated with itching, pain on pressure for up to a week after the injection.

Induration or nodules at the site of injection.

Erythema without swelling that resolved within one week or in extreme cases after up to 2 months.

Hypersensitivity to sodium hyaluronate.

**Adverse Reactions:**

Prolonged erythema that should resolve in time.

Inflammatory reactions that last longer than one week should be reported to the healthcare professional who should treat with appropriate therapy.

**Storage:**

Store between 2°C and 8°C.

Do not freeze.

Protect from light ☒.

Remove from cold storage approximately one hour before treatment to allow equilibrium to room temperature.

Do not use if sterile packaging has been damaged.

Sterile product for single use only ☒.

Do not use after expiry date ☒.

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**Exclusive distributor:**  
EMCM B.V.  
Nijmegen, The Netherlands  
info@emcm.com  
www.emcm.com

**Manufacturer:**  
Hyaltech Ltd  
Heriot-Watt Research Park  
Edinburgh EH14 4AP UK  
www.hyaltech.com

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