

TEOSYAL Touch Up



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/ЕЕС, регламентирующей технические характеристики медицинских устройств.

Номер, согласно CE, является номером уполномоченного органа.

CE etiketi, tibbi auygurları İliş, kin 93/42/CEE Yönergesine uyumaktadır.

CE yazısının altındaki numara onaylanmış, kurulmuş ve numaralandırılmıştır.

CE märkning överensstämmer med EG-direktiv 93/42/EEG förhållande till medicintekniska produkter.

Numret under CE är numret för det anmälda organet.

Fabriqué par - Manufactured by - Hergestellt durch - Fabricado por - Prodotto da

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Ne pas réutiliser
Do not re-use
Nicht wiederverwenden
No reutilizar
Non riutilizzare
Nao reutilizar
не использовать повторно
Får inte återanvändas
Tékár kullanyávas
Får inte återanvändas

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

Stérile - stérilisé à la chaleur humide
Sterile - sterilised in moist heat
pour des injections autres qu'intradermiques
Steril. Mit Wasserdampf sterilisiert
Esteril - esterilizado por calor húmedo
Sterile - sterilizzate a vapore
Esteril - esterilizado ao calor húmedo
Стерильный шприц - стерилизовано влажной тепловой обработкой
Steril - buhar sisli sterilize edilmiştir
Steril - steriliserad med fuktig värme

Température de stockage
Storage temperature
Lagertemperatur
Temperatura de almacenamiento
Temperatura di conservazione
Temperatura de armazenagem
Температура хранения
Saklama sıcaklığı
Förvaringstemperatur

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

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

Tenir à l'abri de la lumière du soleil
Store away from sunlight
Von der Sonne fernhalten
Mantener al abrigo de la luz del sol
Conservare al riparo dalla luce solare
Mantar ao abrigo da luz do sol
Хранить защищенном от солнечного света
Güneş ışından uzak tutun
Skyddas mot solljus

Numéro de référence
Reference number
Referenznummer
Número de referencia
Número di riferimento
Número de referência
Артикул номер
Referans numarası
Referenznummer

Notice d'utilisation

Description
TEOSYAL® 30G Touch Up est un gel viscoélastique d'acide hyaluronique réticulé, stérile, non pyrogène, transparent, d'origine non animale. Chaque boîte contient deux seringues pré-remplies de TEOSYAL® 30G Touch Up. Pour chaque seringue, la boîte contient une aiguille stérile 30G1/2" et deux étiquettes de traçabilité (dont une à remettre au patient, et une étiquette à conserver par le médecin dans le dossier patient). Le volume de chaque seringue est indiqué sur le conditionnement carton ainsi que sur chaque seringue.

Composition
Acide hyaluronique réticulé 25 mg
Tampon phosphate pH 7,3 qsp 1 ml

Indications
Les actions thérapeutiques des produits TEOSYAL® sont les suivantes:
- modification de la structure de la peau mature : restauration des volumes, comblement des rides et des plis de la peau, restauration de l'hydratation cutanée
- chirurgie reconstructive : comblement des marques dues à des cicatrices, reconstruction des volumes perdus suite à une lipotraphie.

Mode d'action
TEOSYAL® 30G Touch Up s'injecte dans le derme moyen, à l'endroit de la dépression cutanée que l'on souhaite corriger. TEOSYAL® 30G Touch Up crée ainsi un volume qui comble les rides. TEOSYAL® 30G Touch Up est biodégradable et se résorbe lentement dans le temps. En fonction de la profondeur des rides à traiter, en général une, mais parfois deux séances de traitement sont nécessaires à l'obtention d'un niveau de correction optimal. Des séances de retouche périodiques permettent ensuite de maintenir le niveau de correction désiré.

Contre-indications
TEOSYAL® 30G Touch Up ne doit pas être utilisé :
- pour la correction des rides superficielles.
- pour des injections autres qu'intradermiques
- en association avec un peeling, un traitement au laser ou à base d'ultrasounds
- si le patient souffre d'affections cutanées, d'inflammation ou d'infection sur la zone à traiter ou à proximité de cette zone.
- dans le cas de patients ayant une hypersensibilité connue à l'acide hyaluronique, avec des antécédents d'allergies sévères ou de choc anaphylactique.
- dans le cas de patients souffrant de maladies auto-immunes.
- Les interactions avec d'autres implants de comblement n'ayant pas été étudiées, il est déconseillé d'injecter TEOSYAL® 30G Touch Up sur des zones en présence d'autres implants de comblement.
- chez la femme enceinte, allaitant, ou chez les enfants

Posologie et mode d'administration
L'injection de TEOSYAL® 30G Touch Up est réservée à des praticiens formés aux techniques d'injection de produits destinés au comblement des rides. Avant de débuter le traitement, il est nécessaire de bien interroger le patient sur ses antécédents médicaux, de l'informer des résultats prévisibles du traitement, et de ses effets indésirables potentiels. Bien désinfecter les zones à corriger. Il est recommandé d'injecter à l'aide de l'aiguille fournie dans la boîte. TEOSYAL® 30G Touch Up s'injecte lentement dans le derme moyen à l'aide de la technique d'injection linéaire traçante. Si l'injection est faite de façon trop profonde, c'est-à-dire dans le tissu sous-cutané, la correction n'aura pas la durabilité escomptée. Une injection trop profonde se reconnaît au fait que les tissus sous-cutanés n'offrent pas de résistance lors de l'injection du produit, contrairement au derme. Si on peut voir la couleur de l'aiguille sous la peau lors de l'injection, cela signifie que cette injection sera trop superficielle ce qu'il conviendrait également d'éviter, car le résultat de la correction pourra être irrégulier. Le volume à injecter dépend des corrections à effectuer. Il est toutefois recommandé de ne pas dépasser 3 ml par séance. Il est important de ne pas surcorriger. Bien masser les zones traitées afin de s'assurer de la répartition uniforme du produit dans les zones corrigées.

Effets secondaires
Le praticien doit informer le patient qu'il existe des effets secondaires potentiels liés à l'implantation de ce dispositif servant immédiatement après injection ou de façon retardée. Parmi ceux-ci (liste non exhaustive):
- Manifestations locales: réactions inflammatoires (érythème, œdème, douleur au point d'injection), hématomes, démangeaisons, pertes de sensibilité transitoire au niveau de la zone injectée, dyschromie, abcès, indurations, nodules (pouvant être des granulomes), nécroses cutanées, migrations de l'implant.
- Manifestations générales: hypersensibilité immédiate pouvant aller jusqu'à choc anaphylactique.
Tout effet secondaire autre que ceux décrits ci-dessus ou persistant au-delà d'une semaine devra être signalé au praticien par le patient.

Assemblage de l'aiguille sur la seringue
Pour une manipulation optimale des produits TEOSYAL®, il est important que l'aiguille soit montée sur la seringue conformément aux 5 étapes mentionnées dans le schéma (voir figures étapes 1 à 5).

