

# MACDERMOL<sup>®</sup> VOLUME

1ml

## DESCRIPTION

MACDERMOL VOLUME is a sterile, non-pyrogenic, viscoelastic gel containing a highly purified specific fraction of sodium hyaluronate.

## COMPOSITION

Hyaluronic acid (30 mg/ml), sodium chloride, water for injection.

## INDICATION

MACDERMOL VOLUME is indicated for facial volume restoration.

## MODE OF ACTION

MACDERMOL VOLUME is injected into the deep dermis or subcutaneous layer in the areas to be augmented. MACDERMOL VOLUME creates a volume that restores facial volume. MACDERMOL VOLUME is biodegradable and is slowly reabsorbed over time.

## CONTRAINDICATIONS

MACDERMOL VOLUME must not be used:

- for injections other than the intradermal and subcutaneous
- in combination with peeling, laser treatment or ultrasound-based treatment
- if the patient has cutaneous disorders, inflammation or infection at the treatment site or near to this site
- in the case of patients having a known hypersensitivity to hyaluronic acid, with a history of severe allergy or anaphylactic shock
- in case of patients with autoimmune diseases
- in patients with bleeding disorders or patients who have undergone therapy with thrombolytics, anticoagulants or inhibitors of platelet aggregation in the preceding 2 weeks
- due to possible interaction with other filling implants, which have not been researched, it is not advisable to inject MACDERMOL VOLUME into sites in the presence of other filling implants
- in pregnancy, breastfeeding mothers or in children.

Do not inject into blood vessels.

## ADMINISTRATION

- The product does not require a skin test prior to treatment.
- Administration only into intradermal with care and slowly.
- A 26 gauge needle is recommended.
- The topical application of an anesthetic agent is possible.
- Best results are obtained in the zones where these imperfections are easily highlighted by stretching of the skin.
- Contours of the depressions to be filled are drawn on the patient in an upright or sitting position.
- The injection of MACDERMOL VOLUME is reserved for medical practitioners trained in the injection techniques of products intended for the filling of wrinkles.
- Before beginning treatment, patients must be questioned regarding their past medical history and informed regarding the foreseeable outcome of treatment and of potential undesirable effects.
- Correction sites must be properly disinfected (70% alcohol or with another disinfectant). Disinfectants containing quaternary ammonium salts should not be used for skin preparation as hyaluronic acid can precipitate under such conditions.
- MACDERMOL VOLUME is injected by linear threading technique into the deep dermis or subcutaneous layer in the areas to be augmented (cheeks, cheekbones, chin, temples).
- The injection volume is dependent upon the correction required. It is important not to over-correct.
- Massage the treated sites extremely lightly if at all in order to ensure a uniform distribution of the product at the corrected sites.

## SECONDARY EFFECTS

- Redness, swelling, oedema, hematomas, itching and slight pain at the injection site can occur following the treatment and generally subsides over 72 hours.
- Induration, staining, loss of sensitivity at the injection site.
- Rare cases of necrosis in the glabellar region, nodules, granulomas, hypersensitivity and abscess formation have been described in the literature after the injection of hyaluronic acid. The medical practitioner must therefore tell the patient of these potential risks.
- All secondary effects other than those described above or persisting for more than one week must be reported to the practitioner by the patient. In turn, the practitioner will inform the product's supplier of this as soon as possible.

#### PRECAUTIONS FOR USE

- Stop the injection and change the needle if you feel an obstruction or pressure during the injection.
- You should warn the patient against taking high dose of Vitamin E, aspirin, anti-inflammatories or anti-coagulants during the week before the injection session. Advise the patient not to use make-up during the 12 hours following injection and to avoid extreme temperatures (intense cold, sauna, steam room...) during the week following treatment.
- Verify the expire date and the integrity of the packaging before use. Do not use if the expiry date is exceeded or if the packaging is damaged.
- At the end of the treatment, it is essential to discard all used needles and syringes. Each prefilled syringe is for single use only.
- Follow guidelines for use and disposal of medical sharp devices. Discard unshielded needles in approved sharps collectors. Obtain prompt medical attention if injury occurs.
- To avoid needle breakage, do not attempt to straighten a bent needle. Discard it and complete the procedure with a replacement needle.
- Do not resheild used needles. Recapping by hand is a hazardous practice and should be avoided.

#### SHELF LIFE AND STORAGE

As indicated on package. Store between +2°C and +25°C and away from sun light. Do not freeze.

#### HOW SUPPLIED

MACDERMOL VOLUME is supplied in a prefilled syringe containing 1 ml of gel. Each box also contains an injection needle and traceability labels.

#### MANUFACTURER

NOVATEX BIOENGINEERING SAS

4 rue de l'Amiral Courbet

75116 Paris

France

[www.novatex-bioeng.com](http://www.novatex-bioeng.com)

#### SYMBOLS



Do not re-sterilize



Consult instructions for use



Sterilized using steam



Keep away from sunlight



Store between +2°C and +25°C



Do not use if package is damaged



Do not re-use



Manufacturer



Lot number



Date of manufacture



Use by

MACDERMOL is a medical device. To be used under the direction of a physician.

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