EN Only for professional use
FR Réservé à un usage professionnel
ES Solo para uso profesional
PT Apenas para uso profissional

1

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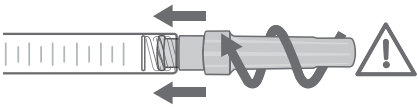

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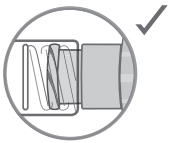

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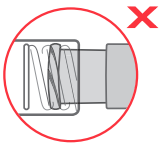

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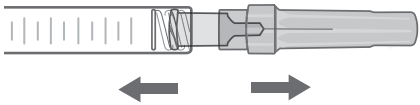

EN

COMPOSITION

Hyaluronic Acid gel	24 mg
Phosphate buffer pH 7.2 q.s.	1 mL

One syringe contains 0.8 mL of ***Juvéderm ULTRA PLUS™***.

DESCRIPTION

Juvéderm ULTRA PLUS™ is a sterile pyrogen-free physiological solution of cross-linked hyaluronic acid which is not of animal origin. The gel is presented in a graduated, pre-filled, disposable syringe. Each box contains two 0.8 mL ***Juvéderm ULTRA PLUS™*** syringes, 4 single-use 27G1/2" sterile needles to be used only for injecting ***Juvéderm ULTRA PLUS™***, an instruction leaflet and a set of labels in order to ensure traceability.

STERILISATION

The contents of the ***Juvéderm ULTRA PLUS™*** syringes is sterilised by moist heat.
The 27G1/2" needles are sterilised by radiation.

INDICATIONS

Juvéderm ULTRA PLUS™ is an injectable implant used for filling mid and/or deep depressions of the skin via mid and/or deep dermis injection, as well as for lip definition and enhancement.

CONTRA-INDICATIONS

• Do not inject ***Juvéderm ULTRA PLUS™*** in the periorbital area (eyelids, crow's feet) and glabellar region (forehead). The application of ***Juvéderm ULTRA PLUS™*** in the under-eye area is to be performed only by specialists specifically trained in this technique who have a sound knowledge of the physiology of this particular area.
• Do not inject into the blood vessels (intravascular). Intravascular injection may lead to embolization, occlusion of the vessels, ischemia or infarction.
• Do not overcorrect.
• ***Juvéderm ULTRA PLUS™*** must not be used in:
- Patients who tend to develop hypertrophic scarring;
- Patients with known hypersensitivity to hyaluronic acid and/or to gram positive bacterial proteins as hyaluronic acid is produced by Streptococcus type bacteria;
- Women who are pregnant or breastfeeding;
- Children.
• ***Juvéderm ULTRA PLUS™*** must not be used in areas presenting cutaneous inflammatory and/or infectious processes (acne, herpes, etc.).
• ***Juvéderm ULTRA PLUS™*** should not be used simultaneously with laser treatment, deep chemical peels or dermabrasion. For surface peels, it is recommended not to inject the product if the inflammatory reaction generated is significant.

PRECAUTIONS FOR USE

• ***Juvéderm ULTRA PLUS™*** is indicated only for intradermal injections and injections in the mucous membrane of the lips.

• ***Juvéderm ULTRA PLUS™*** is not intended for use in breast augmentation/reconstruction.

• As a matter of general principle, injection of a medical device is associated with a risk of infection. Standard precautions associated with injectable materials shall be followed.

• There is no available clinical data about injection of ***Juvéderm ULTRA PLUS™*** into an area which has already been treated with a non–ALLERGAN dermal filler.

• It is recommended not to inject into a site which has been treated with a permanent implant.

• No clinical data is available regarding the efficiency and tolerance of ***Juvéderm ULTRA PLUS™*** injections in patients having a history of, or currently suffering from, autoimmune disease or autoimmune deficiency or being under immunosuppressive therapy. The medical practitioner shall 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 ensure the specific monitoring of these patients. In particular, it is recommended that these patients undergo a preliminary skin testing for hypersensitivity, and to refrain from injecting the product if the disease is active.

• There is no available clinical data concerning the tolerance of ***Juvéderm ULTRA PLUS™*** injection in patients presenting a history of severe and/or multiple allergies. The medical practitioner shall therefore decide on the indication on a case-by-case basis, according to the nature of the allergy, and shall also ensure the specific monitoring of these at-risk patients. In particular, the decision may be taken to propose a skin testing for hypersensitivity or suitable preventive treatment prior to any injection. In case of history of anaphylactic shock, it is recommended not to inject the product.

• Patients showing a history of streptococcal disease (recurrent sore throats, acute rheumatic fever) shall be subjected to a skin testing for hypersensitivity before any injection is administered.