Précautions d'emploi
Vérifier la date de péremption et l'intégrité de l'emballage avant utilisation. Ne pas utiliser si la date de péremption est dépassée ou si l'emballage est endommagé. Il convient de déconseiller au patient de prendre, la semaine précédant la séance d'injection, de la vitamine E à forte dose, de l'aspirine, des anti-inflammatoires ou des anticoagulants. Recommander au patient de ne pas se maquiller pendant les douze heures qui suivent l'injection et de ne pas s'exposer à des températures extrêmes (froid intense, sauna, hammam...) pendant la semaine qui suit le traitement. A la fin de la séance de traitement, il est impératif de jeter tout reste de produit inutilisé. Ce dispositif est destiné à un usage unique. En cas de réutilisation, la stérilité n'est plus garantie, le gel peut être détérioré réduisant son efficacité et le gel peut avoir séché gênant son extrusion à travers une aiguille. Jeter les aiguilles usagées dans des collecteurs appropriés.

Conditions de conservation
Conserver entre 2°C et 25°C, à l'abri du rayonnement direct du soleil. Avant utilisation s'assurer de l'absence de signes visibles de détérioration du conditionnement.

Instruction leaflet

Description
TEOSYAL® 30G Touch Up is a transparent, non pyrogenic, sterile, cross-linked, hyaluronic acid, visco-elastic gel of non-animal origin. Each box contains two pre-filled syringes of TEOSYAL® 30G Touch Up. For each syringe, the box contains one sterile 30G1/2" needle and two traceability 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 packaging carton as well as on each syringe.

Composition
Cross-linked hyaluronic acid 25 mg
Phosphate buffer pH 7.3 q.s. ad 1 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 lipotrophy.
TEOSYAL® 30G Touch Up is indicated for the correction of moderate wrinkles on the face and for touch-up sessions in addition to a treatment with a product from the TEOSYAL® range.

Mode of action
TEOSYAL® 30G Touch Up is injected into the mid dermis at the site of the cutaneous depression to be corrected. TEOSYAL® 30G Touch Up creates a volume that corrects wrinkles. TEOSYAL® 30G Touch Up is biodegradable and is slowly resorbed over time. In general, one, but sometimes two treatment sessions are necessary, depending upon the depth of the wrinkles in need of treatment, to obtain an optimal degree of correction. Periodic touch-up sessions then enable the sought after degree of correction to be maintained.

Contra-indications
TEOSYAL® 30G Touch Up must not be used:
- for the correction of superficial wrinkles.
- for injections other than intradermal
- in combination with peeling, laser treatment or ultrasound-based,
- 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,
- Due to possible interactions with other filling implants, which have not been researched, it is inadvisable to inject TEOSYAL® 30G Touch Up into sites in the presence of other filling implants.
- in pregnancy, breast-feeding mothers, or in children
Do not inject into blood vessels
Do not inject into the eyelids

Posology and method of administration
The injection of TEOSYAL® 30G Touch Up is reserved for practitioners trained in the injection techniques of products intended for the filling of wrinkles. Before beginning treatment, patients must be questioned regarding their past medical history and informed regarding the foreseeable outcome of treatment and of potential undesirable effects. Correction sites must be properly disinfected. It is advised to perform injections using the needle provided in the box. TEOSYAL® 30G Touch Up should be injected slowly into the mid-dermal layer using the linear threading injection technique. If the injection is made too deeply, i.e. into a subcutaneous tissue, the correction will not have the sought after duration of action. An injection which is too deep, will encounter subcutaneous tissue which will not give rise to resistance during injection of the product, in contrast to the dermis. If the colour of the needle is visible under the skin during injection, this indicates that the injection will be too superficial, which it is also advisable to avoid, as the result of the correction might be irregular. The injection volume is dependent upon the correction required. It is however recommended not to exceed 3 ml per session. It is important not to overcorrect. Massage the treated sites carefully in order to ensure a uniform distribution of the product at the corrected sites.

Side effects
The practitioner must inform the patient that there are potential side effects related to the implantation of this device, occurring immediately following injection or after a delay. These include, among others:
- Local manifestations: inflammatory reactions (erythema, oedema, pain at the point of injection), haematomas, itching, temporary loss of sensitivity around the injected area, dyschromia, abscesses, indurations, nodules (possibly granulomas), skin necrosis, migration of the implant.
- General manifestations: immediate hypersensitivity up to anaphylactic shock.
The patient should inform the practitioner of any secondary effect other than those described above or any effect persisting beyond one week.
The practitioner will, in turn, inform the product retailer within the shortest time possible.

Assembly the needle on the syringe
For optimum use of TEOSYAL® products, it is important for the needle to be assembled on the syringe following the 5 steps detailed in the diagrams (see figures for steps 1 to 5).

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 against taking high-dose vitamin E, aspirin, anti-inflammatory or anti-coagulants, during 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...) 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. 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.

F Notice d'utilisation

Description
TEOSYAL® 30G Touch Up est un gel viscoélastique d'acide hyaluronique réticulé, stérile, non pyrogène, transparent, d'origine non animale. Chaque boîte contient deux seringues pré-remplies de TEOSYAL® 30G Touch Up. Pour chaque seringue, la boîte contient une aiguille stérile 30G1/2" et deux étiquettes de traçabilité (dont une à remettre au patient, et une étiquette à conserver par le médecin dans le dossier patient). Le volume de chaque seringue est indiqué sur le conditionnement carton ainsi que sur chaque seringue.

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Indications
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- chirurgie reconstructive : comblement des marques dues à des cicatrices, reconstruction des volumes perdus suite à une lipotraphie.

Mode d'action
TEOSYAL® 30G Touch Up s'injecte dans le derme moyen, à l'endroit de la dépression cutanée que l'on souhaite corriger. TEOSYAL® 30G Touch Up crée ainsi un volume qui comble les rides. TEOSYAL® 30G Touch Up est biodégradable et se résorbe lentement dans le temps. En fonction de la profondeur des rides à traiter, en général une, mais parfois deux séances de traitement sont nécessaires à l'obtention d'un niveau de correction optimal. Des séances de retouche périodiques permettent ensuite de maintenir le niveau de correction désiré.

Contre-indications
TEOSYAL® 30G Touch Up ne doit pas être utilisé :
- pour la correction des rides superficielles.
- pour des injections autres qu'intradermiques
- en association avec un peeling, un traitement au laser ou à base d'ultrasounds
- si le patient souffre d'affections cutanées, d'inflammation ou d'infection sur la zone à traiter ou à proximité de cette zone.
- dans le cas de patients ayant une hypersensibilité connue à l'acide hyaluronique, avec des antécédents d'allergies sévères ou de choc anaphylactique.
- dans le cas de patients souffrant de maladies auto-immunes.
- Les interactions avec d'autres implants de comblement n'ayant pas été étudiées, il est déconseillé d'injecter TEOSYAL® 30G Touch Up sur des zones en présence d'autres implants de comblement.
- chez la femme enceinte, allaitant, ou chez les enfants

Posologie et mode d'administration
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Effets secondaires
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- Manifestations générales: hypersensibilité immédiate pouvant aller jusqu'à choc anaphylactique.
Tout effet secondaire autre que ceux décrits ci-dessus ou persistant au-delà d'une semaine devra être signalé au praticien par le patient.

Assemblage de l'aiguille sur la seringue
Pour une manipulation optimale des produits TEOSYAL®, il est important que l'aiguille soit montée sur la seringue conformément aux 5 étapes mentionnées dans le schéma (voir figures étapes 1 à 5).

