

Patient Information Leaflet HArmonyCa® Lidocaine

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1. NAME AND MODEL

This product is HArmonyCa® Lidocaine.

Each box of HArmonyCa® Lidocaine contains:

- 2 pre-filled syringes, 1.25mL each.
- 2 single-use 27G 1/2" thin-wall sterile needles.

Product Description / What is HArmonyCa® Lidocaine?

HArmonyCa® Lidocaine is a sterile, apyrogenic, viscous, opaque, latex-free, semi-solid, biodegradable injectable dermal implant containing:

- hyaluronic acid,
- calcium hydroxyapatite and
- lidocaine.

2. INTENDED PURPOSE / INDICATIONS

What is the use of HArmonyCa® Lidocaine?

HArmonyCa® Lidocaine is a dermal filler intended for facial soft tissue augmentation and should be injected into the deep dermal and sub-dermal layers. The lidocaine in the product is for reducing pain during treatment.

Who can be injected with HArmonyCa® Lidocaine?

HArmonyCa® Lidocaine is indicated for adults (over the age of 18).

3. CONTRAINDICATIONS, WARNING AND LIMITATIONS FOR USE

You should **not** use this product:

- in patients with a known sensitivity to any of the product components.
- in patients suffering from skin disease or abnormal skin conditions.
- in patients suffering from an infection or inflammation (either acute or chronic) at or near the treatment site.
- in patients susceptible to keloid formation, hypertrophic scarring or developing inflammatory skin conditions.
- in patients with impaired wound healing due to systemic disorders, medicinal drugs or unhealthy or poorly-vascularised tissue.
- in patients suffering from prolonged bleeding or tissue healing due to medical conditions or medicinal drugs.
- in patients with a history of anaphylactic reactions and/or multiple severe allergies.
- in patients with a known sensitivity to steroids or who are contraindicated to be treated with steroids.
- for injection into regions containing foreign bodies.
- in patients presenting with herpes.
- in patients with autoimmune diseases.
- for injection into the epidermis or superficial dermis.
- in breastfeeding or pregnant women.
- in patients below the age of 18.
- in patients with known hypersensitivity to lidocaine or to other amide-type local anaesthetics.
- in patients with conditions for which lidocaine is contraindicated.

Your medical practitioner should not inject HArmonyCa® Lidocaine:

- superficially.
- into blood vessels (intravascular injection) or areas which are highly vascularised.
- into regions containing foreign bodies.
- in the area around the eyes, glabellar region, lip and area around the lips.

4. SPECIAL OPERATING INSTRUCTIONS FOR USE / PRECAUTIONS

How should HArmonyCa® Lidocaine be used?

This product is designed to be injected in the appropriate areas requiring treatment by an authorised health care professional who has had appropriate training and experience in injection techniques for filling skin depressions, face contouring and volume restoration.

You need to abstain from using make-up in the area to be treated for 12 hours before and after the procedure.

Before treatment:

Tell your medical practitioner:

1) If you are using the following medications:

- anti-coagulation medication (substances that can prolong bleeding), such as:
 - warfarin,
 - acetylsalicylic acid,
 - nonsteroidal anti-inflammatory drugs,
 - other substances known to increase clotting time such as herbal supplements with garlic or ginkgo biloba.
- medicines that reduce or inhibit hepatic metabolism (cimetidine, beta-blockers). Their use is not recommended due to the presence of lidocaine.

2) If you have diabetes.

3) If you have had any prior treatments with facial injectables.

