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e.p.t.q. Lidocaine S100 / S300 / S500

Patient Information Leaflet

Please read this document carefully before your treatment, it contains important information about e.p.t.q. Lidocaine.

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1. GLOSSARY

Note: the terms in the glossary are **bold** throughout the document.

Allergic reaction: allergic reactions occur when a person's immune system (needed to fight infections) overreacts to substances that are harmless for most people. Symptoms could include a rash, sneezing, itching, congestion, or difficulty breathing

Anaphylaxis: a severe **allergic reaction** which needs medical treatment right away

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Anesthetic: a medication that reduces pain; it can be added to a cream or a **dermal filler**; sometimes called a numbing medicine

Anticoagulants: medications that thin your blood

Anti-inflammatory: a medicine which reduces pain, heat, redness, and swelling, which are symptoms of inflammation

Common treatment reaction: reactions which can be expected after injection of a **dermal filler**. It includes bruising, firmness, swelling, pain, tenderness, redness, lumps/bumps, change in skin color,and itching

Dermal filler: material which is injected under the skin to help smooth and plump wrinkles and folds

Dynamic: able to move, not fixed in place, such as the skin on the face

Granuloma: localized hardening under the skin, like a lump, appearing weeks or months after theinjection

Herpes: a virus which causes certain skin conditions, such as cold sores

Hyaluronic Acid (HA): a naturally occurring substance found in the human body which helps maintain skin structure and feel. The HA found in e.p.t.q. Lidocaine is a different form than the HA found in the human body

Immunosuppressive therapy: medications that reduce the body's normal response to infections, allergens, anything not normally found in the body

Keloid: a thick tough scar

Lidocaine: a type of **anesthetic** medication which helps reduce pain

Streptococcus equi: a bacteria, which does not cause illness in people, used to make the

hyaluronic acid

Therapy: treatment intended to reduce, heal or cure pain, disease or physical reaction

Touch-up: an additional injection, performed 2 to 4 weeks after the initial injection. Some patientsmay require a touch-up treatment to achieve the desired aesthetic results

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2. PRODUCT DESCRIPTION

What is it?

e.p.t.q. Lidocaine is a sterile, non-pyrogenic, viscoelastic, colourless, transparent gel composed of cross-linked sodium hyaluronate gel of non-animal origin with 0.3% lidocaine hydrochloride in a physiologic phosphate buffer.

A e.p.t.q. Lidocaine is an injectable gel (also called a **dermal filler**) used to treat facial wrinkles and folds. It is injected in the moving (**dynamic**) area of the face. e.p.t.q. Lidocaine is produced with **hyaluronic acid** (**HA**), using an advanced technology to obtain a soft and long-lasting injectable gel to smooth facial wrinkles and folds. The **HA** of the gel is made from a non-animal source.

e.p.t.q. Lidocaine contains a small amount of an **anesthetic** medicine (**lidocaine**), to help reduce discomfortduring injection.

Hyaluronic acid (HA) is a naturally occurring substance found in the human body. Your body's own

HA helps maintain the skin's structure and its natural feel.

3. INDICATION/INTENDED USE

What is it for?

e.p.t.q. Lidocaine is intended to be used for the correction of nasolabial folds. The product is for cosmetic use only. The addition of lidocaine provides a pain-relieving effect during treatment.

Treatment areas

✓ To correct or enhance facial contours; cheeks, temples, jawline, nose, chin

✓ To soften and correct facial wrinkles or folds

How does it work?

e.p.t.q. Lidocaine is injected directly into the skin with an ultrafine needle to provide instant correction.

e.p.t.q. Lidocaine is not a permanent gel. It slowly goes away as the body absorbs the gel. The smoothing and plumping effect will gradually disappear.

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4. CONTRAINDICATIONS

e.p.t.q. Lidocaine is contraindicated:

- in patients with severe allergies manifested by a history of anaphylaxis or history or presence of multiple severe allergies,
- in patients with history of facial keloid formation or hypertrophic scar,
- in patients with known hypersensitivity to one of the product's components, especially to sodium hyaluronate, local anesthetics of the amid type, such as lidocaine,
- in patients presenting with porphyria,
- in pregnant or breastfeeding women,
- in young patients under 18 years old,
- in patients with active (or a history of) autoimmune disease.

e.p.t.q. Lidocaine contains trace amounts of gram positive bacterial proteins and is contraindicated for patients with a history of allergies to such material.

