



# TEOXANE

INFORMATION FOR THE PATIENT

# Teoxane's dermal fillers

## Information for the patient

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## 1. What TEOSYAL® products are and what they are used for

### 1.1. Description of TEOSYAL® products

TEOSYAL® products are dermal fillers which are sterile injectable viscoelastic hyaluronic acid gels (of non-animal origin) and containing lidocaine (0.3%) to help reduce discomfort during injection.

TEOSYAL® products contain residual traces (< 1 ppm) of BDDE (1,4-Butanediol diglycidyl ether) which is used as crosslinking agent.

The composition of the TEOSYAL® PureSense products is presented in the below table:

Product	Hyaluronic acid	Phosphate buffer	Supplemented Phosphate Buffer	Lidocaine
TEOSYAL® PureSense Redensity 1	15 mg/mL	N/A	q.s. ad 1 mL or 3 mL	0.3% by mass
TEOSYAL® PureSense Redensity 2	15 mg/mL	N/A	q.s. ad 1 mL	0.3% by mass
TEOSYAL® PureSense Global Action	25 mg/mL	q.s. ad 1 mL	N/A	0.3% by mass
TEOSYAL® PureSense Deep Lines	25 mg/mL	q.s. ad 1 mL	N/A	0.3% by mass
TEOSYAL PureSense KISS®	25 mg/mL	q.s. ad 1 mL	N/A	0.3% by mass
TEOSYAL® PureSense Ultra Deep	25 mg/mL	q.s. ad 1.2 mL	N/A	0.3% by mass

TEOSYAL® PureSense Ultimate	22 mg/mL	q.s. ad 1 mL	N/A	0.3% by mass
TEOSYAL RHA® 1	15 mg/mL	q.s. ad 1 mL	N/A	0.3% by mass
TEOSYAL RHA® 2	23 mg/mL	q.s. ad 1 mL	N/A	0.3% by mass
TEOSYAL RHA® 3	23 mg/mL	q.s. ad 1 mL	N/A	0.3% by mass
TEOSYAL RHA® 4	23 mg/mL	q.s. ad 1.2 mL	N/A	0.3% by mass
TEOSYAL RHA KISS®	23 mg/mL	q.s. ad 0.7 mL	N/A	0.3% by mass

### 1.2. Categories of users and consumers

To minimize the risk of potential complications, the TEOSYAL® products should be administered only by healthcare professionals who received appropriate training on the conditions to safely use the device. The product should not be injected in patients who are less than 18 years old and having any of the contra-indications referenced in the instruction for use of the products.

### 1.3. Expected performance of the products

The following aesthetic results are expected when you receive an injection of TEOSYAL® products:

Product	Expected performance
TEOSYAL® PureSense Global Action	Creates a volume that corrects wrinkles, cutaneous depressions and restores skin hydration. It may also add volume to the lips and/or enhance their contour.
TEOSYAL® PureSense Deep Lines	Creates a volume that correct wrinkles, cutaneous depressions, and restores skin hydration.

Product	Expected performance
TEOSYAL PureSense KISS®	Creates a volume that corrects cutaneous depressions and restores skin hydration. It may also add volume to the lips and/or enhance their contour.
TEOSYAL® PureSense Ultra Deep	Creates a volume that corrects wrinkles or facial contours and restores skin hydration.
TEOSYAL® PureSense Ultimate	Creates a volume that corrects facial contours and restores skin hydration.
TEOSYAL® PureSense Redensity 1	Thanks to its marked fluidity and its viscoelastic 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	Creates a volume that corrects fine lines/wrinkles and restores skin hydration.
TEOSYAL RHA® 1	Thanks to its malleability and its specific viscoelastic properties, it is evenly distributed into the tissue injected, ensuring an optimal level of dermal hydration and leading to a lasting improvement in skin elasticity.
TEOSYAL RHA® 2	Creates a volume that correct wrinkles, cutaneous depressions and restores skin hydration. It may also add volume to the lips and/or enhance their contour.
TEOSYAL RHA® 3	Creates a volume that correct wrinkles, cutaneous depressions and restores skin hydration. It may also add volume to the lips and/or enhance their contour.
TEOSYAL RHA® 4	Creates a volume that corrects wrinkles, cutaneous depressions and restores skin hydration.
TEOSYAL RHA KISS®	Creates a volume that corrects wrinkles, cutaneous depressions and restores skin hydration. It may also add volume to the lips and/or enhance their contour.

## 2. What you need to know before you are given TEOSYAL® products

### 2.1. Contraindications

Are there any reasons why you should not receive TEOSYAL® products?

Prior to any injection of TEOSYAL® products, your injector must ask you about your past medical history and your current condition or medication that could affect the procedure. So, you should inform the injector about recent or current pathologies, as well as chronic illnesses, chronic or current allergies, and chronic or ongoing treatments.