4) If you are suffering from any of the following medical conditions:

- History of, or currently suffering from, autoimmune disease or immune deficiency or immunosuppressive therapy. Your medical practitioner will therefore decide on the indication on a case-by-case basis, according to the nature of the disease and its corresponding treatment and shall also advise you if any specific monitoring will be required in your case. Your medical practitioner may also require you to have skin testing for hypersensitivity before any injection is administered and may also refrain from injecting the product if the disease is active.
- History of streptococcal disease (such as recurrent sore throats or acute rheumatic fever). Your medical practitioner may require you to have skin testing for hypersensitivity before any injection is administered. In the event of acute rheumatic fever with heart complications, it is recommended that you do not receive treatment with HArmonyCa® Lidocaine.
- Symptoms of heart disease.
- History of severe and/or multiple allergies. According to the nature of the allergy, your medical practitioner will decide on the use of the product as well as whether you require any specific monitoring. In particular, a decision may be taken to propose skin testing for hypersensitivity or suitable preventive treatment for you prior to any injection. If you have a history of anaphylactic shock, it is recommended that you do not receive treatment with HArmonyCa® Lidocaine.

You should not have this procedure at the same time as epilation, UV irradiation or laser, mechanical or chemical peeling. For surface peels, it is not recommended to receive treatment with HArmonyCa® Lidocaine if there is significant inflammation from the skin peel treatment still present.

This product is not intended to be injected into an area which has been previously treated with a permanent implant to limit risk of chronic/serious adverse events such as granuloma/areas of inflammation which have been reported with subsequent injections.

After treatment:

- You should avoid strenuous activity and exposure to sunlight and tanning lamps or extreme weather conditions for 24 hours post-treatment in order to reduce redness, swelling and irritation.
- You should apply an ice pack or cold compresses to the treated area for 24 hours post-treatment in order to reduce redness, swelling and irritation.
- If nodules appear, you should massage the treated area.
- Note that the injected material may be palpable for a long period after treatment.

5. INTENDED PERFORMANCE

HArmonyCa® Lidocaine is a dermal filler intended for facial soft tissue augmentation and should be injected into the deep dermal and sub-dermal layers. The lidocaine in the product is for reducing pain during treatment sensitivity to pain.

6. UNDESIRABLE SIDE EFFECTS

What are the possible side effects?

- The most common side effects include temporary reactions at the treatment site such as erythema, oedema, itching sensation, bruising, pain, tenderness to touch, nodules, local reaction or inflammation at the injection site. These side effects are consistent with other injectable soft tissue fillers.
Less common side effects include granulomas, seroma, extrusion, induration and fistula formation.
- Other side effects such as haematoma, skin discolouration, allergic reaction, migration, infection, unintentional injection into a blood vessel may lead to vascular occlusion, embolisation, vision abnormalities, blindness, stroke or skin necrosis.
- Although most common side effects will resolve within 1 week, some side effects may last for 30 days or longer. If unresolved, your healthcare/medical practitioner will treat them appropriately.
- Adverse events are reported following the use of soft tissue fillers, including hyaluronic acid fillers with or without calcium hydroxyapatite. Some of these events necessitate counselling and management by your healthcare/medical practitioner. In certain instances, surgical interventions may be required, such as draining haematomas or necrotic tissue, or removing the implant due to severe allergic reactions, inflammation, hypersensitivity or infection.

Please see section 7: *SYMPTOMS OR SIGNS OF DEVICE OR TREATMENT MALFUNCTION* for further information.

When should I call my medical practitioner?

If you believe that you have experienced an undesirable effect related to HArmonyCa® Lidocaine injectable gel, you should call your medical practitioner and/or the local sponsor of the product, AbbVie Pty Ltd, please see section 13: *ADDITIONAL INFORMATION / CONTACT*.

7. SYMPTOMS OR SIGNS OF DEVICE OR TREATMENT MALFUNCTION

What are the symptoms or signs that could indicate the device is malfunctioning or treatment is not as expected?

Your medical practitioner will stop the procedure if any of the following symptoms are seen during the injection: changes in vision, signs of stroke, whitening/paling of the skin or unusual pain during or shortly after the procedure.

There are potential side effects associated with implantation of this product, which may occur immediately or may be delayed. Please see section 6: *UNDESIRABLE SIDE EFFECTS* for further information.

What precautions and other measures should you take if the performance of the device changes or if you experience any undesirable side effects?

Before treatment:

Your medical practitioner should have discussed with you the products' indications, warnings, contra-indications, incompatibilities and potential undesirable effects/risks associated with dermal filler injection and ensure that you are aware of the signs and symptoms of potential complications.