In the event of acute rheumatic fever with heart complications, it is recommended not to inject the product.

• Patients on anti-coagulation medication or using substances that can prolong bleeding (warfarin, acetylsalicylic acid, nonsteroidal anti-inflammatory drugs, or other substances known to increase coagulation time such as herbal supplements with garlic or ginkgo biloba, etc.) must be warned of the potential increased risks of bleeding and haematomas during injection.

• There is no data available regarding the safety of injecting greater amount than 20 mL of ALLERGAN dermal fillers per 60 kg (130 lbs) body mass per year.

• Please recommend that the patient not use any makeup during the 12 hours following the injection treatment and that any extended exposure to the sun, UV rays and temperatures below 0°C be avoided, as well as any sauna or hammam sessions during the two weeks following the injection treatment.
• The composition of this product is compatible with fields used for magnetic resonance imaging.

INCOMPATIBILITIES

Hyaluronic acid is known to be incompatible with quaternary ammonium salts such as benzalkonium chloride. ***Juvéderm ULTRA PLUS™*** should therefore never be placed in contact with these substances or with medical-surgical instrumentation which has been treated with this type of substance.

UNDESIRABLE EFFECTS

The patients must be informed that there are potential side effects associated with implantation of this product, which may occur immediately or may be delayed. These include, but are not limited to:
• Inflammatory reactions (redness, oedema, erythema, etc.) which may be associated with itching and/or pain on pressure and/or paresthesia, occurring after the injection. These reactions may last for a week.
• Haematomas.
• Induration or nodules at the injection site.
• Staining or discolouration of the injection site might be observed, especially when HA dermal filler is injected too superficially and/or in thin skin (Tyndall effect).
• Poor effect or weak filling effect.
• Rare but serious adverse events associated with intravascular injection of dermal fillers in the face and tissue compression have been reported and include temporary or permanent vision impairment, blindness, cerebral ischemia or cerebral hemorrhage, leading to stroke, skin necrosis and damage to underlying structures. Immediately stop the injection if a patient exhibits any of the following symptoms, including changes in the vision, signs of stroke, blanching of the skin or unusual pain during or shortly after the procedure. Patients should receive prompt medical attention and possibly evaluation by an appropriate medical practitioner specialist should an intravascular injection occur. Abscesses, granuloma and immediate or delayed hypersensitivity after hyaluronic acid injections have also been reported. It is therefore advisable to take these potential risks into account.
• Patients must report inflammatory reactions which persist for more than one week, or any other side effect which develops, to their medical practitioner as soon as possible. The medical practitioner should use an appropriate treatment.
• Any other undesirable side effects associated with injection of ***Juvéderm ULTRA PLUS™*** must be reported to the distributor and/or to the manufacturer.

METHOD OF USE – POSOLOGY

• This product is designed to be injected into the dermis or the mucous membrane of the lips by an authorized medical practitioner in accordance with local applicable regulation. In order to minimize the risks of potential complications and as precision is essential to a successful treatment, the product should be only used by medical practitioners who have appropriate training, experience and who are knowledgeable about the anatomy at and around the site of injection. The nappage technique can also be used with this product.

• ***Juvéderm ULTRA PLUS™*** is to be used as supplied. Modification or use of the product outside the Directions for Use may adversely impact the sterility, homogeneity and performance of the product and it can therefore no longer be assured.

• Prior to treatment, medical practitioners shall inform their patients about the product's indications, contra-indications, incompatibilities and potential undesirable effects/risks associated with dermal fillers injection and ensure that patients are aware of signs and symptoms of potential complications.

• The area to be treated should be disinfected thoroughly prior to the injection.

• Remove tip cap by pulling it straight off the syringe as shown in fig. 1. Then firmly push the needle provided in the box (fig. 2) into the syringe, screwing it gently clockwise. Twist once more until it is fully locked and has the needle cap in the position shown in fig. 3. If the needle cap is positioned as shown in fig. 4, it is incorrectly attached.

Next, remove the protective cap by holding the body of the syringe in one hand, the protective cap in the other, as shown in fig. 5, and pulling the two hands in opposite directions.

Prior to injecting, depress the plunger rod until the product flows out of the needle.

Inject slowly and apply the least amount of pressure necessary.

If the needle is blocked, do not increase the pressure on the plunger rod. Instead, stop the injection and replace the needle.

Failure to comply with these precautions could cause a disengagement of the needle and/or product leakage at luer-lock level and/or increase the risk of vascular compromise.

• After needle insertion and before injection, it is recommended to withdraw slightly the plunger to aspirate and verify the needle is not intravascular.

• If immediate blanching occurs at any time during the injection, the injection should be stopped and appropriate action taken such as massaging the area until its return to a normal color.