Are there any reasons why I should not receive e.p.t.q. Lidocaine?

Your doctor will ask about your medical history to see if e.p.t.q. Lidocaine is right for you. You should not use the product if you have a history of:

- severe **allergic reactions** (**anaphylaxis**) or history or presence of multiple severe allergies.An injection of e.p.t.q. Lidocaine may result in an **allergic reaction**.
- **allergic reactions** to the material (from ***Streptococcus equi***) used to make the **HA** in e.p.t.q. Lidocaine. An injection of e.p.t.q. Lidocaine may result in an **allergic reaction**.
- **allergic reactions** to **lidocaine** or other similar substances used to reduce pain. An injectionof e.p.t.q. Lidocaine may result in an **allergic reaction**.
- bleeding disorders. Any injection, including e.p.t.q. Lidocaine and other **dermal fillers**, may result in ahigher risk of bruising or bleeding in the treated area.

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5. PRECAUTIONS

How should it be used?
e.p.t.q. Lidocaine is to be administered by a physician or healthcare professional only.

e.p.t.q. Lidocaine is designed to be injected in the appropriate areas requiring treatment by an authorized health care professional who has had appropriate training and experience in injection techniques for volume restoration and wrinkle correction.

Are there precautions that I should discuss with my doctor?

The following are important treatment considerations that you should discuss with your doctor.These hazards, if not avoided, could result in unsatisfactory results or complications.

- Tell your doctor if you are under 18 years of age.
- Tell your doctor if you are pregnant (or plan to be) or breastfeeding.
- Tell your doctor if you are taking medicine that reduces your body's ability to fight infection(**immunosuppressive therapy**). Taking this type of medicine may increase the risk of infection following the injection of e.p.t.q. Lidocaine or other **dermal fillers**.
- Be sure to tell your injecting doctor if you are using "blood thinners" (**anticoagulants**) or anyother medications that affect bleeding. Do not stop taking them until you speak with the doctor who prescribed them for you. Tell your prescribing doctor that you are consideringhaving your wrinkles treated with e.p.t.q. Lidocaine. These blood thinning medications may cause increased bleeding and/or bruising in the treated area.
- Tell your doctor if you have a history of cold sores (**herpes**). Any injection, including e.p.t.q. Lidocaine, in the general area may trigger a recurrence of your cold sores (**herpes**).
- Tell your doctor if you have an injury, or other skin condition near the injection site(s). Injection of a **dermal filler** in this situation may lead to a worsening of your condition or infection. You may have to wait until you are completely healed before using e.p.t.q. Lidocaine.
- Tell your doctor if you have ever developed a thick tough scar (**keloid**) or had

problems with skin discoloration. It is possible that injection of any **dermal filler** may make the skin thicker and change color.

- Tell your doctor if you have already been injected with **dermal fillers** in the same area as the one(s) you are about to be treated for. This information helps your doctor decide whenand whether you should get treatment with e.p.t.q. Lidocaine.
- Tell your doctor if you have recently had (within 6 months), or are considering, laser treatment, chemical peeling or any other facial procedure. Use of e.p.t.q. Lidocaine with these skin treatments may lead to an increased severity of the **common treatment reactions** such asredness, swelling, heat or pain in the area.
- You should not take Vitamin E, aspirin, or **anti-inflammatories** during the week prior to the injection. Taking these medications can thin your blood and may result in increased bleeding and/or more bruising in the treated area.

If you have any additional questions about more information on details below, please discuss further with yourdoctor.

General considerations relevant to injectable medical devices

▪As with all transcutaneous procedures, product implantation carries a risk of infection. Standard precautions associated with injectable materials should be followed.

▪In order to minimize the risks of potential complications, this product should only be used by health care practitioners who have appropriate training, experience, and who are knowledgeable about the anatomy at and around the site of injection, such as, plastic surgeons and dermatologists.

