croma revitalis

EN PATIENT INFORMATION

What is this product? This product is a type of facial filler called a viscoelastic implant. A viscoelastic implant is a gel-like substance. The filler contains an ingredient called hyaluronic acid (HA, 1.80 %). The hyaluronic acid is made from bacteria called *Streptococcus equi*. The product also contains an ingredient called glycerol (2.12 %), which is a syrupy liquid. A substance (phosphate buffer: 0.13 % disodium phosphate dodecahydrate and 0.01 % citric acid) is added to the product to match the natural pH of your skin. The ingredients are dissolved in water for injection.

Who is this product for? This product is used to treat adults aged 18 or older with fine lines or wrinkles at the outer corners of the eyes and/or around the mouth. The device helps the skin to stay moist and improves its tone and elasticity. It is not to be used in people under the age of 18.

How is this product used? A healthcare professional injects the product just below the surface of your skin. The hyaluronic acid in the implant helps your skin to stay moist, which makes it look and feel more toned and plump.

Who can use this product? The product can only be used by healthcare professionals who have been trained and who are qualified under national laws. It must not be used by lay persons. The users received appropriate training on the conditions to safely use the device.

Is this product safe for everyone?

Your healthcare professional will not treat you with this product if you: tend to develop unusual scarring | have skin colouration (pigment) disorders | tend to form keloids (a type of raised, lumpy scar) | are highly sensitive to any ingredients of the product | are highly sensitive to proteins from bacteria used to make hyaluronic acid | are pregnant or breastfeeding | are younger than 18 years of age. This is because the treatment may trigger these complications or allergies.

You may not be suitable for treatment with this product if you: are taking blood thinners (anticoagulants) | are taking medicines that stop cells in the blood from sticking together (such as acetylsalicylic acid) | have a history of disease where the body's immune system attacks its own body (autoimmune disease) | have an underlying connective tissue disease | have severe allergies | have had a serious allergic reaction (anaphylactic shock) in the past.
Your healthcare professional will help you decide if treatment with this product is right for you. There are no study data on the use of this product in male consumers as well as people under the age of 28 and above 77 years of age.

Which warnings should I know about? You should seek urgent medical help if you develop any of the following symptoms: severe headaches | dizziness or confusion | white or pale skin | unusual pain during treatment or shortly afterwards.

Other safety information: No information is available about whether this product is safe and effective if you have previously been treated with facial fillers or with botulinum toxin. It is safe to have an MRI (magnetic resonance imaging) scan after treatment with this product.

What should I do after treatment? Do not apply any make-up for 12 hours after the injection. Do not exercise hard in the first 48 hours after the procedure. Avoid strong sunlight or heat in the first 48 hours after the procedure. If you are told to massage the treated area, ensure your hands are clean to prevent infection. There is no need for a mandatory follow-up.

Which unwanted side effects should I know about? You may experience side effects after treatment with this product. These may occur right away or over time. Side effects are usually mild and do not usually last for longer than a few days. Some side effects were seen during the clinical study of the product.
These include: 1 in 10 people or more: a pooling of blood under the skin | swelling.
Up to 1 in 10 000 people: triggering of a cold sore.
Other side effects were seen after the product was placed on the market.
These include:
1 in 10 people or more: bleeding | pain | unusual colouring of the skin, including redness of the skin | inflamed or irritated skin | lumps under the skin.
Up to 2 in 1 000 people: itching.
Up to 1 in 10 000 people: bacterial infection | small areas of inflammation | allergic reaction (hypersensitivity).
The following side effects have been seen with similar gel-like implants: 1 in 10 people or more: bruise | hardening of the skin around the implant. Up to 1 in 10 000 people: bluish hue that is visible within the skin.
You should seek medical help straight away if you experience any side effects.
After consultation with a healthcare professional swelling, oedema, bleeding, hematoma may be prevented or decreased by applying cold compress, arnica cream, topical Vitamin K, antihistamines, or corticosteroids.
Please report unwanted side effects and serious incidents to the manufacturer. You can do this by using this email address: complaint@croma.at or you can use the contact information on your implant card. Please report any serious incident from the use of this product to the competent authority in your country of residence.

Which effect does the product have and expected device lifetime? The manufacturer carried out a clinical study for this product for its indication to correct fine lines on the face such as at the outer corners of the eyes and/or around the mouth. The purpose of the clinical study was to ensure that the product is safe and effective. Study participants were treated 3 times over the course of 6 weeks (i.e. the first injection was at Week 0, the second at Week 3 and the last at Week 6). Healthcare professionals noted an improvement in appearance up to 4 months at the corner of the eyes and up to 6 months around the mouth after the first injection of the device. The treatment helped the skin to stay moist and improved its tone and elasticity. Most study participants continued to be satisfied up to 9 months after the first injection of the device. The time it takes for the product to be broken down and absorbed by the body may vary but is estimated to take 2 weeks after injection.
This depends on: which type of treatment you get | how severe your defect is before the treatment starts | how much of the product you receive | the skin layer which the implant was injected into | and how your body responds to the implant. Different people may have different results. Your treatment might not fully live up to the expectations you had before you got the implant.

Residual Material: This product does not contain any manufacturing residuals that can pose a risk to patients.

Serious Incidents/Contact: Related to the use of this product, contact the Manufacturer, Australian Sponsor and the Therapeutic Goods Administration at the below details:

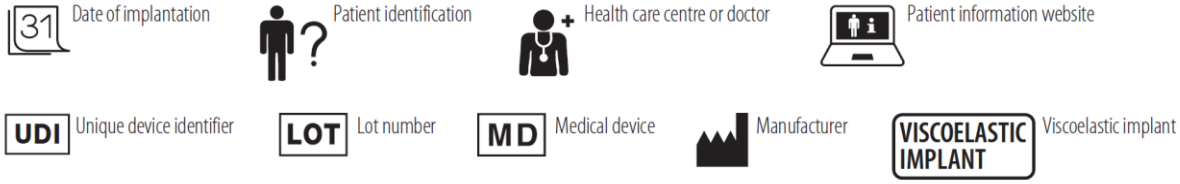
AUSTRALIAN SPONSOR
MDSS AU Pty Ltd
Ground Floor, Suite 55
97-99 Bathurst Street
Sydney NSW 2000
Australia

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION
www.tga.gov.au

MANUFACTURER
CROMA-PHARMA GmbH
Industriezeile 6
2100 Leobendorf
Austria,
www.cromapharma.com

Which harmonized standards and regulations were followed for this product?
Commission Implementing Regulation (EU) 2022/2346 Annex I and Annex IV,
Fully applied standards: EN ISO 13485:2016+A11:2021, EN ISO 14971:2019+A11:2021
Applicable parts applied: EN ISO 10993-9:2021, EN ISO 10993-10:2023, EN ISO 10993-12:2021, EN ISO 10993-17:2009, EN ISO 10993-18:2020, EN ISO 10993-23:2021, EN ISO 11607-1:2020, EN ISO 11737-1:2018, EN ISO 15223-1:2021

What do the symbols mean?



Last revised: 2024-04

This leaflet relates to the instructions for use for healthcare professionals dated 2024-04.