Précautions d'emploi
Vérifier la date de péremption et l'intégrité de l'emballage avant utilisation. Ne pas utiliser si la date de péremption est dépassée ou si l'emballage est endommagé. Il convient de déconseiller au patient de prendre, la semaine précédant la séance d'injection, de la vitamine E à forte dose, de l'aspirine, des anti-inflammatoires ou des anticoagulants. Recommander au patient de ne pas se maquiller pendant les douze heures qui suivent l'injection et de ne pas s'exposer à des températures extrêmes (froid intense, sauna, hammam...) pendant la semaine qui suit le traitement. A la fin de la séance de traitement, il est impératif de jeter tout reste de produit inutilisé. Ce dispositif est destiné à un usage unique. En cas de réutilisation, la stérilité n'est plus garantie, le gel peut être détérioré réduisant son efficacité et le gel peut avoir séché gênant son extrusion à travers une aiguille. Jeter les aiguilles usagées dans des collecteurs appropriés.

Conditions de conservation
Conserver entre 2°C et 25°C, à l'abri du rayonnement direct du soleil. Avant utilisation s'assurer de l'absence de signes visibles de détérioration du conditionnement.

Instruction leaflet

Description
TEOSYAL® 30G Touch Up is a transparent, non pyrogenic, sterile, cross-linked, hyaluronic acid, visco-elastic gel of non-animal origin. Each box contains two pre-filled syringes of TEOSYAL® 30G Touch Up. For each syringe, the box contains one sterile 30G1/2" needle and two traceability 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 packaging carton as well as on each syringe.

Composition
Cross-linked hyaluronic acid 25 mg
Phosphate buffer pH 7.3 q.s. ad 1 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 lipotrophy.
TEOSYAL® 30G Touch Up is indicated for the correction of moderate wrinkles on the face and for touch-up sessions in addition to a treatment with a product from the TEOSYAL® range.

Mode of action
TEOSYAL® 30G Touch Up is injected into the mid dermis at the site of the cutaneous depression to be corrected. TEOSYAL® 30G Touch Up creates a volume that corrects wrinkles. TEOSYAL® 30G Touch Up is biodegradable and is slowly resorbed over time. In general, one, but sometimes two treatment sessions are necessary, depending upon the depth of the wrinkles in need of treatment, to obtain an optimal degree of correction. Periodic touch-up sessions then enable the sought after degree of correction to be maintained.

Contra-indications
TEOSYAL® 30G Touch Up must not be used:
- for the correction of superficial wrinkles.
- for injections other than intradermal
- in combination with peeling, laser treatment or ultrasound-based,
- 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,
- Due to possible interactions with other filling implants, which have not been researched, it is inadvisable to inject TEOSYAL® 30G Touch Up into sites in the presence of other filling implants.
- in pregnancy, breast-feeding mothers, or in children
Do not inject into blood vessels
Do not inject into the eyelids

Posology and method of administration
The injection of TEOSYAL® 30G Touch Up is reserved for practitioners trained in the injection techniques of products intended for the filling of wrinkles. Before beginning treatment, patients must be questioned regarding their past medical history and informed regarding the foreseeable outcome of treatment and of potential undesirable effects. Correction sites must be properly disinfected. It is advised to perform injections using the needle provided in the box. TEOSYAL® 30G Touch Up should be injected slowly into the mid-dermal layer using the linear threading injection technique. If the injection is made too deeply, i.e. into a subcutaneous tissue, the correction will not have the sought after duration of action. An injection which is too deep, will encounter subcutaneous tissue which will not give rise to resistance during injection of the product, in contrast to the dermis. If the colour of the needle is visible under the skin during injection, this indicates that the injection will be too superficial, which it is also advisable to avoid, as the result of the correction might be irregular. The injection volume is dependent upon the correction required. It is however recommended not to exceed 3 ml per session. It is important not to overcorrect. Massage the treated sites carefully in order to ensure a uniform distribution of the product at the corrected sites.

Side effects
The practitioner must inform the patient that there are potential side effects related to the implantation of this device, occurring immediately following injection or after a delay. These include, among others:
- Local manifestations: inflammatory reactions (erythema, oedema, pain at the point of injection), haematomas, itching, temporary loss of sensitivity around the injected area, dyschromia, abscesses, indurations, nodules (possibly granulomas), skin necrosis, migration of the implant.
- General manifestations: immediate hypersensitivity up to anaphylactic shock.
The patient should inform the practitioner of any secondary effect other than those described above or any effect persisting beyond one week.
The practitioner will, in turn, inform the product retailer within the shortest time possible.

Assembly the needle on the syringe
For optimum use of TEOSYAL® products, it is important for the needle to be assembled on the syringe following the 5 steps detailed in the diagrams (see figures for steps 1 to 5).

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 against taking high-dose vitamin E, aspirin, anti-inflammatory or anti-coagulants, during 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...) 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. 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.

GB Instruction leaflet

Description
TEOSYAL® 30G Touch Up is a transparent, non pyrogenic, sterile, cross-linked, hyaluronic acid, visco-elastic gel of non-animal origin. Each box contains two pre-filled syringes of TEOSYAL® 30G Touch Up. For each syringe, the box contains one sterile 30G1/2" needle and two traceability 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 packaging carton as well as on each syringe.

Composition
Cross-linked hyaluronic acid 25 mg
Phosphate buffer pH 7.3 q.s. ad 1 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 lipotrophy.
TEOSYAL® 30G Touch Up is indicated for the correction of moderate wrinkles on the face and for touch-up sessions in addition to a treatment with a product from the TEOSYAL® range.

Mode of action
TEOSYAL® 30G Touch Up is injected into the mid dermis at the site of the cutaneous depression to be corrected. TEOSYAL® 30G Touch Up creates a volume that corrects wrinkles. TEOSYAL® 30G Touch Up is biodegradable and is slowly resorbed over time. In general, one, but sometimes two treatment sessions are necessary, depending upon the depth of the wrinkles in need of treatment, to obtain an optimal degree of correction. Periodic touch-up sessions then enable the sought after degree of correction to be maintained.

Contra-indications
TEOSYAL® 30G Touch Up must not be used:
- for the correction of superficial wrinkles.
- for injections other than intradermal
- in combination with peeling, laser treatment or ultrasound-based,
- 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,
- Due to possible interactions with other filling implants, which have not been researched, it is inadvisable to inject TEOSYAL® 30G Touch Up into sites in the presence of other filling implants.
- in pregnancy, breast-feeding mothers, or in children
Do not inject into blood vessels
Do not inject into the eyelids

Posology and method of administration
The injection of TEOSYAL® 30G Touch Up is reserved for practitioners trained in the injection techniques of products intended for the filling of wrinkles. Before beginning treatment, patients must be questioned regarding their past medical history and informed regarding the foreseeable outcome of treatment and of potential undesirable effects. Correction sites must be properly disinfected. It is advised to perform injections using the needle provided in the box. TEOSYAL® 30G Touch Up should be injected slowly into the mid-dermal layer using the linear threading injection technique. If the injection is made too deeply, i.e. into a subcutaneous tissue, the correction will not have the sought after duration of action. An injection which is too deep, will encounter subcutaneous tissue which will not give rise to resistance during injection of the product, in contrast to the dermis. If the colour of the needle is visible under the skin during injection, this indicates that the injection will be too superficial, which it is also advisable to avoid, as the result of the correction might be irregular. The injection volume is dependent upon the correction required. It is however recommended not to exceed 3 ml per session. It is important not to overcorrect. Massage the treated sites carefully in order to ensure a uniform distribution of the product at the corrected sites.