▪Health care practitioners are encouraged to discuss all potential risks of soft tissue injection with their patients prior to treatment and ensure that patients are aware of signs and symptoms of potential complications.

▪ Knowledge of the anatomy of treatment site and special caution are required in order to avoid perforation or compression of vessels, nerves and other vulnerable structures.

▪ Injection procedures are associated with a risk of infection. Aseptic technique and standard practice to prevent cross-infections are to be observed.

▪ Special caution should be exercised when treating areas with limited collateral circulation, due to increased risk of ischemia.

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▪ Special caution should be exercised in treating facial areas with limited soft tissue support or soft tissue cover, such as the periorbital area, to avoid formation of palpable lumps.

▪ Patients with pre-existing pigmented dark lower eye lid circles, thin skin and pre-existing tendency toward oedema formation are not suitable candidates for treatment of the lower periorbital region.

▪ Patients using immunosuppressants are not suitable candidates for treatment.

▪ Special caution should be exercised in treating patients with a tendency to form hypertrophic scars or any other healing disorders.

▪ Injection procedures can lead to reactivation of latent or subclinical herpes viral infections.

▪ Patients who are using substances that affect platelet function, such as aspirin and nonsteroidal anti-inflammatory drugs or high dose vitamin C may, as with any injection, experience increased bruising or bleeding at injection sites.

▪ Patients with unattainable expectations are not suitable candidates for treatment.

▪ Check the integrity of the inner packaging and the expiry date for both syringe and the needle prior to use. Do not use beyond the expiry date or if package is opened or damaged.

▪ In case of re-use, this can cause to depress performance of the product and may lead to severe cross-infection.

▪ After use, syringes, remaining product and needles should be handled as potential biohazards. Disposal should be in accordance with accepted medical practice and applicable local, state and federal requirements.

Specific considerations relevant to the use of this product

▪ Considerations should be given to the total dose of lidocaine administered if dental block or topical administration of lidocaine is used concurrently. High doses of lidocaine can cause acute toxic reactions manifesting as symptoms affecting the central nervous system and cardiac conduction. The recommended maximum adult dose of lidocaine for dermatology local anesthesia is 3.0 mg/kg (max : 200mg).

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▪ Lidocaine should be used with caution in patients receiving other local anaesthetics or agents structurally related to amide-type local anaesthetics e.g., certain antiarrhythmics, since the systemic toxic effects can be additive.

▪ Lidocaine should be used cautiously in patients with epilepsy, impaired cardiac conduction, severely impaired hepatic function or severe renal dysfunction.

▪ Practitioners and athletes should consider that lidocaine may produce positive results to anti-doping tests.

▪ It should be noted that the presence of lidocaine may cause local redness or hypersensitivity.

▪ 0.3% lidocaine injection has no reported effect on driving and operating machinery.

▪ If the product is injected too superficially this may result in visible lumps and/or bluish discoloration.

▪ The patient should avoid applying makeup for at least 12 hours after treatment and to avoid prolonged exposure to sunlight, UV, as well as extreme cold and heat for two weeks after the injection. Patients should also avoid putting pressure on and/or handling the treated area.

▪ If laser treatment, chemical peeling or any other procedure based on active dermal response is performed after treatment with this product there is a theoretical risk of eliciting an inflammatory reaction at the implant site. This also applies if the product is administered before the skin has healed completely after such a procedure.

▪ The product is a clear, colorless gel without particulates. In the event that the content of a syringe shows signs of separation and/or appears cloudy, do not use the syringe and notify the manufacturer.

▪ Glass is subject to breakage under a variety of unavoidable conditions. Care should be taken with the handling of the glass syringe and with disposing of broken glass to avoid laceration or other injury.

6. BENEFITS

What are the expected benefits of e.p.t.q. Lidocaine ?

It will temporarily correct volume that has been lost due to aging and help smooth and plump wrinkles and folds and will provide a smoother contour and more youthful appearance to the face.

7. RISKS

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

The product does not contain any manufacturing residuals that could pose a risk to patients.

What were the common treatment reactions of Dermal filler?

