AQUAMID®

AQUAMID®

Reconstruction

INSTRUCTIONS FOR USE

Aquamid®/Aquamid® Reconstruction

PRODUCT DESCRIPTION

Aquamid®/Aquamid® Reconstruction is a non-absorbable, injectable transparent, hydrophilic gel for soft tissue augmentation. Aquamid®/ Aquamid® Reconstruction consists of approximately 2.5% cross-linked polyacrylamide and 97.5% non pyrogenic water. Aquamid® Reconstruction is slightly more viscous compared to Aquamid®. Aquamid®/Aquamid® Reconstruction is a biocompatible, non-biodegradable polyacrylamide hydrogel. The hydrogel is supplied in a sterile, pre-filled 1 ml syringe sealed with a Tip Cap. Aquamid®/Aquamid® Reconstruction is intended to be injected subcutaneously with a sterile 25/27G needle. A 3-part label with the LOT number is available on the blister pack. Attach one label to the patient record to ensure product traceability and one to the patient consent form.

MODE OF ACTION

Aquamid®/Aquamid® Reconstruction acts by adding volume to the soft tissue. The injected hydrogel becomes a stable and integrated part of the soft tissue.

INDICATIONS AND USAGE

Aquamid®/Aquamid® Reconstruction is designed for soft tissue augmentation for aesthetic and reconstructive purposes, including corrections of facial lipoatrophy.

CONTRAINDICATIONS

Aquamid®/Aquamid® Reconstruction must not be injected in actively infected areas or areas with an active skin disease. Aquamid®/ Aquamid® Reconstruction should not be used in patients with autoimmune diseases. Outbreaks of herpes labialis or active acne are contraindications for Aquamid®/Aquamid® Reconstruction injections. Aquamid®/Aquamid® Reconstruction is not recommended for use in patients with chronic diseases receiving treatment with systemic corticosteroids Do not inject Aquamid®/Aquamid® Reconstruction above the infraorbital ridge, in the crow's feet, eye circle, eyelid, breasts or in the genital areas.

WARNINGS

Avoid the use of corticosteroids, for details refer to Adverse events. **The use of steroids will prolong and worsen the duration and treatment of the potential bacterial infection.** Anamnesis data of ongoing infections, concomitant medication, surgery, dental work etc. must be reviewed prior to injection in order to prevent possible infections. When injecting fillers including Aquamid®/ Aquamid® Reconstruction there is an increased risk of local infection due to the limited immune system access. Avoid the use of non-steroid anti-inflammatory Drugs (NSAIDS). Aquamid®/ Aquamid® Reconstruction should not be used in patients with unrealistic expectations. Injection of Aquamid®/ Aquamid® Reconstruction is not recommended for patients with recurring herpes labialis or acne. Aquamid®/ Aquamid® Reconstruction should not be injected in patients receiving anticoagulant treatment. Aquamid®/ Aquamid® Reconstruction should not be injected during pregnancy or lactation. Aquamid®/Aquamid® Reconstruction must not be injected in a site where other non-absorbable and/ or long-lasting soft tissue fillers are present. Other non-absorbable and/or long-lasting soft tissue fillers must not be injected in a site where Aquamid®/Aquamid® Reconstruction is present. If the injection site has previously been treated with absorbable soft tissue filler, absorption of this filler must be complete prior to injection with Aquamid®/Aquamid® Reconstruction (minimum 6 months). Cosmetic treatments including injection of fillers in a site previously treated with Aquamid®/Aquamid® Reconstruction may increase the risk of iatrogenic infection, so caution should be taken. Do not inject Aquamid®/Aquamid® Reconstruction intradermally, intramuscularly or intravascularly. Do not mix Aquamid®/Aquamid® Reconstruction with any other substances. Do not inject any pharmaceuticals into the hydrogels. Do not use Aquamid®/Aquamid® Reconstruction if the package is opened or damaged. Do not re-sterilize Aquamid®/Aquamid®Reconstruction. The Aquamid®/Aquamid® Reconstruction syringe is intended for single use and single patient only – **do not store un-sealed syringes and reuse. Reuse increases the risk of contamination and hereby increases the risk of infection.** Do not use Aquamid®/Aquamid® Reconstruction once expired.

PRECAUTIONS

In patients, who have undergone laser, waxing, peeling, skin resurfacing, lip tattoos, pigmentation, teeth bleaching using UV light or other aesthetic treatments, Aquamid®/Aquamid® Reconstruction should not be injected until the skin surface has healed and become fully revitalised. These treatments must not be performed in the injected area for 6 months pre and post Aquamid®/Aquamid® Reconstruction injection. Do not pierce the injected area. Avoid surgery and major dental work 6 months pre and post Aquamid®/Aquamid® Reconstruction injection. Should the patient need surgery or major dental work post injection, antibiotic treatment is recommended. Patients receiving treatment for HIV infection should only be injected with Aquamid®/Aquamid® Reconstruction providing effective treatment is given and the HIV infection has been sufficiently suppressed. Special attention must be paid to patients suffering from diabetes. Only well regulated diabetics should be considered for Aquamid®/Aquamid® Reconstruction injections. Safety and effectiveness of treatment in the periorbital area have not been established. Caution should be taken when injection patients pre-disposed to kelloid formation and/ or patients in the high end of the Fitzpatrick scale, since the aesthetic result may be unsatisfactory. Safety and effectiveness have not been established in patients under the age of 18 years.