• 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. The amount injected will depend on the areas which are to be corrected based on the experience of the medical practitioner.
• Do not overcorrect as injection of an excessive volume can be at the origin of some side effects such as tissue necrosis and oedema.
• A touch up (for achieving optimal correction) and/or a repeat (for maintaining optimal correction) treatment with ***Juvéderm ULTRA PLUS™*** might be required.
• It is recommended to wait until side effects are resolved (with a minimal interval of 2 weeks) between two injections.
• It is important to massage the area treated after the injection in order to ensure that the substance has been uniformly distributed.

WARNINGS

• Check the expiry date on the product label.
• In the event that the content of a syringe shows signs of separation and/or appears cloudy, do not use the syringe.
• Do not re-use. Sterility of this device cannot be guaranteed if the device is re-used.
• Do not re-sterilise.
• For the needles (CE 0123 TSK Laboratory, Japan):
EC-Representative : Emergo Europe
Molenstraat 15
2513 BH The Hague (NL)
- Used needles must be thrown away in the appropriate containers. Do the same for the syringes. Please consult the current applicable directives to ensure their correct elimination.
- Never try to straighten a bent needle; throw it away and replace it.

STORAGE CONDITIONS

• Store between 2°C and 25°C.
• Fragile.

• Il n'y a pas de données quant à la sécurité d'injection d'un volume supérieur à 20 mL de produits de comblements ALLERGAN par 60kg de masse corporelle par an.
• Recommander au patient de ne pas se maquiller pendant les 12 heures qui suivent l'injection et d'éviter l'exposition prolongée au soleil, aux UV, aux températures inférieures à 0°C, ainsi que la pratique du sauna ou hammam pendant les deux semaines qui suivent l'injection.
• La composition du dispositif rend le produit compatible avec les champs utilisés pour l'imagerie de résonance magnétique.

INCOMPATIBILITES

Il existe une incompatibilité connue entre l'acide hyaluronique et les sels d'ammonium quaternaire tels que le chlorure de benzalkonium. Il conviendra donc de ne jamais mettre ***Juvéderm ULTRA PLUS™*** en contact avec de tels produits, ni avec du matériel médico-chirurgical traité avec ce type de produit.

EFFETS INDESIRABLES

Le patient doit être informé qu'il existe des effets secondaires potentiels liés à l'implantation de ce dispositif survenant immédiatement ou de façon retardée. Parmi ceux-ci (liste non exhaustive) :
• Des réactions inflammatoires (rougeur, œdème, érythème...) pouvant être associées à des démangeaisons, des douleurs à la pression ou des picotements peuvent survenir après l'injection. Ces réactions peuvent persister une semaine.
• Hématomes.
• Induration ou nodules au point d'injection.
• Coloration ou décoloration de la zone d'injection peuvent être observées en particulier quand le produit de comblement est injecté trop superficiellement dans une peau fine (effet Tyndall).
• Faible efficacité ou faible effet de comblement.
• Des événements indésirables rares mais graves associés à l'injection intravasculaire de produit de comblement dans le visage et à une compression des tissus ont été reportés. Cela inclue des troubles temporaires ou permanents de la vision, la cécité, une ischémie ou hémorragie cérébrale, conduisant à un AVC, une nécrose de la peau et des dommages aux structures sous-jacentes. Arrêter immédiatement l'injection si un patient présente l'un des symptômes suivants, modification de la vision, des signes d'AVC, blanchiment de la peau ou douleur inhabituelle pendant ou peu de temps après l'injection. Ces patients doivent faire l'objet d'une prise en charge médicale rapide et, si possible, d'une évaluation par un médecin spécialisé si une injection intravasculaire se produit. Des cas d'abcès, de granulome et d'hypersensibilité immédiate ou retardée ont aussi été rapportés après injection d'acide hyaluronique. Il convient donc aussi de prendre en compte ces risques potentiels.

• Après insertion de l'aiguille et avant d'injecter, il est recommandé d'effectuer une légère rétro-aspiration afin de vérifier que l'aiguille ne se trouve pas dans un vaisseau sanguin.
• Si un blanchiment de la zone traitée apparait immédiatement au cours de l'injection, l'injection doit être arrêtée et un traitement approprié doit être envisagé comme masser la zone jusqu'à reprise d'une coloration normale.
• Le degré et la durée de correction dépendent de la nature du défaut traité, de la contrainte tissulaire au site d'injection, de la profondeur d'implantation dans le tissu et de la technique d'injection. La quantité à injecter est fonction de la zone à corriger et est basée sur l'expérience du praticien.
• Ne pas sur-corriger car l'injection d'un volume excessif peut être à l'origine d'effets indésirables tels qu'une nécrose tissulaire ou un œdème.
• Une retouche (pour obtenir une correction optimale) et/ou un traitement répété (pour maintenir une correction optimale) avec ***Juvéderm ULTRA PLUS™*** peut être requis.
• Il est recommandé d'attendre la résolution des effets secondaires (avec un intervalle minimal de 2 semaines) entre 2 injections.
• Après l'injection, il est important de masser la zone traitée afin de s'assurer que le produit est bien réparti uniformément.