Side effects
The practitioner must inform the patient that there are potential side effects related to the implantation of this device, occurring immediately following injection or after a delay. These include, among others:
- Local manifestations: inflammatory reactions (erythema, oedema, pain at the point of injection), haematomas, itching, temporary loss of sensitivity around the injected area, dyschromia, abscesses, indurations, nodules (possibly granulomas), skin necrosis, migration of the implant.
- General manifestations: immediate hypersensitivity up to anaphylactic shock.
The patient should inform the practitioner of any secondary effect other than those described above or any effect persisting beyond one week.
The practitioner will, in turn, inform the product retailer within the shortest time possible.

Assembly the needle on the syringe
For optimum use of TEOSYAL® products, it is important for the needle to be assembled on the syringe following the 5 steps detailed in the diagrams (see figures for steps 1 to 5).

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 against taking high-dose vitamin E, aspirin, anti-inflammatory or anti-coagulants, during 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...) 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. 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.

Gebruiksaanwijzing

Beschreibung
TEOSYAL® 30G Touch Up ist ein viskoelastisches Gel mit retikulierter steriler, nicht pyrogenen, transparenter Hyaluronsäure nicht animalischen Ursprungs. Jede Packung enthält zwei Spritzen mit TEOSYAL® 30G Touch Up. Pro Spritze befinden sich in der Packung eine sterile 30G1/2" Kanüle und zwei Rückverfolgbarkeitsetiketten (von denen eines dem Patienten zu übergeben ist und eines vom Arzt in der Patientenakte aufzubewahren ist). Der Inhalt der Spritzen ist auf die Karton-Verpackung sowie die einzelnen Spritzen aufgedruckt.

Zusammensetzung
Retikuliertes Hyaluronsäure 25 mg
Phosphatpuffer pH 7,3 Menge ausreichend für 1 ml

Indikationen
Die therapeutische Wirkung von TEOSYAL® Produkten umfasst:
- Verbesserung der Hautstruktur reiferer Haut: Wiederherstellung des Volumens, Auffüllung von Gesichtsfalten und Hautfurchen, Regulierung des Feuchtigkeitsgehalts der Haut
- Wiederherstellungschirurgie: Auffüllen von narbenbedingten Hautvertiefungen, Wiederherstellung des durch Lipotrophie verlorenen Volumens.
TEOSYAL® 30G Touch Up ist ein Mittel zur Korrektur von Gesichtsfalten mittlerer Tiefe sowie für ergänzende Nachbehandlungen zur bereits erfolgten Behandlung mit einem Produkt aus der Reihe TEOSYAL®.

Wirkungsweise
TEOSYAL® 30G Touch Up wird an der Stelle in die mittlere Dermis injiziert, wo die störende Falte korrigiert werden soll. TEOSYAL® 30G Touch Up füllt auf diese Weise die Falten wieder auf. TEOSYAL® 30G Touch Up ist biologisch abbaubar und wird mit der Zeit resorbiert. Je nach Tiefe der zu behandelnden Falten sind in der Regel eine, manchmal aber auch zwei Sitzungen nötig, um ein optimales Korrekturergebnis zu erreichen. Durch regelmäßige Nachbehandlungen kann das gewünschte Korrekturergebnis aufrechterhalten werden.

Gegenanzeigen
TEOSYAL® 30G Touch Up darf nicht verwendet werden:
- zur Korrektur oberflächlicher Falten.
- für nicht intradermale Injektionen
- in Verbindung mit Peelings, Laserbehandlungen oder auf Ultraschallbasis,
- wenn beim Patienten am Behandlungsbereich oder in der Umgebung dieses Bereichs Hautkrankheiten, Entzündungen oder Infektionen vorliegen.
- falls dem Patienten bekannt ist, dass er Hyaluronsäure nicht verträgt und er nach entsprechender Behandlung bereits einmal schwere allergische Reaktionen bzw. einen Allergieschock erlitten hat,
- bei

I Modalità d'uso**Descrizione**

TEOSYAL® 30G Touch Up è un gel viscoelastico a base di acido ialuronico reticolato, sterile, non pirogeno, trasparente, di origine non animale. Ogni confezione contiene due siringhe preimpiegate di TEOSYAL® 30G Touch Up. Per ciascuna siringa, la confezione contiene inoltre uno o due aghi sterili da 30G1/2" e due etichette di tracciabilità (di cui una da consegnare al paziente e una che deve essere conservata dal medico nel fascicolo del paziente). Il volume di ogni siringa è indicato sulla scatola, nonché su ogni siringa.

Composizione

Acido ialuronico reticolato 25 mg
Tampone fosfato pH 7,3 q.b a 1 ml

Indicazioni

Le azioni terapeutiche dei prodotti TEOSYAL® sono le seguenti:

- modifica della struttura della pelle matura: ripristino dei volumi, riempimento delle rughe e delle pieghe della pelle, ripristino dell'idratazione cutanea
 - chirurgia ricostruttiva: riempimento delle depressioni cicatriziali, ricostituzione dei volumi persi a seguito di lipotrofia.
- TEOSYAL® 30G Touch Up è indicato per il riempimento delle rughe medie del viso e per le sessioni di ritocco come trattamento complementare a un altro prodotto della gamma TEOSYAL®.

Azione

TEOSYAL® 30G Touch Up si inietta in derma media, nel punto in cui si trova la depressione cutanea che si desidera correggere. TEOSYAL® 30G Touch Up crea così un volume che riempie le rughe. TEOSYAL® 30G Touch Up è biodegradabile e si assorbe lentamente. In funzione della profondità delle rughe da trattare, in linea generale sono necessarie una o a volte due sedute di trattamento per ottenere un livello di correzione ottimale. Alcune sedute di ritocco periodiche consentono poi di mantenere il livello di correzione desiderato.

Controindicazioni

- TEOSYAL® 30G Touch Up non deve essere utilizzato:
- per la correzione di rughe superficiali
 - per iniezioni che non siano intradermiche
 - in associazione con peeling, trattamento laser o a base di ultrasuoni
 - in caso di affezioni cutanee, infiammazioni o infezioni sulla zona da trattare o in prossimità di tale zona
 - in caso di pazienti con ipersensibilità all'acido ialuronico nota, severe reazioni allergiche o shock anafilattici antecedenti,
 - in caso di pazienti che soffrono di malattie autoimmuni,
 - Non avendo studiato interazioni con altri fillers, è sconsigliato iniettare TEOSYAL® 30 G Touch Up in aree già trattate con altri riempitivi.
 - in gravidanza, allattamento e in bambini.
- Non iniettare nei vasi sanguigni.
Non iniettare nelle palpebre.

