

New Zealand Datasheet

Name of Medicine

AQUAMID

Polyacrylamide gel injection

Presentation

AQUAMID is soft tissue filler, a transparent polyacrylamide gel consisting of approximately 2.5% cross-linked polyacrylamide and approximately 97.5% sterilised water.

Uses

Actions

AQUAMID acts by adding volume to the subcutaneous tissue or the lips, thereby restoring skin contours or enhancing the lips to the desired level. AQUAMID becomes a soft and stable part in the connective tissue.

Indications

AQUAMID can be used for aesthetic corrections of soft tissue contour deformities of the face such as wrinkles and folds and for lip enhancement. AQUAMID can be used to correct aesthetic defects caused by congenital, traumatic or ageing alterations.

Dosage and Administration

The injection of the gel may be performed under local anaesthesia, depending upon the specific application. The procedure must be performed under sterile conditions.

Inject only the necessary amount of AQUAMID subcutaneously in a retrograde manner by injecting the gel while withdrawing the needle. Once the desired volume of gel has been administered, stop the pressure on the plunger before extracting the needle. After the injection perform a light manipulation in order to obtain an even distribution of the gel. The injected gel will form a stable, soft part in the connective tissue. Avoid overcorrection, do not inject more than up to a few ml per injection site at a time. If necessary, additional injections can be performed following cessation of post-operative swelling. AQUAMID must always be injected with due consideration to the elasticity of the tissue and to the blood supply to adjacent structures. The injected gel must not cause excessive pressure to the tissue.

Do not inject the gel intradermally and do not inject any pharmaceuticals into the gel. The gel must not be injected in a site where another permanent filler is present. If the area has previously been treated with temporary filler, absorption must be complete prior to injection of AQUAMID.

POST-OPERATIVE PROCEDURES: If oedema occurs a pack of ice can be applied locally. The patient should be advised to avoid exposure to direct sunlight or extreme cold/heat until the initial swelling and redness have resolved.

A patient record label is part of the label. Remove it and attach it to the patient record to ensure that the product is traceable.

Contraindications

Outbreak of herpes labialis is a contraindication for AQUAMID injections. Application of AQUAMID is not recommended in persons with recurring herpes labialis.

Warnings and Precautions

AQUAMID must only be administered by qualified physician. AQUAMID must not be injected in actively infected areas or areas with an active skin disease or inflammation. Before any injection the patients all-round health condition with respect to infections shall be evaluated to prevent possible cross-infections.

AQUAMID should not be used in patients with autoimmune diseases affecting the skin area. Special attention should be paid to patients with autoimmune disorders receiving intermediate or lasting medical treatment with, e.g. corticosteroids, to evaluate if they are suitable for injection with AQUAMID.

AQUAMID must not be injected in a site where another permanent filler is present. If the area has previously been treated with temporary filler, absorption must be complete prior to injection of AQUAMID (minimum six months). AQUAMID is intended only to be used in the subcutaneous part of the skin. Never inject AQUAMID intravascularly, intradermally or intramuscularly. Correct injection technique is crucial for the final result of the treatment.

AQUAMID is provided sterile. If the package is damaged or opened, do not use. Do not re-sterilise AQUAMID. Do not mix AQUAMID with any other substance. The expiry date is printed on the packaging. Do not use the product after this date.

AQUAMID is not intended for use in the breasts or in the genital areas.

In the event of infection, the use of fluoroquinolones, eg Ciproxin 750 mg x 2 is recommended. If oedema occurs and the infection has been excluded, the patient could be treated with nonsteroid anti-inflammatory drugs. Avoid the use of corticosteroids.

Surgical intervention should be avoided as it may cause iatrogenic infection.

Safety and effectiveness has not been established in children.

Use in Pregnancy and Lactation

AQUAMID should not be used during pregnancy or lactation

Adverse Effects

SHORT TERM: Some patients will develop pain within the first postoperative hours. In addition, there is also a slight risk of haematoma, mild oedema, discoloration or infection.

MEDIUM TERM: Within 1-2 weeks after treatment there is a slight risk that the patient may develop transient oedema and tenderness near the treatment sites. If not caused by infection, these reactions are self-limiting and will resolve within a couple of weeks. Single cases of iatrogenic infections have been reported. Allergic reactions to AQUAMID have not been reported, however the potential for allergic reactions cannot be excluded. Dislocation of gel has occurred in rare instances due to overfilling. Tissue necrosis following proper injection of AQUAMID, have not been reported.

LONG-TERM: Long term effects are not known. During a 3 year follow-up period, no cases of fibrosis or granulomas were reported following injection of AQUAMID. However, until further data is available these sequelae cannot be excluded as potential long term effects. Any adverse events must be reported.

Pharmaceutical Precautions

The gel must be stored protected from direct sunlight. Do not freeze. Keep out of reach from children.

Medicine Classification

Prescription Medicine.

Package Quantities

Aquamid gel is prefilled in sterile syringes of 1 ml and sealed with a luer fitting and is intended to be injected subcutaneously with a sterile 27G needle.

Further Information

Patient Information

The patient should be informed about the indications, expected results, contraindications, precautions, warnings and potential adverse events. The patient must sign an informed consent form.

Name and Address

Clinical and Regulatory Services Limited
PO Box 480
Pukekohe
Ph (09) 238 3447
Fax (09) 238 9239

for Mondeal Contura Pty Ltd

Date of Preparation

18 March 2004