saypha filler Lidocaine

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 cross-linked hyaluronic acid (2.3 %) and a numbing agent (local anaesthetic) called lidocaine hydro chloride (0.3 %). The hyaluronic acid is made from bacteria called *Streptococcus equi*. A substance (phosphate buffer: 0.24 % di sodium phosphate dodecahydrate and 0.05 % sodium dihydrogen phosphate dihydrate) is added to the product to match the natural pH of your skin. The product also contains 0.75 % sodium chloride and ≤ 2 ppm 1,4-butanediol diglycidyl ether as crosslinking agent. The ingredients are dissolved in water for injection.

Who is this product for? The product is used to treat adults aged 18 or older with moderate to severe nasolabial folds. Nasolabial folds are deep lines which run from the edge of your nose to the outer corners of your mouth. The product is also used to make lips fuller. It is not to be used in people under the age of 18.

How is this product used? A healthcare professional injects it into the layers of skin beneath folds or wrinkles, or into the lips. The tissues around the implant expand, reducing folds or making the lips fuller.

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 hyaluronic acid | are highly sensitive to proteins from bacteria used to make hyaluronic acid | are highly sensitive to numbing agents, particularly lidocaine | are highly sensitive to a type of numbing agent called amide-type anaesthetics | 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 people with very light or extreme nasolabial folds.

Which warnings should I know about? If the product is injected into a blood vessel by accident or compresses a blood vessel, it can block the flow of blood. This can reduce the supply of oxygen in the area and lead to tissue damage which may not be reversible. If the oxygen supply is reduced, it can lead to rare but serious side effects. These include: temporary or permanent damage to your eyesight | blindness | loss of movement (paralysis) of your eye muscles | areas of dead skin tissue (necrosis) | damage to structures under your skin.
The blockage of blood vessels can also cause a stroke. The following symptoms can be signs of a stroke: difficulty with speaking or remembering words | numbness or weakness in your arms, legs or face | difficulty with walking | drooping on one side of your face.
You should seek urgent medical help if you experience any of these symptoms. You should also 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 other 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 procedure. 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. Do not massage the area where the implant was injected in the first two days after the procedure. The implant may move, and the puncture site may not heal as well. 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 studies of the product.
These include:
1 in 10 people or more: a pooling of blood under the skin | bruise | discomfort | headache | itching | pain | unusual colouring of the skin, including redness of the skin | swelling | lumps under the skin.
Up to 2 in 1 000 people: nerve damage | blocked or obstructed blood vessels.
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 included:
1 in 10 people or more: bleeding | inflamed or irritated skin.
Up to 2 in 1 000 people: movement of the implant.
Up to 1 in 10 000 people: small areas of inflammation | allergic reaction (hypersensitivity).

Other side effects were seen when the product was used in ways that the manufacturer did not intend.
These included:
Up to 2 in 1 000 people: inflamed blood vessels.
Up to 1 in 10 000 people: areas of dead skin tissue.
The following side effects have been seen with similar gel-like implants:
1 in 10 people or more: reduced or altered sense of touch | hardening of the skin around the implant | loss of some or all feeling | increased feeling to touch.
Up to 2 in 1 000 people: swelling just under the skin | dizziness | feeling of unease | sensation of discomfort and urge to vomit | feeling of pins and needles | peeling of the skin | feeling faint or dizzy | unusual texture or colour of the skin due to irritation | hardening and tightening of the skin | bumps on the skin | burning feeling | skin disorders.
Up to 1 in 10 000 people: the collection of pus in the skin tissue | bacterial infection | hard lumps under the skin | fever | thickening of the skin caused by a build-up of connective tissue | uneven appearance between one side and the other | fainting.

Your body may react to the lidocaine in the product and your skin may turn red or become highly sensitive where the implant was injected. 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? The manufacturer carried out three clinical studies for this product. The purpose of the studies was to ensure that the product is safe and effective. In the first study, the investigators saw an improvement in the appearance of the nasolabial folds in 9 out of 10 study participants after 6 months, while in the second study, 8 out of 10 study participants showed improvement in nasolabial folds after 6 months. After 9 months, this improvement was still visible in 9 out of 10 participants in the first study and in 8 out of 10 participants in the second study. In the third study, the investigators saw an improvement in the lip fullness in 9 out of 10 participants after 6 weeks. The improvement was still visible after 6 months in 9 out of 10 participants.

Expected Device Lifetime: These study results show that treatment with the product works as intended for up to 9 months for nasolabial folds, and up to 6 months for lip fullness. The time it takes for the product to be broken down and absorbed by the body is determined to be 6 months for lip augmentation and 9 months for nasolabial folds. 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.

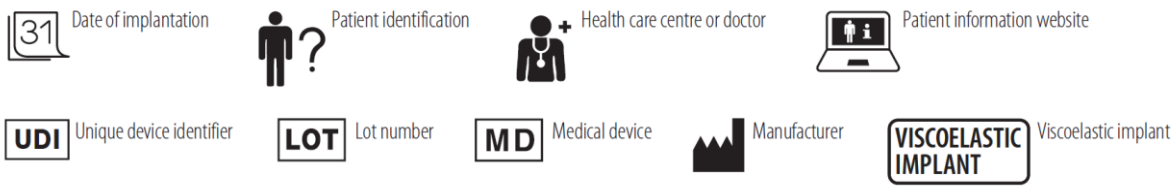
Serious Incidents/Contact: Related to the use of this product, contact the Manufacturer, Australian Sponsor and the Therapeutic Goods Administration at the below details:

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 15223-1:202

What do the symbols mean?



Last revised: 2024-04

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