Posologia e modalità di somministrazione

L'iniezione di TEOSYAL® 30G Touch Up deve essere effettuata da medici con formazione tecnica sull'iniezione di prodotti destinati al riempimento di rughe. Prima di iniziare il trattamento, è necessario interrogare il paziente circa la sua anamnesi e informarlo dei possibili risultati del trattamento e dei potenziali effetti indesiderati. Disinfettare accuratamente le zone da correggere. Si raccomanda di iniettare mediante l'ago contenuto nella confezione. TEOSYAL® 30G Touch Up si inietta lentamente nel derma profondo, mentre la tecnica di iniezione lineare tracciate. Se l'iniezione è effettuata ad un livello troppo profondo, ovvero nel tessuto sottocutaneo, la correzione non avrà la durata prevista. Un'iniezione troppo profonda si riconosce poiché, contrariamente al derma, i tessuti sottocutanei non manifestano resistenza al momento dell'introduzione del prodotto. Se si riesce a vedere il colore dell'ago sotto la pelle, l'iniezione è troppo superficiale: questo effetto è da evitare, poiché tale operazione causa irregolarità sulla pelle. Il volume da iniettare dipende dalla correzione da effettuare. Si consiglia tuttavia di non superare 3 ml per seduta. Evitare di sovraccaricare bene le zone trattate, per ripartire il prodotto uniformemente nelle zone corrette.

Effetti secondari

- Il professionista deve informare il paziente dei possibili effetti collaterali associati all'impianto di questo dispositivo, che si possono verificare subito dopo l'iniezione o in modo ritardato. Questi comprendono (elenco non esaustivo):
- Manifestazioni locali: reazioni infiammatorie (eritema, edema, dolore nell'area di iniezione), ecchimosi, prurito, perdita temporanea di sensibilità nell'area di iniezione, discromia, accessi, indurimento, noduli (possibile formazione di granulomi), necrosi della pelle, migrazione dell'impianto.
 - Patologie sistemiche: ipersensibilità immediata fino allo shock anafilattico.
- Eventuali effetti collaterali diversi da quelli sopra descritti o persistenti dopo una settimana devono essere segnalati al medico da parte del paziente.
- Il professionista informerà a sua volta il rivenditore del prodotto nel minor tempo possibile.

Assemblaggio dell'ago sulla siringa

Per una manipolazione corretta dei prodotti TEOSYAL®, è importante che l'ago sia montato sulla siringa conformemente alle 4 fasi descritte nello schema (vedi figura 1-5).

Precauzioni d'uso

Controllare la data di scadenza e l'integrità della confezione prima dell'utilizzo. Non utilizzare il prodotto se è scaduto o se la confezione è danneggiata. Sconsigliare al paziente di assumere, durante la settimana precedente la seduta di iniezioni, vitamina E e forti dosi, aspirina, anti-infiammatori o anticoagulanti. Raccomandare alla paziente di non truccarsi nelle dodici ore che seguono l'iniezione e di non esporsi a temperature estreme (freddo intenso, sauna, bagno turco...) durante la settimana seguente il trattamento. Alla fine della seduta di trattamento, è obbligatorio gettare i resti di prodotto non utilizzato. Questo dispositivo è destinato ad un unico uso. In caso di riutilizzo, la sterilità non è più garantita. Il gel può essere deteriorato (e quindi avere un'efficacia ridotta) e può essere seccato, ostacolando così la sua estrusione attraverso un ago. Eliminare gli aghi utilizzati nei raccoglitori appropriati.

Condizioni di conservazione

Conservare tra 2°C e 25°C, al riparo dai raggi del sole diretti.

Prima dell'utilizzo, verificare che la confezione sia perfettamente integra.

P Instruções de utilização**Descrição**

O TEOSYAL® 30G Touch Up é um gel visco-elástico de ácido hialurónico reticulado, estéril, não pirogeno, transparente, de origem não animal. Cada caixa contém duas seringas previamente preenchidas com TEOSYAL® 30G Touch Up. Para cada seringa, a caixa contém uma ou duas agulhas estéreis 30G1/2" e duas etiquetas de rastreabilidade (uma deve ser entregue ao paciente e outra conservada pelo médico no dossier do paciente). O volume de cada seringa é indicado no acondicionamento de cartão bem como em cada seringa.

Composição

Ácido hialurónico reticulado 25 mg
Tampão fosfato pH 7,3 q.s. 1 ml

Indicações

As ações terapêuticas dos produtos TEOSYAL® são as seguintes:

- modificação da estrutura da pele madura: restauração dos volumes, preenchimento das rugas e das obras da pele, restauração da hidratação cutânea
 - cirurgia reconstrutiva: preenchimento das marcas causadas por cicatrizes, reconstrução dos volumes perdidos após uma lipotrofia.
- O TEOSYAL® 30G Touch Up é indicado para o preenchimento das rugas médias do rosto e para as sessões de retoque em complemento de tratamento de um produto da gama TEOSYAL®.

Modo de ação

O TEOSYAL® 30G Touch Up injecta-se na derme média, no lugar da depressão cutânea que se deseja corrigir. O TEOSYAL® 30G Touch Up cria assim um volume que preenche as rugas. O TEOSYAL® 30G Touch Up é biodegradável e dissolve-se lentamente ao tempo. Em função da profundidade das rugas a tratar, geralmente uma sessão de tratamento, mas por vezes duas são necessárias para a obtenção de um nível de correção ótimo. Sessões de retoque periódicas permitem em seguida manter o nível de correção desejado.

Contra-indicações

- O TEOSYAL® 30G Touch Up não deve ser utilizado:
- para a correção das rugas superficiais,
 - para injeções outras que intradérmicas
 - em associação com um peeling, um tratamento ao laser ou à base de ultrassons
 - se o paciente sofrer de afecções cutâneas, de inflamação ou de infecção na zona a tratar ou próximo dessa zona,
 - no caso de pacientes com uma hipersensibilidade conhecida ao ácido hialurónico, com antecedentes de alergias graves ou de choques anafiláticos,
 - no caso de pacientes que sofrendo de doenças auto-imunes,
 - como as interacções com outros implantes de preenchimento não foram ainda estudadas, não aconselhamos injectar o TEOSYAL® 30G Touch Up nas zonas onde existem outros implantes de preenchimento.
 - na mulher grávida, que aleita, ou nas crianças
- Não injectar nos vasos sanguíneos
Não injectar nas palpebras

Posologia e modo de administração

A injeção de TEOSYAL® 30G Touch Up é reservada a médicos formados às técnicas de injeção de produtos destinados ao preenchimento das rugas. Antes de começar o tratamento, é necessário interrogar bem o paciente sobre os seus antecedentes médicos, informá-lo sobre os resultados previsíveis do tratamento, e sobre os seus efeitos indesejáveis potenciais. Desinfetar bem a zona a corrigir. Recomendamos injectar com a ajuda da agulha fornecida na caixa. O TEOSYAL® 30G Touch Up injecta-se lentamente na derme média com a ajuda da técnica de injeção linear retrógrada. Se a injeção for feita demasiado profunda, ou seja no tecido subcutâneo, a correção não terá a duração esperada. Uma injeção demasiado profunda reconhece-se pelo facto que os tecidos subcutâneos não oferecem resistência na injeção do produto, contrariamente à derme. Quando finger a injeção se poder-se ver a cor agulha sob a pele, isso significa que essa injeção é demasiado superficial ou que convém igualmente evitar, porque o resultado da correção poderá ser irregular. O volume a injectar depende das correções a efectuar. É no entanto recomendado não ultrapassar 3 ml por sessão. É importante não corrigir em demasia. Massajar bem as zonas tratadas a fim de se assegurar da distribuição uniforme do produto nas zonas corrigidas.

