Disclaimer:

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HYALURONIC ACID

TEOSYAL Ultimate

CE 0086 *Syringe*

CE 0197 *Needle*

- Marquage CE conforme à la Directive 93/42/CEE relative aux dispositifs médicaux. Le numéro sous le marquage CE est le numéro de l'organisme notifié.
- CE labelling conforms to the 93/42/CEE EC Directive in relation to medical devices. The number below the CE is the number of the notified body.
- CE-Kennzeichen gemäß der Richtlinie 93/42/EWG für medizinische Produkte. Die Nummer unter dem CE-Kennzeichen ist die Nummer der zuständigen Stelle.
- Marcado CE conforme a la Directiva 93/42/CEE relativa a los dispositivos médicos. El número indicado bajo la marca CE es el número del organismo notificado.
- Marchio CE ai sensi della Direttiva 93/42/CEE relativa ai dispositivi medici. Il numero sotto il marchio CE è il numero dell'organismo notificato.
- Marcação CE conforme à Directiva 93/42/CEE relativa aos dispositivos médicos. O número por baixo do CE é o número do organismo notificado.
- Маркировка CE соответствует Директиве 93/42/EEC, регламентирующей технические характеристики медицинских устройств. Номер, согласно CE, является номером уполномоченного органа.
- CE etiketi, tıbbi aygıtlara ilişkin 93/42/CEE Yönergesine uymaktadır. CE yazısının altındaki numara onaylanmış kuruluşun numarasıdır.

Fabriqué par / Manufactured by
Hergestellt durch / Fabricado por
Prodotto da / Fabricado por
Изготовитель / Üretici firma

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- Ne pas réutiliser
- Do not re-use
- Nicht wiederverwenden
- No reutilizar
- Non riutilizzare
- Não reutilizar
- Не использовать повторно
- Tekrar kullanmayın

- Se reporter à la notice intérieure
- Refer to the package insert leaflet
- Beiliegende Gebrauchsanweisung beachten
- Ver el prospecto interior
- Attenersi al foglietto illustrativo interno
- Consultar as instruções no interior
- Ознакомьтесь с пояснительной запиской внутри коробки
- Ambalajın içindeki talimatlar sayfasına bakın

STERILE *Only for syringe*

- Stérile - stérilisé à la chaleur humide
- Sterile - sterilised in moist heat
- Steril. Mit Wasserdampf sterilisiert
- Estéril - esterilizado por calor húmedo
- Sterile - sterilizzare a vapore
- Estéril – esterilizado ao calor húmido
- Стерильный шприц – стерилизовано влажной тепловой обработкой
- Steril - buhar ısısıyla sterilize edilmiştir

25°C
2°C

- Température de stockage
- Storage temperature
- Lagertemperatur
- Temperatura de almacenamiento
- Temperatura di conservazione
- Temperatura de armazenamento
- Температура хранения
- Saklama sıcaklığı

LOT

- Numéro de lot
- Batch number
- Chargennummer
- Número de lote
- Lotto numero
- Número de lote
- Номер партии
- Parti no

- Date de péremption
- Expiry date
- Verfalisdatum
- Fecha de caducidad
- Data di scadenza
- Data de expiração
- Дата истечения срока годности
- Son kullanma tarihi

(GB) Instruction leaflet

Description
Teosyal Ultimate is a transparent, no pyrogenic, visco-elastic gel of reticulated hyaluronic acid, of non animal origin. Each box contains one syringe prefilled with Teosyal Ultimate, two sterile 23G1" needles and two tracability labels (one to be given to the patient, and one to be kept by the doctor in the patient's file).
The volume of each syringe is shown on the box as well as on each syringe.

Composition
Reticulated hyaluronic acid .....66 mg
Phosphate buffer pH 7.3.....q.s. ad 3 mL

Indications
The therapeutic purposes of Teosyal® products are;
- to modify the anatomy of aged skin: restoration of volumes, filling of skin depression and wrinkle, restoration of skin hydration,
- reconstructive surgery: filling of depressions due to scars, reconstruction of volumes lost by lipoatrophy.

Teosyal Ultimate is indicated for adding volume to facial tissue, in areas such as the cheeks, chin and other areas of volume loss. Facial contours are remodelled.

