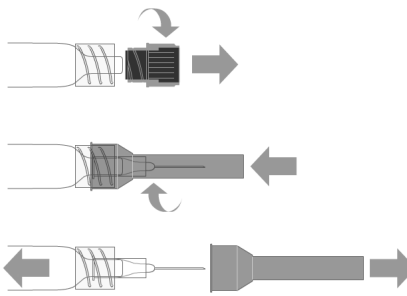
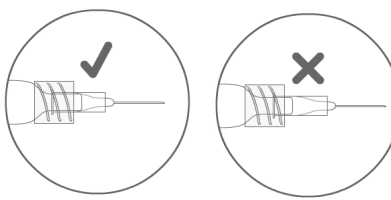
MOLDERM®
GLOW





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INSTRUCTIONS FOR USE

MOLDERM GLOW
Hyaluronic Bio-revitalizing gel

DESCRIPTION:
MOLDERM GLOW is a sterile, biodegradable, isotonic dermal filler.
MOLDERM GLOW consists of medium chain (1,0-1,5 x10^6 Dalton) hyaluronic acid, obtained from Streptococcus equi bacteria, formulated to a concentration of 20 mg/ml in a physiologic buffer. Each box contains one syringe of MOLDERM GLOW, two 30G ½" disposable sterile needles reserved for injection of MOLDERM GLOW and a product leaflet. A set of two labels showing the batch number is contained in the box. One of these labels should be attached to the patient's file and the other should be given to the patient to ensure traceability.

COMPOSITION:
Sodium hyaluronate 20 mg/ml, sodium chloride, sodium dihydrogen phosphate dihydrate, dibasic sodium phosphate dodecahydrate, WFI grade water.
One syringe contains 2.0 ml of non-pyrogenic gel, sterilized using moist heat.

INDICATIONS:
MOLDERM GLOW is indicated:
- in the physiological process of ageing of the skin, the effects of which include inspissation of the horny layer (roughness and reduced radiance of the skin) and changes in the elastic fibers of the dermis (wrinkles),
- in the dermal tissue repair process, in cases of scar results following superficial cutaneous trauma (e.g. acne and chickenpox scars).

EXCLUSION CRITERIA:
MOLDERM GLOW must not be used in:
- patients who tend to develop hypertrophic scarring,
- patients with a history of autoimmune disease or who are receiving immune therapy,
- patients who are known to be hypersensitive to hyaluronic acid,
- pregnant or breastfeeding women,
- patients under 18 years of age.

Anticoagulated patients or patients receiving platelet aggregation inhibitors should not be treated with MOLDERM GLOW without consulting their doctors.
MOLDERM GLOW must not be used in areas presenting cutaneous inflammatory and/or infectious processes (e.g. acne, herpes, ...). MOLDERM GLOW must not be used in association with laser therapy, chemical peeling or dermabrasion.

PRECAUTIONS FOR USE:
MOLDERM GLOW is only indicated for intradermal injections and must only be dispensed by a doctor who has received specific training on the intradermal injection technique. Sensitive skin may be pretreated using a local anesthetic patch or cream. Please note that any anesthesia may cause redness or local hypersensitivity. There are no available clinical data (efficiency, tolerance) about injecting MOLDERM GLOW into an area which has already been treated with another filling product. Patients should be advised not to apply any make-up for 12 hours after the injection and to avoid prolonged exposure to sun light and UV or using saunas or Turkish baths for one week after the injection. If the needle is blocked, do not increase the pressure on the plunger rod but stop the injection and replace the needle. Do not inject into blood vessels. Do not use MOLDERM GLOW in bones, tendons, ligaments or muscles. Do not inject MOLDERM GLOW into naevi.
Discard the syringe and remaining product after use.
Do not use if packaging has been damaged.

INTERACTIONS WITH OTHER AGENTS:
There are incompatibilities between sodium hyaluronate and quaternary ammonium compounds such as benzalkonium chloride solutions. Therefore MOLDERM GLOW should never be placed in contact with these substances or with medical-surgical instruments that have been in contact with these substances.

UNDESIRED SIDE EFFECTS:
Physicians must inform the patient that there are potential side effects and/or incompatibilities associated with the implantation of this device, which may occur immediately or may be delayed. These include (non-exhaustive list):
- Inflammatory reactions (e.g. redness, edema, erythema ...) which may be associated with itching and pain on pressure after the injection. These reactions may last for a week.
- Indurations or nodules at the injection site especially in cases of too superficial placement.
- Discoloration of the injection site.
- Poor effect if MOLDERM GLOW is injected incorrectly.
Patients must inform their physician as soon as possible about any inflammatory reactions which persist for more than one week or any other secondary effect which develops. The physician should treat these as appropriate. Any other undesirable side effects associated with the injection of MOLDERM GLOW must be reported to the distributor and/or to the manufacturer.

METHOD OF USE:
MOLDERM GLOW must be injected into non-inflamed, disinfected, healthy skin. The technique used is essential for the success of the treatment. Therefore this device must only be used by doctors who have received specific training on the injection technique. The area to be treated should be disinfected thoroughly prior to the injection. Use the 30G ½" needle which is provided with the syringe and inject slowly by applying the appropriate injection technique.
inject MOLDERM GLOW at room temperature and with strict asepsis conditions.
Inject MOLDERM GLOW intradermally with a linear technique or with picotage at a medium deep level.
The amount injected will depend on the wrinkle or depression which is to be corrected. After the injection, doctors may apply a light massage in order to distribute the product uniformly.
An initial course of three treatment sessions at one week intervals is recommended, followed, if necessary, by monthly maintenance sessions.

WARNINGS:
Verify the integrity of the syringe and the expiry date before use. Do not use any other needle or syringe than provided by the manufacturer. Do not re-use; quality and sterility can only be guaranteed for an originally closed syringe.
The re-use of the product creates a potential injection risk for patients or users. Do not re-sterilize. After use the needle must be disposed of in a suitable container.

STORAGE:
Store MOLDERM GLOW at 2-25°C (36-77°F) in a dry place in the original box
Protect from light, heat and frost and handle with care.

LAST REVISED:
February 2020

SYMBOLS

 Consult instructions for use

 Store between + 2 ° C and + 25 ° C

 Manufacturer

 Batch number

 Do not re-sterilize

 Sterile fluid path sterilized using steam

 Sterilized using ethylene oxide

 Do not use if package is damaged

 Do not reuse

 Store in a dry place

 Use by

 Keep away from sunlight

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Kiwa Belgelendirme Hizmetleri A.Ş.

Tepeören Mevkii Ankara Asfaltı Maret Arkası

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Distributed by

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