Efeitos secundários

- O médico deve informar o doente que existem efeitos secundários potenciais associados à implantação deste dispositivo, que ocorrem imediatamente após a injeção ou de forma retardada. Estão incluídos (lista não exaustiva):
- Manifestações locais: reacções inflamatórias (eritema, edema, dor no local de injeção), hematomas, comichão, perda de sensibilidade transitória ao nível da zona injectada, discromia, abscesso, indurações, nódulos (possivelmente granulomas), necroses cutâneas, migrações do implante.
 - Manifestações gerais: hipersensibilidade imediata, que pode chegar ao choque anafilático.
- Qualquer efeito secundário não indicado acima ou que persista durante mais de uma semana deverá ser comunicado pelo doente ao médico.
- O médico, por sua vez, informará o revendedor do produto com a maior brevidade possível.

Montagem da agulha na seringa

Para uma manipulação otimizada dos produtos TEOSYAL®, é importante que a agulha seja montada na seringa de acordo com as 4 etapas mencionadas no esquema (Ver Figuras 1 a 5).

Precauções de emprego

Verificar a data de expiração e a integridade da embalagem antes da utilização. Não utilizar se a data de expiração for ultrapassada ou se a embalagem estiver danificada. O paciente deve ser desaconselhado de tomar, na semana que precede a sessão de injeções, vitamina E em fortes doses, aspirina, anti-inflamatórios ou anticoagulantes. Recomendar ao paciente de não se maquiar durante as doze horas que seguem a injeção e de não se expor a temperaturas extremas (frio intenso, sauna, hammam...) durante a semana que segue o tratamento. No fim da sessão de tratamento, é imperativo deitar fora qualquer resto do produto inutilizado. Este produto destina-se a um uso único. Em caso de reutilização, a esterilidade deixa de ser garantida, o gel poderá ficar deteriorado reduzindo a sua eficácia e este poderá secar prejudicando a sua extrusão através da agulha. Deitar fora as agulhas utilizadas nos coletores adequados.

Montagem da agulha na seringa

Conservar entre 2°C e 25°C, ao abrigo da luz do sol directa.

Antes da utilização assegurar-se da ausência de sinais visíveis de deterioração da embalagem.

R Instrukcija po primenjenju**Opisane**

TEOSYAL® 30G Touch Up predstavlja soboj viskoelastičnyj gely retikuljarnoj gyaluronovoj kisloty, sterilnyj, net pirogennyj, prozrachnyj, nezhegimovoj proisxozhdenija. V kazhdoj korobke sozderzhit'sya dva špricja, predvaritel'no napolnennyj gelyu TEOSYAL® 30G Touch Up. Dlja kazhdogo špricja v korobke imyut'sya odin ili dva sterilnyje igly 30G1/2" i dve identifikacionnyje etichetki (odna iz kotoryh peredается pacijentu, a druga xranitsja vrazčom v ličnoj dele pacijenta). Ob'emy kazhdogo špricja ukazany na uklopke, a takzhe na samom špricje.

Sostav

Retikuljarnaja gyaluronovaja kislotaja 25 mg
Fosfatnyj bufer pH 7,3 dostatočnoe količestvo dlja 1 ml

Pokazania

Prodykty TEOSYAL® oblađajut sledujušimi terapevтиčeskimy vozdeystvijami:

- izmenenie anatomii sostarivšej kozi: vosstanovlenie ob'jemoj, zapolnenie moršcin i skladok kozi, vosstanovlenie kožnoj gidratacii
 - rekonstruktivnaja xirurgija: zapolnenie deformacij, svyazannyx so šramami, vosstanovlenie ob'jemoj, poteryannyx v svyazi s lipotrofiej.
- TEOSYAL® 30G Touch Up pokazan dja zapolnenija srednix moršcin ličja i procedur korrekcii v zaključenie terapii odnim iz preparatov gammy TEOSYAL®.

Sposob deystvija

TEOSYAL® 30G Touch Up vveditsja v srednij sloj dermy, v mesto kožnoj depressii, podležajęej korrekcii. TEOSYAL® 30G Touch Up takzhe sozdaet ob'emy, zapolnjajęy moršcinu. TEOSYAL® 30G Touch Up javljaetsja biorazlaęajemyj sredstvom, kotoroje so vremenem postepenno rassasyvается. S učetom glubiny moršcin, trebujošyx zapolnenija, kak pravilo, dostatočno odnoj, a v nekotoryx slučax: dnuh procedur terapii dja polučenia optimal'nogo urovnja korrekcii. Periodičeski provodimye dopolnitel'nyje procedury korrekcii pozvoljajut soxranit' želaemyj urovneň korrekcii.

Protivopokazania

- TEOSYAL® 30G Touch Up ne sleduet ispol'zovat'sja:
- dja korrekcii poveryxnyx moršcin,
 - dja in'ekcij, ne vvolnjajęux vnutrichimnymi
 - sovmesto s spilingom, lazernoj ili ul'trazvukovoj terapij
 - esli u pacijenta imyut'sya kožnye zabolevania, vospalenie ili infekcija v oblasti primenjenija ili vblizni znoj oblasti.
 - v slučae giperčuvstvitel'nosti pacijenta k gyaluronovoj kislotе, s anamnezom ser'eznyx allergij ili anafilaktičeskogo šoka,
 - v slučae esli pacijent stradaet avtoimmunnym zabolevanijem,
 - vzaимodejstvie s drugimi implantami ne bylo izučeno, ne rekomenduet'sja vvodit' TEOSYAL® 30G Touch Up pri nalichii drugih implantov v oblasti primenjenija.
 - u beremennyx i kormyšim ženščinom, det'm.
- Ne vvodit' preparat v krvotokovosye sosudy.
Ne vvodit' v veči.

Dozirovka i sposob vvedenija

In'ekcija gelya TEOSYAL® 30G Touch Up vyполняется kvalificirovannymi vrazčimi, obučennyimi tekhnike vvedenija preparatov, prednaznačennyx dja zapolnenija skladok. Перед началом терапии необходимо подробно распросить пациента о его анамнезе, информировать его о предполагаемых результатах терапии и о ее потенциальных нежелательных действиях. Хорошо продезинфицируйте зону, подлежащую коррекции. Инъекция следует осуществлять иглой, входящей в комплект. TEOSYAL® 30G Touch Up медленно вводится в средний слой дермы с использованием линейно-трансверсальной техники инъекции. Если инъекция делается слишком глубоко, то есть в подкожную ткань, коррекция не будет иметь ожидаемого длительного эффекта. Слишком глубокая инъекция распознается следующим образом: при вводе препарата в подкожную ткань отсутствует сопротивление, ощущаемое при инъекции в дерму. Если введен цвет иглы под кожей во время инъекции, это означает, что данная инъекция является слишком поверхностной. Такой инъекции тоже следует избегать, поскольку результат коррекции может быть нерегулярным. Объем инъекции зависит от требуемых типов коррекции. Тем не менее, рекомендуется не превышать объема 3 мл на одну процедуру. Важно не превышать степень коррекции. Хорошо помассируйте обработанные области для обеспечения равномерного распределения препарата в откорректированных областях.

