



TEOSYAL® PURESENSE ULTRA DEEP (2x1.2ml) Product Specifications

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LEAFLET FOR PATIENT



Patient name



Name and address of the healthcare professional



Injection date



Medical Device name



Manufacturer



Expiration date



Lot number

This patient information leaflet is also available online on Teoxane website at the following link:
<https://www.teoxane.com/productinfo>

TEOXANE dermal fillers are sterile injectable viscoelastic hyaluronic acid gels (of non-animal origin). The products include lidocaine, which is a local anesthetic that helps reduce the sensation of pain during the injection process.

This patient information leaflet covers the following products of the TEOSYAL® PureSense range:

- TEOSYAL® PureSense Redensity 1
- TEOSYAL® PureSense Redensity 2
- TEOSYAL® PureSense Global Action
- TEOSYAL® PureSense Deep Lines
- TEOSYAL PureSense Kiss®
- TEOSYAL® PureSense Ultra Deep
- TEOSYAL® PureSense Ultimate
- TEOSYAL® RHA 1
- TEOSYAL® RHA 2
- TEOSYAL® RHA 3
- TEOSYAL® RHA 4

Intended purpose and categories of users and consumers:

TEOSYAL® RHA dermal fillers are intended for the treatment of deep wrinkles on the face, deep lines and creases, cheek augmentation and to restore the shape of the face.

TEOSYAL® PureSense dermal fillers are intended to correct cutaneous contour deformities of the skin (e.g wrinkles, folds, scars).

TEOSYAL® PureSense and RHA dermal fillers are designed to be injected in adults only by authorized medical practitioners or health care professionals when applicable, in accordance with local regulations.



Expected performance of the devices:

TEOSYAL® PureSense Global Action / TEOSYAL® PureSense Deep Lines / TEOSYAL® RHA 2 / TEOSYAL® RHA 3: Create a volume that correct wrinkles and cutaneous depressions and/or enhance their contour.

TEOSYAL® PureSense Ultra Deep / TEOSYAL® PureSense Ultimate / TEOSYAL® RHA 4: Create a volume that corrects cutaneous depressions or facial contours.

TEOSYAL PureSense Kiss®: Creates a volume that correct cutaneous depressions and restores the lip volume.

TEOSYAL® PureSense Redensity 1: Thanks to its marked fluidity and its visco-elastic properties, it is evenly distributed, ensuring an optimal level of hydration and leading to a lasting improvement in the skin's texture and elasticity.

TEOSYAL® PureSense Redensity 2: Fills evenly the under-eye circles cavity and creates a volume that correct the fine lines/wrinkles.

TEOSYAL® RHA 1: Creates a volume that correct fine lines.

Potential undesirable side effects (risks linked to the use of the products):

As with all hyaluronic acid-based products, the products in the TEOSYAL® Puresense and TEOSYAL® RHA range may have side effects. These reactions are most often temporary and common, and result in:

- Redness, bruising, haematomas, bumps, oedema, erythema, temporary loss of sensation, itching, pain and dyschromia at the injection site. You must see a doctor if your symptoms do not improve.
- Swelling or nodules that may appear in a delayed manner at the injection site. In that case, you must consult your doctor.

Despite being rare, serious side effects may occur: abscess, granuloma, immediate hypersensitivity which may even lead to anaphylactic shock, vascular complications which may extend to necrosis of the injected area, visual disturbances or even blindness.

A post-administration monitoring of 30 minutes is strongly recommended to allow the practitioner to detect any serious immediate incidents.

In case of dissatisfaction with the expected aesthetic result or side effects persisting beyond one week following treatment, with a product of TEOSYAL® PureSense and RHA ranges, you should immediately report that serious incident to your practitioner, the Therapeutic Goods Administration and to the manufacturer TEOXANE Laboratories.

Therapeutic Goods Administration: <https://www.tga.gov.au/reporting-problems>

TEOXANE Laboratories: 00 41 (0) 22 344 96 36 - medical@teoxane.com

Expected lifetime of TEOSYAL® PureSense and RHA products and any necessary follow-up:

TEOSYAL® PureSense and RHA products	Estimated in vivo lifetime
TEOSYAL® PureSense Redensity 1	At least 3 months
TEOSYAL® PureSense Redensity 2	At least 12 months
TEOSYAL® RHA 1	At least 12 months
TEOSYAL® PureSense Global Action	12 to 18 months
TEOSYAL® PureSense Deep Lines	12 to 18 months
TEOSYAL PureSense Kiss®	12 to 18 months
TEOSYAL® PureSense Ultra Deep	12 to 18 months
TEOSYAL® PureSense Ultimate	12 to 18 months
TEOSYAL® RHA 2	12 to 18 months
TEOSYAL® RHA 3	12 to 18 months

TEOSYAL® RHA 4	15 to 18 months
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Your practitioner will choose the product suitable for injection according to your needs and taking into account your request. The duration of the treatment depends on several factors including skin type, the severity of the wrinkle to be treated, the injection area, the volume injected, your physiology and your lifestyle. Your practitioner will tell you if a touch-up session may be required for optimal results.

After the injection, the following recommendations must be considered:

- Within 12 hours following the injection: do not apply make-up, avoid any violent effort.
- During the week following the treatment: avoid drinking alcohol, prolonged exposure to the sun or UV rays, temperatures below 0°C, as well as the practice of sauna or hammam.
- Within 15 days following the treatment: do not perform dental or other aesthetic procedures.

Any contraindications to the procedure:

Prior to any injection of TEOSYAL® products, the practitioner must question the patient regarding its past medical history and its current condition or medication that could affect the procedure. The practitioner should inform the patient about the indications, expected outcomes, contraindications, precautions, and potential side effects.

The patient must report aesthetic treatments performed previously. Indeed, as interactions with other filling implants have not been studied, it is recommended not to inject TEOSYAL® products in areas where other dermal fillers are present.

The following recommendations must be considered before the injection of TEOSYAL® PureSense and RHA products:

- Inform the practitioner about:
 - o All your recent or current pathologies, as well as your chronic illnesses
 - o All your chronic or current allergies
 - o All your chronic or ongoing treatments
- Avoid getting an injection if you have had a dental procedure within the previous 15 days.
- Avoid taking aspirin, anti-inflammatory drugs, anticoagulants, and vitamin E during the week prior to the injection. Ask your doctor for advice prior to stopping any treatment.
- Avoid drinking alcohol or exposing yourself to strong sunlight the day before and the day of the injection.
- Remove your make-up thoroughly prior to the injection.

The following precautions for use related to the composition of TEOXANE's products must be taken:

Hyaluronic acid:

- o TEOXANE's products contain between 15 and 25 mg/mL of Hyaluronic Acid.
- o Advise your doctor in case of known hypersensitivity to Hyaluronic Acid, with a history of severe allergy or anaphylactic shock.

Lidocaine:

- o TEOSYAL PureSense and RHA products contain 0.3% of lidocaine.
- o Advise your doctor for guidance in case of:
 - Known hypersensitivity, allergy to lidocaine and/or local anesthetics of the amide type;
 - Athletes: lidocaine can induce a positive reaction to anti-doping tests;
 - Heart diseases and/or patient under treatment for heart disease (beta-blockers).
- o Inform your doctor if any of the above precautions apply to you as it is recommended that you do not use products from TEOSYAL® PureSense and RHA ranges.



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