Juvéderm®

HYDRATE™

ALLERGAN

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Revision 2011-10-20

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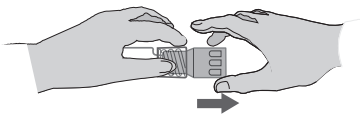

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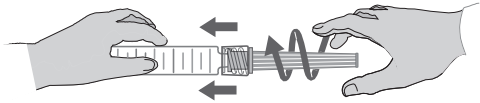

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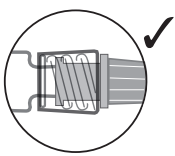

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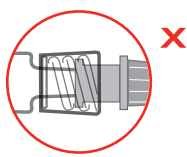

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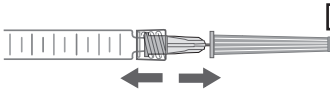

COMPOSITION

Hyaluronic acid	13.5 mg
Mannitol	9 mg
Phosphate buffer pH 7.2 q.s.p.	1 mL

One syringe contains 1 mL of ***Juvéderm® HYDRATE™***.

DESCRIPTION

Juvéderm® HYDRATE™ is a sterile apyrogenic, physiological solution of hyaluronic acid of non-animal origin containing 0.9% mannitol. The gel is presented in a graduated pre-filled syringe for single use. Each box contains 1 syringe of ***Juvéderm® HYDRATE™***, 2 sterile 30G1/6" for single use reserved for injection of ***Juvéderm® HYDRATE™***, an instruction leaflet and a set of labels in order to ensure traceability.

STERILISATION

The ***Juvéderm® HYDRATE™*** filled syringes are sterilised by moist heat.

The 30G1/6" needles are sterilised by ethylene oxide.

INDICATIONS

Juvéderm® HYDRATE™ is a solution indicated for use in improving skin hydration and elasticity by multi-injection into the dermal epidermal junction and into the superficial dermis.

CONTRA-INDICATIONS

• Do not inject ***Juvéderm® HYDRATE™*** into the eyelids. The application of ***Juvéderm® HYDRATE™*** in the bags under the eyes is reserved to specialists specifically trained in this technique and having a sound knowledge of the physiology for this particular area.

• Do not inject into blood vessels (intravascular).

• ***Juvéderm® HYDRATE™*** must not be used in:

- patients with a tendency to develop hypertrophic scarring;
- patients with known hypersensitivity to hyaluronic acid and/ or mannitol;
- pregnant or breast-feeding women;
- children.

• ***Juvéderm® HYDRATE™*** must not be used on areas with inflammatory and/or infectious (acne, herpes…) skin problems.

• ***Juvéderm® HYDRATE™*** should not be used simultaneously with laser treatment, deep chemical peels or dermabrasion.

For surface peels, it is recommended not to inject the product if the inflammatory reaction generated is significant.

PRECAUTIONS FOR USE

• ***Juvéderm® HYDRATE™*** is not indicated for injections other than intradermal injections.

• As a matter of general principle, injection of a medical device is associated with a risk of infection.

• No clinical data are available in terms of efficiency and tolerance of injection of ***Juvéderm® HYDRATE™*** into an area which has already been treated with another filling product. It is recommended not to inject it in site which has been treated with a permanent implant.

• No clinical data is available regarding the efficiency and tolerance of ***Juvéderm® HYDRATE™*** injections in patients having a history of or currently suffering from autoimmune disease. Depending on the nature of the disease, the medical practitioner shall therefore decide on the administration and associated treatment on an individual case-by-case basis. He/she shall also ensure the specific monitoring of this type of patients. In particular, it is recommended

that these patients undergo a preliminary dual test, and to refrain from injecting the product if the disease is active.

• There is no available clinical data concerning the tolerance of the ***Juvéderm® HYDRATE™*** injection in patients presenting a history of severe multiple allergies or anaphylactic shock. The medical practitioner must therefore decide on the indication according to the individual case, depending on the nature of the allergy, and must ensure that there is individual surveillance of these patients who are at risk. In particular, the decision may be taken to propose a double test or preventive adapted treatment previously to any injection.