Mode of action
Teosyal Ultimate is injected at variable depth depending on the area to be treated: this varies from fatty subcutaneous tissue to pre-periosteal facial areas. Teosyal Ultimate creates a volume that fills the cutaneous depression and restores the contours of the face.
Teosyal Ultimate is biodegradable and is slowly resorbed over time.
Generally, one or sometimes two treatment sessions are necessary, depending upon the depth of the injection and the area to be treated, to obtain an optimal degree of correction.
Later touch-up sessions may be useful to enable the sought-after degree of correction to be maintained. The effectiveness of the correction depends on many parameters such as the injection technique, as well as the nature and elasticity of the area to be treated.

Contra-indications
Teosyal Ultimate must not be used:
- for injections other than subcutaneous and/or pre-periosteal injections
- in combination with peeling, laser or ultrasound-based treatments
- if the patient has cutaneous disorders, inflammation or infection at the treatment site or near to this site,
- in the case of patients having a known hypersensitivity to hyaluronic acid, with a history of severe allergy or anaphylactic shock
- in case of patients with autoimmune diseases
- since interactions with other filling implants have not been researched, it is inadvisable to inject Teosyal Ultimate into sites where filling implants other than those in the Teosyal range are present.
- in pregnancy, breast-feeding mothers, or in children
- Do not inject into blood vessels

Dosage and method of administration
The injection of Teosyal Ultimate is reserved for practitioners trained in sub-cutaneous and/or pre-periosteal injection techniques for adding volume to the sub-cutaneous facial tissue.
Before beginning treatment, patients will be required to complete a medical history and must be informed of the foreseeable outcome of treatment and of potential undesirable effects.
Patients may ask their practitioner directly about the possibility of using either local or regional anaesthetic block.
The areas to be treated must be disinfected with a suitable antiseptic solution.
Teosyal Ultimate should be injected using hypodermic needles of size 23G1", such as the needles supplied with the product. Depending on the injection technique, it is also possible to use a round cannula with side holes, available from your distributor.
- Inject the product slowly ensuring the needle advances along the desired trajectory, checking the position of the needle with your free hand and adjusting the quantity of product injected. The injection technique may vary according to the area to be treated and the quantity administered. It is therefore essential that the practitioner be qualified in the techniques for adding volume to subcutaneous facial tissue.
- Stop the injection well before withdrawing the needle from the skin to avoid the product flowing out of the treatment site.

• For optimum results, massage the treated sites carefully in order to ensure a uniform distribution of the product at the corrected sites.
• Avoid injecting superficially
• In the event of slight swelling on the site immediately after the injection, melted ice may be applied to the site for a few moments.

The injection volume depends upon the correction required. It is however recommended not to exceed the contents of one syringe per treatment site during each session. It is important not to overcorrect.

Side effects
- Redness, swelling, oedema, hematomas, itching and slight pain at the injection site may occur following treatment. These generally disappear within 1-2 weeks.
- induration, staining
- rare cases of necrosis, nodules, granulomas, hypersensitivity, abscess formation and migration of the implant have been described in the literature after the injection of hyaluronic acid. The practitioner must therefore inform the patient of these potential risks.

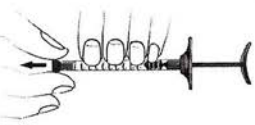
All side effects other than those described above or persisting for more than 2 weeks must be reported to the practitioner by the patient. In turn, the practitioner will inform the product's retailer of this as soon as possible.

Assembly the needle on the syringe
For optimum use of Teosyal® products, it is important for the needle to be assembly on the syringe following the 4 steps detailed in the diagrams (see figures for steps 1 to 5).
Stop the injection and change the needle if you feel an obstruction or pressure during the injection.

Precautions for use
Verify the expiry date and the integrity of the packaging before use. Do not use if the expiry date is exceeded or if the packaging is damaged. You should warn the patient not to take high-dose Vitamin E, aspirin, anti-inflammatories or anti-coagulants the week before the injections session. Advise the patient not to use make-up during the 12 hours following injection and to avoid extreme temperatures (intense cold, sauna, etc.) during the week following treatment.
At the end of the treatment session, it is essential to discard all remaining unused product. This device is intended for single use only. Sterility is not guaranteed in the event of re-use. The gel can deteriorate, reducing its efficiency and the gel can dry out, hindering its extrusion through a needle. The implantation of Teosyal Ultimate consists of a subcutaneous and/or pre-periosteal injection. It is therefore a medical procedure which involves an inherent risk of infection, like any procedure of this type. It must be carried out in a suitable environment and all the usual precautions must be taken. In addition, the medical practitioner must have good knowledge of the facial anatomy.
Dispose of used needles in appropriate containers.

