10111-001 November 2021

AQUAMID®

A minimally invasive treatment for adding volume to the tissue

Patient Information leaflet

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contura

Please read the entire brochure and discuss it with your physician

Contents

Glossary

Adverse event
Complication or side effect due to the treatment with Aquamid®.

Aquamid® is an injectable, non-absorbable soft-tissue filler.

Contraindication
A medical condition that indicates that Aquamid® should not be used as it may cause harm.

Precaution
A statement in the product information that alerts the physician to take measures to avoid a problem.

What is Aquamid®?

Aquamid® is a gel consisting of 97.5% water and 2.5% polyacrylamide. The gel is supplied in a sterile pre-filled 1 ml syringe.
Aquamid® is an injectable, non-absorbable and non-degradable gel designed for giving volume to the soft tissue for reconstructive purposes. Aquamid® is injected in fine lines under the skin and becomes a stable and integrated part of the soft tissue.
The gel will remain in the body for lifetime as a natural part of the skin. During the aging process the visible results of the Aquamid® presence may diminish as a result of sagging skin.

Indications

Aquamid® is used for the reconstructive treatment of volume loss in the face and soft tissue defects including corrections of diffuse loss of adipose tissue under the skin.

Is Aquamid® a treatment for me?

Aquamid® can be used in adults over 18 years of age in need of a reconstructive treatment of volume loss in the face or soft tissue defects. The physician will perform the treatment, injection of the gel will be done under sterile conditions.

You should not be treated with Aquamid® if you:
- have an autoimmune disease
- have a chronic disease receiving treatments with systemic corticosteroids (“steroids”)
- receive anticoagulant treatment
- have diabetes that is not well regulated
- are pregnant or breastfeeding

The treatment must not be performed in an area previously treated with another permanent filler than Aquamid® or in a pierced area.

If you have had any of the treatments listed below, at least 6 months should pass before the Aquamid® treatment is performed:
- Laser
- Waxing
- Peeling
- Skin resurfacing
- Lip tattoos
- Pigmentation
- Teeth bleaching using UV light
- Injection of absorbable fillers
- Other aesthetic treatments
- Piercing of the injected area
- Surgery and major dental work

You should also wait to have Aquamid® treatment if you have outbreaks of herpes labialis or active acne.

Possible adverse events of Aquamid® treatment

The treatment has been used for 20 years and it is estimated that more than ½ million treatments have been provided worldwide. A low number of complications and adverse events have been reported.

The known possible adverse events for Aquamid® treatment are:

Local adverse events following immediately after the treatment
The following reactions may occur at the injection site:
- Slight redness
- Bruising
- Swelling
- Hematoma formation (pain, swelling, redness and disfiguring bruises)
- Itching
- Mild oedema
- Discoloration
- Change in pigmentation
- Moderate pain

The above symptoms should resolve spontaneously. Contact the injecting physician if the symptoms do not diminish and disappear within 3-4 days after the injection.

Rare adverse events (less than 0.1% of treatments)
Aquamid® is injected through the skin, and as for any injections through the skin there is always a risk of infection.

The following rare adverse events may occur after treatment with Aquamid®:
- Infection at the injection site. The symptoms on infection are:
  - Tingling sensation
  - Swelling
  - Redness

Contact the injecting physician if you experience these symptoms. Infections must be treated immediately with antibiotics. When in doubt contact the injection physician.

- Hydrogel accumulation or displacement caused by superficial injection or overcorrecting of the gel. The symptoms are lumps in the skin.

Very rare events (less than 0.01% of treatments)
Adverse events caused by poorly treated or unrecognized infections are very rare and may result in tissue hardening, lumps and nodules that emerge years post injection. This may lead to increased sensitivity of the skin and pain in the injected area.

Tissue injury may occur if Aquamid® is injected too superficially or if overcorrection has been done.

Before Aquamid® treatment

As with any injections there is a small risk of infection when injecting Aquamid®. The physician will give you antibiotics 1-6 hours before the treatment to reduce the risk of infection. Consult your injecting physician about the antibiotic treatment.

After Aquamid® treatment

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

If you experience symptoms like tingling sensation, swelling or redness, it may be a sign of infection – contact the injecting physician immediately. If it is an infection, it must be treated with antibiotics as fast as possible. Infections must not be treated with corticosteroids or Non-Steroid Anti-Inflammatory Drugs (NSAIDs), as this will prolong and worsen the duration and treatment of the infection.

Avoid the treatments listed below for 6 months after the Aquamid® treatment:
- Laser
- Waxing
- Peeling
- Skin resurfacing
- Lip tattoos
- Pigmentation
- Teeth bleaching using UV light
- Injection of absorbable fillers
- Other aesthetic treatments
- Piercing of the injected area
- Surgery and major dental work

If you need surgery or dental work after the Aquamid® treatment, prophylactic antibiotic treatment is recommended.

Important Safety Information

Intended use: Aquamid® is intended for patients over 18 years of age in need of a reconstructive treatment of volume loss in the face or soft tissue defects including corrections of diffuse loss of adipose tissue under the skin.
Contraindications: Aquamid® must not be injected in actively infected areas or areas with an active skin disease. Aquamid® should not be used in patients with autoimmune diseases. Outbreak of herpes labialis or active acne are contraindications for Aquamid® injections. Aquamid® is not recommended for use in patients with chronic diseases receiving treatment with systemic corticosteroids. Do not inject in breasts. Do not use in patient under the age of 18 years.
Warnings: As with any invasive procedure there is a small risk of infection when injecting Aquamid®, therefore a single dose of antibiotics before the treatment is recommended to be administered.
Infections must not be treated with corticosteroids or non-steroid anti-inflammatory Drugs (NSAIDs), as this will prolong and worsen the duration and treatment of the infection. Injection of Aquamid® is not recommended for patients with recurring herpes labialis or acne. Aquamid® should not be injected during pregnancy or lactation.
Precautions: In patients who have undergone laser, waxing, peeling, skin resurfacing, lip tattoos, pigmentation, teeth bleaching using UV light or other aesthetic treatments Aquamid® should not be injected until the skin surface has healed and become fully revitalized. These treatments must not be performed in the injected area for 6 months pre and post Aquamid® injection.

Do not pierce the injected area. Avoid surgery and major dental work 6 months pre and post Aquamid® injection. Should the patient need surgery or major dental work post injection, antibiotic treatment is recommended.

Special attention must be paid to patients suffering from diabetes. Only well-regulated diabetics should be considered for Aquamid® injections.

Patients receiving treatment for HIV infection should only be injected with Aquamid® providing effective treatment is given and the HIV infection has been sufficiently suppressed.

Safety and effectiveness of treatment in the genital area and gingiva area have not been established.

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 pigmentations 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 unrecognized “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 injury (necrosis) may occur, if Aquamid® is injected too superficially or if overcorrection has been done.

Any serious incident that occurs in relation to the device should be reported to both Contura International at complaints@contura.com and to the Therapeutic Goods Administration at the TGA website https://www.tga.gov.au