• Patients showing a history of streptococcal disease (recurrent sore throat, acute rheumatic fever) shall be subjected to a dual test before any injection is given to them. In the event of acute rheumatic fever with heart complications, it is recommended not to inject the product.

• Patients on anti-coagulation medication (anticoagulants, aspirin or nonsteroidal anti-inflammatory drugs) must be warned of the potential increased risks of haematomas and bleeding during injection.

• Please recommend the patient not to use any make up during the 12 hours that follow the injection treatment and to avoid any extended exposure to the sun, UV light and temperatures below 0°C, as well as any sauna or hammam session during the two weeks that follow the injection treatment.

• If the needle is blocked, do not increase the pressure on the plunger rod but stop the injection and replace the needle.

• The composition of this product is compatible with fields used for magnetic resonance imaging.

INCOMPATIBILITIES

Hyaluronic acid is incompatible with quaternary ammonium salts such as benzalkonium chloride. ***Juvéderm® HYDRATE™*** should never, therefore, be placed in contact with such products or in contact with medico-surgical equipment treated with this type of substance.

UNDESIRABLE EFFECTS

• The patients must be informed that there are potential side effects associated with implantation of this product, which may occur immediately or may be delayed. These include (non-exhaustive list):

• Inflammatory reaction (redness, oedema, erythema etc.) which may be associated with stinging or pain on pressure, may occur after the injection. These reactions may last for one week.

• Haematomas.

• Induration or nodules at the injection site.

• Coloration or discolouration of the injection site.

• Poor effect or weak treatment effect.

• Cases of necroses in the glabellar region, abscesses, granuloma, and immediate or delayed hypersensitivity after hyaluronic acid injections have been reported. It is therefore advisable to take these potential risks into account.

• Patients must report inflammatory reactions which persist for more than one week, or any other side effect which develops, to their medical practitioner as soon as possible. The medical practitioner should use an appropriate treatment.

• Any other undesirable side effect associated with injection of ***Juvéderm® HYDRATE™*** must be reported to the distributor and/or to the manufacturer.

METHOD OF USE - POSOLOGY

• This product is designed to be injected by an authorized medical practitioner in accordance with local applicable regulation. The technicality of the latter is essential to the success of the treatment. The device must be used by medical practitioners having undertaken specific training in injection techniques.

• ***Juvéderm® HYDRATE™*** is to be used as supplied. Modification or use of the product outside the Directions for Use may adversely impact the sterility, homogeneity and performance of the product and it can therefore no longer be assured.

• Before undertaking treatment the patient should be informed of the indications of the device, its contra-indications, incompatibilities and potential side effects.

• If storage in a refrigerator (see storage conditions) leave the product to come to room temperature before performing the injection.

• Before the injection, thoroughly disinfect the area to be treated.

• Remove tip cap by pulling it straight off the syringe as shown in fig. 1.

Hold the syringe body, firmly insert the needle provided in the package (fig. 2).

Firmly attach the needle turning it gently clockwise as shown fig.2 until you get it well engaged into the syringe Luer Lock system.

Check the needle visually according to figs. 3 and 4.

Holding the syringe body in one hand and needle cap in the other, pull the two hands in opposite direction to remove it, as shown in fig.5.

Inject slowly.

Failure to comply with these precautions could cause a disengagement of the needle and/or product leakage at luer-lock level.

• The amount injected will depend on the areas which are to be treated.

• After injection and where necessary the overall area treated may be massaged.

• It is recommended not to repeat treatments more frequently than every 15 days.

WARNINGS

• Check the expiry date on the product label.

• Do not re-use. Sterility of this device can not be guaranteed if the device is re-used.

• Do not re-sterilise.

• For the needles (CE 0476 GALLINI Italy):

- It's recommended to inject with needles provided, the use of other needles by the medical practitioner engages his own responsibility.

- Used needles must be thrown away in the appropriate containers. Do the same for the syringes. Please consult the current directives in force to ensure their correct elimination.

- Never try to straighten a bent needle, throw it away and replace it.

STORAGE CONDITIONS

• Store between 2°C and 25°C.

• Fragile.