The most common side effects include temporary reactions at the treatment site such as tenderness, swelling, firmness, lumps/bumps, bruising, pain, redness, discoloration, and itching. These side effects are consistent with other facial-injection procedures, and moderate (uncomfortable) in nature, and generally lasted 2 to 4 weeks.

Although most side effects will resolve with time, some side effects may persist longer than 30days. Your doctor may choose to treat them with medications, such as antibiotics, steroids, or hyaluronidase (an enzyme that breaks down **HA**).

What other possible reactions could occur?

Other possible reactions can occur after the injection of a **dermal filler**.

- Infection – Any time a **dermal filler** is injected under the skin there is a risk of infection at thesite of injection. It may create hard and swollen lumps that may contain pus.
- **Granuloma** – Red raised lumps that may appear weeks or months after injection. They mayneed to be treated by a doctor to make them go away.
- Acne-like rashes – If you have a sensitive skin, the injection of a **dermal filler** may create anirritation or rash at the site of the treatment that can be compared to acne.
- Displacement of the gel - It is possible the injected gel may move out of the desired treatment area. Your appearance may be affected.
- Blisters – Any injection, may lead to formation of blisters at the point of injection.
- Scars – With any type of injection, scarring may occur.

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- Scab - The injection of a **dermal filler**, may result in the skin becoming dry and crusty.
- Skin peeling (shedding) – The skin may dry as a reaction to the cleansing agent. The dry skin may be stressed with the injection and result in peeling or shedding.

You should contact your doctor if you experience any of these reactions or if you notice anythingunusual at the site of the treatment. Most of these reactions go away within a few days on their own but some may persist for more than 30 days. Your doctor may choose to treat them with medications.

Other serious reactions may occur following the injection of **dermal fillers** to smooth wrinkles. Contact your doctor immediately if any of these happen:

- One of the risks with using this product is unintentional injection into a blood vessel. The chances of this happening are very small, but if it does happen, the complications can beserious, and may be permanent. These complications, which have been reported for facialinjections, can include vision abnormalities, blindness, stroke, temporary scabs, or permanent scarring of the skin. If you have changes in your vision, signs of a stroke (including sudden difficulty speaking, numbness or weakness in your face, arms, or legs, difficulty walking, face drooping, severe headache, dizziness, or confusion), white appearance of the skin, or unusual pain during or shortly after treatment, you should notifyyour health care practitioner immediately.
- Severe **allergic reactions** (**anaphylaxis**) - An **allergic reaction** to a material used to make a**dermal filler** that could occur shortly after the injection. Symptoms could include a rash, sneezing, itching, congestion or difficulty breathing.

You should discuss the potential treatment risks, adverse events and benefits with your doctor before the injection

[ADVERSE EVENTS]

Patients must be informed of the potential risks and adverse events related to the injection procedure and to the use of this product. A slight bleeding may occur during the injection, and it disappears spontaneously as soon as the injection is finished. In occasional cases one or more of the following may occur either immediately or as a delayed reaction (list not exhaustive):

- Reactions usually associated with injections such as redness, erythema, oedema or pain sometimes accompanied by itching in the treated area. These reactions may last for a week.
- Hematomas in the treated area,
- Swelling in the treated area,
- Indurations or nodules in the treated area,
- Coloration or discolouration in the treated area,
- Poor effect or weak filling effect,
- Allergy to one of the product's components, especially to sodium hyaluronate. and lidocaine hydrochloride.
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- Cases of necrosis, abscesses and granulomas after sodium hyaluronate injections have been reported in the literature. These rare potential risks must nevertheless be considered. Patients should be instructed to report any side effects which last for more than one week to his/her practitioner.

The practitioner may then prescribe the patient appropriate treatment.

Any other undesirable side effects associated with injection of the product must be reported to the distributor and/or to the manufacturer.

8. PROCEDURE

What happens in the doctor's office before the treatment?

Note that each doctor may have their own process for treating patients.

Before the injection procedure, your doctor will ask you questions about your medical history. He/she will ask about your treatment goals. Your doctor will discuss whether you are a good candidate for e.p.t.q. Lidocaine. He/she will review with you what to expect during and after treatment, including possible risks.