After treatment:

Please report the following to your medical practitioner as soon as possible for appropriate treatment:

- any common adverse event which doesn't resolve within the typical time frame or which worsens or
- any other side effect that has developed.

If you believe that you have experienced an undesirable effect related to HArmonyCa® Lidocaine injectable gel, you should call your medical practitioner and/or the local sponsor of the product, AbbVie Pty Ltd, please see section 13: *ADDITIONAL INFORMATION / CONTACT*.

8. RISKS & ASSOCIATED PRECAUTIONS

What are residual risks?

Residual risks could arise due to any shortcoming of the protection measures adopted as part of the medical device guideline. Please refer to information provided in section 12: *RESIDUAL MATERIAL*.

What are risks that could arise from interaction of HArmonyCa® Lidocaine with other equipment or material?

Hyaluronic acid is known to be incompatible with quaternary ammonium salts such as benzalkonium chloride.

HArmonyCa® Lidocaine contains lidocaine, there is no known interaction with other local anaesthetics.

Because of the risks associated with treatment with HArmonyCa® Lidocaine, the following precautions and other measures, should be taken:

By Health care professionals/Medical practitioners:

HArmonyCa® Lidocaine should never be placed in contact with quaternary ammonium salts such as benzalkonium chloride or with medical-surgical instrumentation which has been treated with this type of substance.

By the patient:

Please refer to Section 4: *SPECIAL OPERATING INSTRUCTIONS FOR USE / PRECAUTIONS* for further information with regards to precautions to be followed before and after treatment with HArmonyCa® Lidocaine.

9. FOLLOW-UP CONSULTATION

What is the nature and frequency of regular follow-up, examination, monitoring or maintenance following treatment that you need to undertake?

It is suggested to have a follow-up consultation with your healthcare professional approximately 2 weeks after the procedure. This is an opportunity to discuss any potential adverse effects you have observed.

A touch-up treatment (for achieving optimal correction) with HArmonyCa® Lidocaine might be required which can also be completed at this follow-up appointment.

10. DEVICE LIFETIME / DURATION OF TREATMENT EFFECT

What is the lifetime of the product? What could shorten or lengthen the treatment lifetime?

The correction is temporary. The degree and duration of the correction depend on the character of the defect treated, the tissue stress at the implant site, the depth of the implant in the tissue and the injection technique. It will also vary with the individual patient being treated.

What precautions and other measures should you take at, or near, the end of the expected treatment lifetime?

For maintaining optimal correction, a repeat treatment with HArmonyCa® Lidocaine might be required. You can contact your medical practitioner for further information.

Under what circumstances should you contact a health professional in relation to the operation/use of HArmonyCa® Lidocaine?

Please refer to information provided in section 7: *SYMPTOMS OR SIGNS OF DEVICE OR TREATMENT MALFUNCTION*.

11. COMPOSITION

What material & substances are included in HArmonyCa® Lidocaine?

Each 1 mL syringe of HArmonyCa® Lidocaine contains:

- Calcium hydroxyapatite microspheres of 25-45 microns diameter (55.7%),
- Cross-linked sodium hyaluronate gel (20mg/ml),
- Lidocaine hydrochloride (3mg/ml),
- Phosphate buffer pH 7.2 to make 1.2 mL.

12. RESIDUAL MATERIAL

What are the manufacturing residuals that could pose a risk to you?

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

13. ADDITIONAL INFORMATION / CONTACT

What to do in case of any serious incident that occurs in relation to HArmonyCa® Lidocaine?

Any serious incident with HArmonyCa® Lidocaine should be reported to the manufacturer and to the Therapeutic Goods Administration. If you believe you have experienced an incident/side effect after treatment with HArmonyCa® Lidocaine injectable gel, you should contact Allergan Aesthetics by email to MedDeviceComplaintsAPAC@AbbVie.com or call 1800 252 224 and contact the Therapeutic Goods Administration at <https://www.tga.gov.au/>.

PANAXIA

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Aesthetics

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