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METHOD OF ADMINISTRATION

Aquamid®/ Aquamid® Reconstruction must be administered by a qualified physician familiar with the procedure. If prophylactic antibiotic treatment is prescribed, the following combination is recommended: macrolides and quinolones administered as a single dose 2 - 6 hours prior to injection. The above combination of antibiotics will reach a high concentration in the tissue and should be given only once. This combination of antibiotics will cover most bacterial strains. However, some strains e.g. MRSA may not be sensitive to above mentioned treatment. The procedure must be conducted under aseptic conditions. It is essential that at least 5 cm around the injection site is swabbed prior to injection using, e.g. chlorhexidine with alcohol twice with a five minute interval. The injection of the hydrogel may be performed under local anaesthesia. Remove the protective Tip Cap by turning it in the same direction as is used to tighten the needle. Secure the needle firmly into the Luer Lock socket and make sure the needle is mounted correctly. Do not increase the pressure on the plunger should the needle be clogged. Stop the injection and replace the needle. Inject the desired amount of Aquamid®/ Aquamid® Reconstruction subcutaneously in a retrograde, fan-shaped manner. Inject the hydrogel while withdrawing the needle. Avoid overcorrection. The injected hydrogel must not cause excessive pressure on the tissue. Carefully consider the volume of Aquamid®/Aquamid® Reconstruction to be injected depending on the site of injection. When the desired volume of hydrogel has been administered, release the pressure on the plunger before removing the needle. Post injection; perform a light manipulation to obtain an even distribution of the hydrogel. Additional injections can be performed when swelling has disappeared, with a minimum interval of 14 days. Aquamid®/Aquamid® Reconstruction should be injected with consideration to tissue elasticity and the blood supply.

POST-OPERATIVE PROCEDURES

If oedema occurs, a cold pack can be applied locally. Do not treat oedema with NSAIDs or corticosteroids. The patient should be advised

- not to touch the injected area for at least 6 hours.
- not to kiss or perform oral sex on the day of injection
- not to use make-up and skin care products on the treated area on the day of injection
- not to shave on day of injection
- not to pierce or wax the injected area.
- to avoid exposure to direct sunlight (including solarium and other sun tanning devices) or extreme cold conditions the first 4 weeks post injection.
- to avoid sunburn or frostbite in the area where Aquamid®/Aquamid® Reconstruction is injected.

ADVERSE EVENTS

Adverse events are limited to local reactions at injection site.

Common adverse events:

Injection related, transient, local reactions that resolve spontaneously including slight redness, bruising, swelling, hematoma formation, itching, mild oedema, discoloration, change in pigmentation and moderate pain.

Rare adverse events (less than 0.1% of treatments):

Infections can occur at the injection site and must be treated immediately with antibiotics. Symptoms include tingling sensation, swelling or redness. Superficial injection or overcorrecting may lead to hydrogel accumulation (lumps) or displacement.

Very rare adverse events (less than 0.01% of treatments):

Poorly treated or unrecognised, "low grade" infections may result in tissue hardening, lumps and nodules that emerge years post injection. This may lead to increased dermal sensitivity and pain in the injected area. Tissue necrosis may occur if Aquamid®/ Aquamid® Reconstruction is injected too superficially or if overcorrection has been done.

As with any transcutaneous procedures, when injecting Aquamid®/ Aquamid® Reconstruction, there is a risk of infection. Standard precautions associated with any injectable product should be adhered to. Adverse events are related to infections or effects following infections. Should an infection be suspected, antibiotic treatment must be initiated immediately. Combinations or monotherapy with macrolides, quinolones and tetracycline will in most cases cover the bacteriae that may cause infection after use of fillers. However some bacteria strains, e.g. MRSA may not be sensitive to above mentioned treatment. To determine an effective treatment a fine needle biopsy should be taken, under aseptic conditions, and a microbiologist should be consulted. The treatment should not be delayed. A negative culture does not exclude the presence of bacteria. If necessary, detection of most bacteria can be performed by PCR analysis. Normally the foreign body reaction after injection with Aquamid®/Aquamid® Reconstruction is minor and not clinically detectable. This reaction will markedly increase in the presence of a bacterial infection. In case of persistent infection it may be necessary to surgically remove the implant. This may cause scarring. Do not administer steroids or NSAID's as this will prolong and worsen the duration and treatment of the bacterial infection.

REPORTING OF ADVERSE EVENTS

All Adverse events/complications must be reported to the local distributor or directly to Contura International A/S via Email to: info@contura.com. Download Incident Report Form at www.aquamid.com/physician/documents or report the incident via the online Incident Report Form.

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PATIENT INFORMATION

The patient should be informed about indications, expected results, contraindications, warnings, precautions and potential complications. The patient must sign an informed consent form provided by the distributor or download the form from www.aquamid.com/physician/documents. In case of complications the patient should contact the injecting physician immediately for treatment.

SUPPLY AND STORAGE

Sterile: Aquamid®/Aquamid® Reconstruction is sterilized by moist heat. The hydrogel must be stored protected from direct sunlight. Do not freeze. Keep out of reach of children.

Symbols used in packaging


Refers to instruction for use


For single use only. Do not re-use

Sterile. Sterilised by moist heat


Use before the date printed on the label

Product batch number


Manufacturer


Keep away from sunlight

Do not freeze


Do not use if package is damaged


Do not resterilize

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