You must report to your injector, aesthetic treatments performed previously. Due to the absence of data concerning the possible interactions with other filling implants (HA filling implants or other, possibly permanent), your injector will assess and decide on further injections with

other filling implants, depending on the nature and the time of the previous injection.

Especially, you should not use TEOSYAL® products if:

- You have any cutaneous disorders, inflammation, or infection at or near the treatment site. Injection procedures can lead to reactivation of latent or subclinical herpes viral infections.
- You are allergic to hyaluronic acid, with a history of severe allergy or anaphylactic shock.
- You are allergic to lidocaine and/or amide local anesthetic agents.
- You recently had a peeling, laser or ultrasound-based treatment.
- You have any autoimmune diseases.
- You have any cardiac diseases and/or undergoing treatment for heart disease (beta blockers).
- You have any hepatocellular insufficiency and/or undergoing treatment for a liver disease.
- You are suffering from epilepsy or porphyria.
- You are pregnant, or a breast-feeding mother, or a patient less than 18 years old.

### 2.2. Precautions

Are there precautions that you should discuss with your injector?

Your injector should inform you about the indications, expected outcomes, contraindications, precautions, and potential side effects.

Before the injection, the following precautions should be considered:

- 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.

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.

### 2.3. Possible side effects (risks linked to the use of TEOSYAL® products)

What possible reactions could occur following the injection?

As with all hyaluronic acid-based products, the following side effects can be seen after the injection of TEOSYAL® PureSense products:

Common treatment reactions ( $\geq 1/100$ ) at the injection site, usually mild and self-resolving: pain at the point of injection,

tenderness, redness/erythema, bruising/haematomas with potential bleeding and/or blister formation, swelling/oedema, firmness/induration, lumps/bumps (including papules), itching.

Probable but less common complications ( $\geq 1/1,000$  and  $\leq 1/100$ ): dyschromia/discoloration, inflammatory reactions (with potential hyperthermia), infection (including localized or generalized infection, abscesses), loss of sensitivity around the injected area or temporary paresthesia (with potential associated transient movement impairment), risk of allergy (including hypersensitivity, dermatitis allergy, urticaria), nodules (possibly granuloma), implant migration.

Rare but serious adverse events may occur ( $\leq 1/1,000$ ): immediate hypersensitivity which may even lead to anaphylactic shock, vascular complications which may extend to necrosis of the injected area. Although extremely rare (about 1/1,000,000), most serious cases of vascular occlusion may lead to visual disturbances or even blindness, cerebral ischemia/ hemorrhage leading to stroke which can cause death.

Other non-serious reactions reported to Teoxane (in rates inferior to 1/100,000) and possibly related to the device or procedure including headache, formation of fibrotic tissue under the skin, infection and inflammation of the dermis and subcutaneous tissue (known as cellulitis), scarring and appearance of vessels at the surface of the skin (known as telangiectasia).

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

#### Reporting of side effects:

In case of dissatisfaction with the expected aesthetic result or if any side effects occurred following treatment with a TEOSYAL® product, you should immediately contact your injector and/or TEOXANE Laboratories:

**00 41 (0) 22 344 96 36 - medical@teoxane.com**

Most of the reactions described above are gone within one week after the injection, however, you must see a doctor if your symptoms persist.

### 3. Expected lifetime of the products and any necessary follow-up

The lifetime of the product is understood as the duration of the aesthetic effect. It depends on several factors including skin type, the severity of the wrinkle to be treated, the injected area, the injected volume, the patient's physiology, and lifestyle.

Your injector will choose the product suitable for injection according to your needs and taking into account your request and will tell you if a touch up session may be required for optimal results.

The estimated lifetime of TEOSYAL® PureSense products is:

Estimated in vivo lifetime of at least 3 months:

- TEOSYAL® PureSense Redensity 1

Estimated in vivo lifetime of at least 12 months:

- TEOSYAL® PureSense Redensity 2
- TEOSYAL RHA® 1

Estimated in vivo lifetime between 12 to 18 months:

- TEOSYAL® PureSense Global Action
- TEOSYAL® PureSense Deep Lines
- TEOSYAL PureSense KISS®
- TEOSYAL RHA® 2
- TEOSYAL RHA® 3
- TEOSYAL RHA KISS®

Estimated in vivo lifetime between 15 to 18 months:

- TEOSYAL® PureSense Ultra Deep
- TEOSYAL® PureSense Ultimate
- TEOSYAL RHA® 4

### 4. Reference to any harmonized standard and common specifications

Some harmonized standards and Common specifications apply to the TEOSYAL® PureSense products. The complete list is available in the Summary of Safety and Clinical Performance (SSCP) which is available on Eudamed at the following website: [ec.europa.eu/tools/eudamed/#/screen/home](https://ec.europa.eu/tools/eudamed/#/screen/home).