Побочные действия

Лечащий врач должен сообщить пациенту о том, что существуют потенциальные побочные эффекты, связанные с имплантацией данного средства. Эти побочные эффекты могут возникнуть сразу же после инъекции или спустя некоторое время. Они включают (среди прочих):

- местные проявления: воспалительные реакции (эритема, отек, боль в точке инъекции), гематомы, зуд, временную потерю чувствительности в области инъекции и близости, дисхромия, абсцессы, уплотнение, узелки (возможно, гранулемы), некроз кожи, миграция имплантата.
- Общие проявления: гиперчувствительность немедленного типа вплоть до анафилактического шока.

Пациент должен сообщить лечащему врачу о любом побочном эффекте, если такое нарушение здоровья не описано выше, а также обо всех нарушениях, которые продолжаются более одной недели.

В свою очередь, лечащий врач в кратчайшие сроки обязан сообщить эту информацию лицам, которые занимаются розничной продажей продукта.

Подсоединение иглы к шприцу

Для оптимального пользования препаратами TEOSYAL®, важно, чтобы игла была подсоединена к шприцу согласно 4 этапам, как на схеме (см. рис. с 1 по 5).

Меры предосторожности

Перед использованием препарата проверьте дату истечения его срока годности и целостность упаковки. Не используйте препарат, если истек его срок годности или если повреждена упаковка. Посоветуйте пациенту воздержаться от приема значительных доз витамина E, аспирина, противовоспалительных средств или антикоагулянтов в течение недели, предшествующей сеансу инъекций. Посоветуйте пациенту не пользоваться косметикой в течение двадцати часов после инъекции и не подвергаться воздействию экстремальных температур (сильный холод, сауна, хаммам и т. д.) на протяжении недели после терапии. По окончании процедуры терапии обязательно выбросьте остатки неиспользованного препарата. Данное приспособление предназначено для разового употребления. В случае повторного употребления стерильность не гарантируется, степень эффективности геля может ухудшиться и гель может подсохнуть, что затруднит его введение через иглу. Выбрасывайте использованные иглы в соответствующие приемники.

Условия хранения

Хранить при температуре от 2°C до 25°C, вдали от прямых солнечных лучей.

Перед использованием препарата следует убедиться в отсутствии видимых признаков повреждения упаковки

T Talimat sayfası**Tanım**

TEOSYAL® 30G Touch Up hayvan kökenli olmayan, saydam, kan pirojenik, steril, retikuler, hialuronik asitli, viskoelastik bir jeldir. Her kutuda bir veya iki adet doldurulmuş TEOSYAL® 30G Touch Up şırıngası bulunur. Kutularda her şırınga için bir veya iki steril iğne veya iki adet sterilizasyon iğnesi 30G1/2" ve iki tanımlama etiketi (biri hasta tarafından doktora teslim edilmelidir, diğeri doktor tarafından hastaya verilmelidir) bulunur. Her bir şırınganın hacmi şırıngaların üstünde ve karton ambalajda belirtilmiştir.

Bileşim

Retikülü hialuronik asit 25 mg
Fosfat tamponu pH 7.3 1 ml için yeterli miktar

Yararlılıklar

TEOSYAL® ürünlerinin tedavi amaçları:

- yaşlanms derinin anatomisini değiştirmek: hacimlerin yeniden oluşturulması, deri çökmelerinin ve alın doldurulması, deri hidrasyonunun yeniden oluşturulması
 - rekonstrüktif cerrahi: yara izlerinin sebep olduğu çökmelerin doldurulması, lipotroji ile kaybedilen hacimlerin yeniden oluşturulması.
- TEOSYAL® 30G Touch Up, Teosyal ürün yelpazesindeki bir ürün ile tedaviye ilâve olarak rütüs yapmak ve orta dereceli yüz kırışıklarının doldurulması için endikedir.

Etki şekli

TEOSYAL® 30G Touch Up düzeltilmesi istenen deri cöküntülerinin bölgesindeki derinin orta tabakasına enjekte edilir. TEOSYAL® 30G Touch Up böylece çizgileri dolduran bir hacim sağlar. TEOSYAL® 30G Touch Up biyolojik çözünürlüğe sahiptir ve zamanla yavaşça emilir. Her bir çizgi düzeltilmesi için, tedavi gerektiren çizgilerin derinliğine bağlı olarak genellikle bir, bazen iki tedavi seansı gerekir. Periyodik ufak düzeltmeler yapılan işlemin sürekliliğini sağlar.

Kontrendikasyonları

TEOSYAL® 30G Touch Up aşağıdaki durumlarda kullanılmamalıdır:

- Yüzeysel çizgilerin düzeltilmesi için,
- Intradermal yol dışında,
- Soyma ya da lazer tedavisi ile birlikte veya ultrason tedavisi.
- Tedavi bölgesinde ya da yakınında deri hastalığı, infli amasyonu ya da enfeksiyonu olan hastalarda,
- Anafiltik şok ve ciddi alerji antedandanları ile, hialuronik aside bilinen aşırı hassasiyeti bulunan hastalarda,
- Otomimm hastalıkları olan kişilerde,
- Diğer dolgu implantlarıyla henüz araştırılmamış olan reaksiyonlara girebilme ihtimali olduğundan, TEOSYAL® 30G Touch Up'in diğer dolgu implantlarının bulunduğu alanlarda kullanılması tavsiye edilmez.
- Hamilelikte, emziren kadınlarda veya çocuklarda
- Kam damarlarının içine şırınga etmeminiz.
- Göz kapaklarına enjekte etmemiz.

Düzeltilim (pozoloji) ve uygulama metodu

TEOSYAL® 30G Touch Up enjeksiyonunu kırışıklıkların doldurulması için tasarlanmış ürünlerin enjeksiyon teknikleri konusunda eğitimli uzmanlarca kullanılmıdır. Tedaviye başlamadan önce, hastalara hastalık geçmiřleriyle ilgili sorular sorulmalı; tedavinin tamir edilebilir sonuçları ve potansiyel istenmeyen etkileri hakkında bilgi verilmelidir. Düzeltilcek olan bölgeler tamamen mikropsüzleştirilmiştir (dezenfekte) edilmelidir. Kuru içinde verilen iğneler vastası ile enjekte edilmesi tavsiye edilir. TEOSYAL® 30G Touch Up doğrusal vidalama tekniği kullanılarak derinin orta tabakasına yavaş yavaş enjekte edilmelidir. Enjeksiyon çok derin, yani derialtı veya derialtı dokularına yapılsa derizleme etki süresi aradan devam etmez. Çok derin bir enjeksiyon, derimsin tersine, mukavemeti yükselme sağlamayacak olan altı deri dokuya denk gelecektir. Enjeksiyon sırasında iğnenin rengi deri altından seçilebilirse, bu enjeksiyon fazla yüzeysel olduğunu gösterir. Bundan da kaçınmak gerekir çünkü düzeltilmenin sonucu düzensiz olacaktır. Enjeksiyon hacmi gereken düzeltilmenin boyutuna bağlıdır. Ancak saans başına 3ml'ın aşılması önerilir. Aşırı düzeltme yapılmaması önemlidir. Ürünün düzeltilen bölgelere eşit biçimde dağıldığından emin olmak için tedavi edilen bölgeye dikkatlice masaj yapın.