Storage conditions
Store between 2°C and 25°C, away from direct sunlight.
Make sure there are no visible signs of damage to the packaging before use.

1



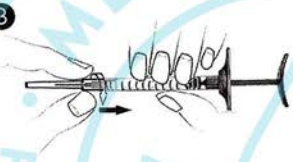
- Enlever le bouchon de la seringue en le tirant, comme illustré à la figure 1
- Remove the stopper from the syringe by pulling it, as shown in figure 1
- Schutzkappe der Spritze abziehen, wie in Abbildung 1 illustriert
- Retirar el tapón de la jeringuilla tirando de él, como se ilustra en la figura 1

2

- Retirer le capuchon de l'aiguille fournie, puis insérer le pas de vis de l'aiguille fermement dans l'embout de la seringue (fig. 2).

- Remove the cap from the needle provided, then insert the screw thread of the needle firmly into the syringe end-piece (fig. 2).
- Die mitgelieferte Nadel an der Schutzkappe entnehmen, dann den Gewindeteil der Schraube fest in das Ansatzstück der Spritze einführen (Abb. 2).
- Retirar el capuchón de la aguja proporcionada, luego introducir el paso de tornillo de la aguja firmemente en la boquilla de la jeringuilla (fig. 2).

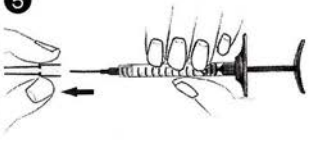
3



4

- Visser l'aiguille dans le sens des aiguilles d'une montre, tout en maintenant une légère pression entre l'aiguille et la seringue (fig 3). Continuer de visser jusqu'à ce que le bord du capuchon de l'aiguille entre en contact avec le corps de la seringue. Il ne doit pas rester d'espace entre ces 2 éléments (fig. 4). Le non-respect de cette consigne peut entraîner un risque d'éjection d'aiguille et / ou de fuite au niveau du Luer-Lock.
- Screw the needle clockwise, while maintaining slight pressure between the needle and the syringe (fig. 3). Continue screwing until the edge of the cap of the needle contacts the body of the syringe. There must be no space between these two parts (fig. 4). Failure to respect this instruction means that the needle could be ejected and/or leak at the Luer-Lock.
- Die Nadel im Uhrzeigersinn einschrauben und dabei einen leichten Druck auf Nadel und Spritze ausüben (Abb. 3). Weiter einschrauben, bis die Kante der Schutzkappe der Nadel den Spritzenkörper berührt. Es darf kein Zwischenraum zwischen diesen 2 Elementen bestehen bleiben (Abb. 4). Das Nichtbefolgen dieser Anweisung kann ein Abfallen der Nadel und/oder ein Lösen des Luer Lock Anschlusses zur Folge haben.
- Atornillar la aguja en dirección de las manecillas del reloj, manteniendo al mismo tiempo una ligera presión entre la aguja y la jeringuilla (fig 3). Seguir atornillando hasta que el borde del capuchón de la aguja entre en contacto con el cuerpo de la jeringuilla. No debe quedar ningún espacio entre estos 2 elementos (fig. 4). El incumplimiento de esta consigna puede conllevar un riesgo de eyección de la aguja y/o fuga a nivel del Luer-Lock.

5



- Retirer ensuite la protection de l'aiguille, en tirant fermement celle-ci avec une main, tout en tenant le corps de seringue avec l'autre main. (fig.5).

- Remove the needle's protection by pulling it firmly with one hand while holding the body of the syringe with the other (fig.5).
- Entfernen Sie dann den Nadelschutz durch kräftiges Ziehen mit der einen Hand, während sie den Spritzenkörper mit der anderen Hand festhalten. (Abb.5).
- Seguidamente, retirar la protección de la aguja, tirando firmemente de él con una mano, y sujetando al mismo tiempo el cuerpo de la jeringuilla con la otra mano. (fig.5).