MISE EN GARDE

• Vérifier la date de péremption sur l'étiquetage.
• Dans le cas où le contenu de la seringue montre des signes de phasage et/ou semble trouble, ne pas utiliser la seringue.
• Ne pas réutiliser. En cas de réutilisation de ce dispositif, la stérilité du produit ne peut être garantie.
• Ne pas restériliser.
• Pour les aiguilles (CE 0123 Laboratoire TSK , Japon):
Mandataire européen : Emergo Europe
Molenstraat 15
2513 BH The Hague (NL)
- Les aiguilles usagées devront être mises au rebut dans un collecteur prévu à cet effet. Procéder de même pour les seringues. Se référer aux directives en vigueur pour assurer leur élimination.
- Ne jamais tenter de redresser une aiguille recourbée mais la jeter et la remplacer.

CONDITIONS DE CONSERVATION

• Conserver entre 2°C et 25°C.
• Fragile.

ser alertados sobre o aumento potencial dos riscos de sangramento e hematomas no local de aplicação.
• Não há dados clínicos disponíveis relativos à segurança da injeção de volume superior a 20mL de preenchedor intracutâneo ALLERGAN por 60kg (130lbs) de massa corporal por ano.
• Recomendar ao paciente a não utilizar qualquer tipo de maquiagem nas 12 horas seguintes ao tratamento e que qualquer exposição prolongada ao sol, raios UV e temperaturas abaixo de 0 °C sejam evitadas, assim como as sessões de sauna ou banho turco nas duas semanas seguintes ao tratamento por injeção.
• A composição deste produto é compatível com os campos usados para imagiologia por ressonância magnética.

INCOMPATIBILIDADES

O ácido hialurônico é conhecido por ser incompatível com sais de amônio quaternário, tais como cloreto de benzalcônio. Portanto, ***Juvéderm ULTRA PLUS™*** não deve ser colocado em contato com sais de amônio quaternário ou com material médico-cirúrgico que tenha sido tratado com este tipo de substância.
Não é conhecida qualquer interação com outros anestésicos locais.

EFEITOS INDESEJÁVEIS

Os pacientes devem ser informados de que existem potenciais efeitos colaterais associados com a implantação deste produto, os quais podem ocorrer imediatamente ou após algum tempo. Estes incluem, mas não se limitam a:
• Reações inflamatórias (vermelhidão, edema, eritema, etc.) que podem estar associados com prurido e/ou dores ao pressionar e/ou parestesia, podendo ocorrer após a injeção. Estas reações podem persistir durante uma semana.
• Hematomas.
• Endurecimento ou nódulos no local de aplicação.
• Coloração ou descoloração no local de aplicação podem ser observadas, especialmente quando o preenchedor cutâneo é injetado superficialmente e/ou em pele fina (efeito Tyndall).
• Efeito deficiente ou fraco efeito de preenchimento.
• Efeitos adversos raros, porém graves, associados à injeção intravascular de preenchedores cutâneos na compressão do rosto e tecidos têm sido relatados, os quais incluem lesões temporárias ou permanentes da visão, cegueira, isquemia ou hemorragia cerebral, resultando em acidente vascular cerebral, necrose da pele e danos nas estruturas subjacentes. Deve-se parar imediatamente a injeção se um paciente apresentar algum dos seguintes sintomas, incluindo alterações na visão, sinais de acidente vascular cerebral, branqueamento da pele ou dor incomum durante ou logo após o procedimento. Os pacientes devem receber atenção médica imediata e devem ser avaliados por um especialista caso ocorra injeção intravascular. Também

- Do not use if package is damaged
- Ne pas utiliser si l'emballage est endommagé
- No utilizar si embalaje dañado
- Não utilizar se a embalagem estiver danificada

- Attention; see instructions for use
- Attention, voir la notice d'instructions
- Atención, lea las instrucciones para su uso
- Atenção; consultar as Instruções de Uso

- Use-by date
- Utiliser jusqu'à la date
- Utilizar antes de fecha
- Utilizar até

- Sterilized using irradiation
- Stérilisé en utilisant l'irradiation
- Esterilizado usando irradiación
- Esterilizado por irradiação