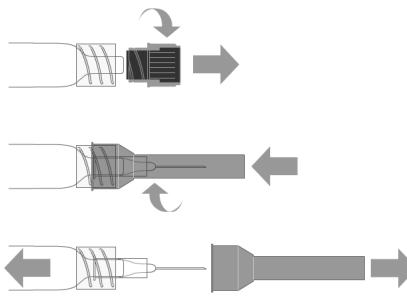
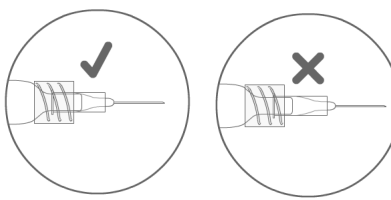
MOLDERM®
GLOW+





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INSTRUCTIONS FOR USE

MOLDERM GLOW+
Hyaluronic Bio-revitalizing gel

DESCRIPTION:
MOLDERM GLOW+ is a sterile, biodegradable, isotonic intradermal gel. MOLDERM GLOW+ consists of high molecular weight hyaluronic acid (1.8-2.6 x 10^6 Dalton), obtained from Streptococcus equi bacteria, formulated at a concentration of 20 mg / ml in physiological buffer. Each pack contains:
- 1 pre-filled syringe of 2 ml of MOLDERM GLOW+ gel
- 2 sterile 30G ½ "disposable needles reserved for the injection of MOLDERM GLOW+
- 1 product leaflet.
- 2 labels showing the lot number. once removed from the graduated label of the vial, one label must be applied to the patient's medical record, the other must be given to the patient to ensure the traceability of the product used.

COMPOSITION:
Sodium hyaluronate 20 mg / ml, sodium chloride, sodium dihydrogen phosphate dihydrate, disodium 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 aging process of the skin, the effects of which include the thickening of the stratum corneum (roughness and reduced brightness of the skin) and alterations of the elastic fibers of the dermis (wrinkles),
- in dermal tissue repair process, in cases of scar results following superficial cutaneous trauma (eg acne scars and chicken pox).

EXCLUSION CRITERIA:
Do not use MOLDERM GLOW+ in:
- patients who tend to develop hypertrophic scars,
- patients with a history of autoimmune disease or who are undergoing immune therapy,
- patients with known hypersensitivity to hyaluronic acid,
- pregnant or breastfeeding women,
- patients under the age of 18.
Anticoagulated patients or patients receiving platelet aggregation inhibitors should not be treated with MOLDERM GLOW+ without consulting their doctor. MOLDERM GLOW+ should not be used in areas with skin, inflammatory and / or infectious processes (e.g. acne, herpes ...). MOLDERM GLOW+ should not be used in conjunction with laser therapy, chemical peeling, ultrasound or dermabrasion.

PRECAUTIONS FOR USE:
MOLDERM GLOW+ is indicated for intradermal injections only and should only be dispensed by a physician who has received specific training in the intradermal injection technique. Sensitive skin can be pre-treated with local anesthetic creams or patches. Please note that any anesthesia can cause local redness or hypersensitivity. There are no clinical data (efficiency, tolerance) on the injection of MOLDERM GLOW+ in an area already treated with another filling product. Patients should be advised not to apply any makeup for 12 hours after the injection and to avoid prolonged exposure to sunlight and UV light or the use of saunas or steam rooms for one week after the injection. If the needle is blocked, do not increase the pressure on the plunger but stop the injection and replace the needle.
Do not inject into blood vessels. Do not use MOLDERM GLOW+ on bones, tendons, ligaments or muscles. Do not inject MOLDERM GLOW+ into nevi. After use, dispose of the syringe and remaining product.
Do not use if the packaging has been damaged. Patients who are aware of sensitizations
o allergies to hyaluronic acid or other components of the medical device should not undergo use. It is a clear, colorless and suspended particulate gel. Do not use the product if the contents of the syringe show signs of separation and / or appear opaque.

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

UNDESIRED SIDE EFFECTS:
Physicians should inform the patient that there are potential side effects and / or incompatibilities associated with the implantation of this device, which may occur immediately or be delayed. These include (non-exhaustive list):
- Inflammatory reactions (e.g. redness, edema, erythema ...) which may be associated with itching and pain after the injection. These reactions can last for a week.
- Indurations or nodules at the injection site especially in cases of too superficial placement.
- Discoloration of the injection site.
- Insufficient effect if MOLDERM GLOW+ is injected incorrectly.
Patients must promptly inform the doctor 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 unwanted side effects associated with the injection of MOLDERM GLOW+ should be reported to the distributor and / or manufacturer.

METHOD OF USE:
MOLDERM GLOW+ must be injected into healthy, non-inflamed and disinfected skin. The technique used is essential for the success of the treatment. Therefore this device should only be used by physicians who have received specific training in the injection technique. The area to be treated must be thoroughly disinfected before injection. Use the 30G ½ "needle provided with the syringe and inject slowly using the appropriate injection technique.
Inject MOLDERM GLOW+ at room temperature and under strict aseptic 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 to be corrected. After the injection, the doctor can apply a light massage to distribute the product uniformly.
An initial course of three treatment sessions at weekly intervals is recommended, followed by monthly maintenance sessions if necessary.

WARNINGS:
Before use, check the integrity of the syringe and the expiration date. Do not use needles or syringes other than those provided by the manufacturer. Do not re-use; quality and sterility can only be guaranteed if the syringe was originally sealed. Reuse of the product creates a potential risk of infection for patients or operators. 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 packaging. Protect from light, heat and frost and handle with care.

LAST REVISED:
06/2021

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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