During this discussion, it is very important to tell your doctor about:

- all medications you are taking, both over the counter and prescription
- any previous facial treatment you may have received
- and any health conditions for which you are receiving medical attention

Your doctor will also examine your skin in and around the treatment area, and may take photos. The treatment area will be cleaned and prepared with a cleansing agent. Your doctor may use apen to mark your face in the planned areas of injection.

Do the injections hurt?

Injections may cause some pain during and after the procedure. Your doctor will discuss differentoptions for pain management with you. e.p.t.q. Lidocaine contains an **anesthetic** medicine (**lidocaine**) to help reduce injection site pain. This pain is temporary, and usually lessens within a few minutes. To prevent or reduce pain from the injection, your doctor may use ice packs, or other **anesthetic**, both before and after the injection.

What happens during the treatment?

e.p.t.q. Lidocaine is slowly injected into the facial skin in small amounts until your doctor sees the desired resultwhich creates a more youthful appearance of the face. For most patients, the procedure only takes 15-30 minutes.

Once your doctor has finished injecting the treatment area, he/she may gently massage your faceto help smooth and distribute the gel evenly.

Your doctor may also apply an ice pack to help decrease swelling and pain.

The amount of e.p.t.q. Lidocaine used depends on the depth of your wrinkles and your treatment goals. Theright amount to be injected will be decided by your doctor during the procedure. Injection of additional e.p.t.q. Lidocaine (**touch-up** treatment) may be needed 2 to 4 weeks after initial treatment to achieve the desired aesthetic outcome.

Your doctor will decide how much e.p.t.q. Lidocaine is needed for the **touch-up** treatment.

What happens after the treatment?

Your doctor may advise you to apply cold compresses to the treated area to help reduce pain and swelling. In order to prevent injury, ask your doctor how long you can leave ice packs on the treated area.

Be aware that numbness, short term loss of touch or feeling, and tingling around the injection areamay occur due to the numbing medicine (**anesthetic**). It usually goes away within a few hours. Due to this numbness, you may not have normal feeling of hot or cold in this area.

Ask your doctor about any limits for exercising and exposure to sun, cold or heat (sauna, steam room). Exposure to any of these for the first 24 hours may increase short term redness, swelling, and/or itching at the injection site.

You should ask your doctor when make-up may be applied after your treatment. Using make-up too soon may increase the risk of infection or change in skin color.

Most **common treatment reactions** like bruising, firmness, swelling, pain, tenderness, redness, lumps/bumps, change of skin color and itching go away on their own within a few days, but yourdoctor may choose to treat them with medications. Refer to section 6, RISKS.

When should I call my doctor?

Call your doctor if you have any questions or concerns after your procedure.

Call your doctor immediately if you have:

- Signs of a stroke (including sudden difficulty speaking, numbness or weakness in your face,arms, or legs, difficulty walking, face drooping, severe headache, dizziness, or confusion)
- Changes in your vision
- Pain which increases after your treatment
- Significant pain away from the injection site
- White appearance of the skin
- Any treatment reaction other than bruising, firmness, swelling, pain, tenderness, redness,lumps/bumps, change in skin color or itching, which occurs in the first two weeks
- Any treatment reaction in the treated area, including lump or hardening under the skin,that appears weeks or months after your injection.

The following are common reactions often seen after treatment with **dermal fillers**. They usually goaway within 2 weeks. If you are concerned, or if they last more than 2 weeks, call your doctor:

- Bruising
- Firmness

- Swelling
- Pain
- Tenderness
- Redness
- Lumps/bumps
- Change in skin colour
- Itching

9. ADDITIONAL INFORMATION

In case you have any further questions, please contact JETEMA Australian Distributor at: 1800-570-036.

Serious Incidents that occur in relation to the use of e.p.t.q. Lidocaine should be reported to the manufacturer (https://www.jetema.com)and to the Australian Therapeutic Goods Administration (TGA) (https://www.tga.gov.au/).

IF SYMPTOMS PERSIST, WORSEN OR CHANGE UNEXPECTEDLY, TALK TO YOUR HEALTHCARE PROFESSIONAL.

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