Yan etkileri

Doktor, cihazın implantasyonu hemen enjeksiyondan sonra veya geçikmeli olarak yapılabildiğini bunun doğuracağı olası yan etkiler konusunda hastayı bilgilendirmelidir. Bu yan etkiler şu belirtiler örnek olarak verebiliriz:

- Lokal belirtiler: İnflamatuvar reaksiyonlar (kızarıklık, ödem, enjeksiyon bölgesinde ağrı), hematolar, kaşıntı, enjeksiyon bölgesinin çevresinde geçici duyu kaybı, diskromi, absesler, sertlik, nodüller (granülom benzeri), cilt nekrozu, implantın yer değiřtirmesi;
- Genel belirtiler: Aniden gelişen ve anafiltik şoka varabilen aşırı duyarlılık sayılabilir.

Hasta yukarıda bahsedilenler dışında herhangi bir ikincil etki ile karşılaşırsa veya istenmeyen etkiler bir haftadan daha uzun süre boyunca doktorunu bilgilendirmelidir.

Boyle bir durumda doktor mümkün olan en kısa sürede ürünün satıcısına konu ile ilgili bilgi verecektir.

İğnenin şırınga ile birleştirilmesi

TEOSYAL® ürünlerinin optimal kullanımı için, iğnenin semada belirtilen 4 aşamaya uygun olarak şırıngaya monte edilmesi önemlidir (1'den 5'e resimlerine bakın).

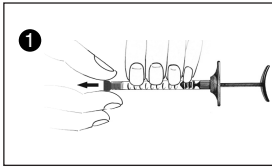
Kullanımı ilişkin önlemler

Kullanım öncesinde, son kullanma tarihini ve ambalajın bütünlüğünü kontrol edin. Son kullanma tarihi geçmiş veya ambalajı ıntılmış kullanmayın. Enjeksiyon seansından önceki hafta hastanın aşırı sıcakta E vitamini, aspirin, iltihabı önleyici ilaçlar veya antioksidanlar kullanmaması tavsiye edilir. Hastaya enjeksiyondan sonra 12 saat boyunca maykaj yapmamasını ve tedaviyi takiben bir hafta boyunca aşırı sıcaklık değişimlerinden (aşırı soğuk, sauna, hamam ...) kaçınmasını tembihleyin. Tedavi seansının bitiminde, geri kalan kullanılmamış ürünün tamamının atılması önemlidir. Ayrıntı tek kullanımlıktır. Tekrar kullanım halinde sterilitate artk garanti değildir, jel bozularak etkinlięi azalabilir ve jel kuruyarak iğneye çekilmesini engelleyebilir. Kullanılmış iğneleri uygun kaplara atın.

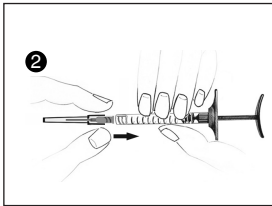
Saklama koşulları

Doğrudan güneş ışıklandırma muhafaza bir yerde, 2°C ile 25°C arasında saklayın.

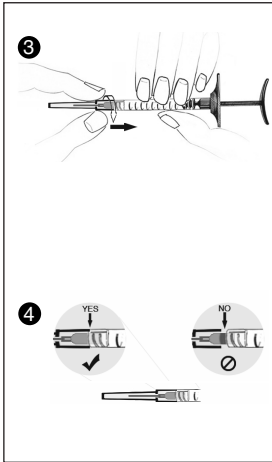
Kullanılmadan önce ambalajın görünür bozulmaları olmadığında emin olunuz.



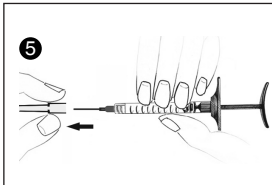
- Togliere il tappo della siringa tirandolo, come mostrato in figura 1.
- Remover o tampão da seringa puxando, conforme ilustrado na figura 1.
- Снимите предохранительный колпачок со шприца, потянув за него, как показано на рисунке 1.
- Şırınganın kapagini resim 1'de görüldüğü gibi çekerek, çıkarın.



- Rimuovere la protezione dell'ago fornito e inserire saldamente la filettatura dell'ago nel becco della siringa (fig. 2).
- Retirar a tampa de agulha fornecida e, de seguida, inserir o passo da rosca da agulha com firmeza na extremidade da seringa (fig. 2).
- Возьмите колпачок с иглой, затем вставьте край иглы с шагом нарезки в отверстие шприца (рис. 2).
- Ürün ile gelen iğnenin kapagini çıkarın, daha sonra iğnenin vida kısmını şırınganın yüksük şeklinde kısmına sağlam bir şekilde geçirin (resim. 2).



- Avvitare l'ago in senso orario, mantenendo una leggera pressione fra ago e siringa (fig.3). Continuare ad avvitare finché il bordo del cappuccio dell'ago non sarà a contatto con il corpo della siringa. Non deve rimanere alcun spazio fra questi 2 elementi (fig. 4). Il mancato rispetto di questa indicazione può generare rischio di espulsione dell'ago e/o di perdite a livello del Luer-Lock.
- Apertar a agulha no sentido dos ponteiros do relógio, mantendo uma ligeira pressão entre a agulha e a seringa (fig. 3). Continuar a apertar até que o rebordo da tampa da agulha entre em contacto com o corpo da seringa. Não deve sobrar espaço entre estes 2 elementos (fig. 4). A inobservância desta instrução pode causar um risco de ejeção da agulha e/ou de fuga a nível do Luer-Lock.
- Закрытые иглу по часовой стрелке, сохраняя небольшое давление между иглой и шприцом (рис. 3). Продолжите закручивать до тех пор, пока край колпачка иглы не достигнет цилиндра. Между этими 2 элементами не должно оставаться пустого места (рис. 4). Несоблюдение этого условия может привести к выталкиванию препарата из иглы и/или вытеканию препарата из иглы на уровне Luer-Lock.
- İğneyi bir saatın kolları yönünde çevirmek, bir taraftan da iğne ve şırınga arasında half bir baskı uygulayarak sıkıştırın (resim. 3). İğnenin kapagının kenarı, şırınganın gövdesi ile teması gerçekleşene kadar sıkırtılmaya devam edin. Bu 2 öge arasında boşluk kalmamalıdır (resim. 4). Bu talimata uyulmaması iğnenin fırlaması riskini ve/veya Luer-Lock'la kaçak ihtimalini ortaya çıkarır.



- Togliere la protezione dell'ago, tirandola fermamente con una mano e tenendo il corpo della siringa con l'altra mano. (fig. 5).
- Retirar, da seguida, a protecção da agulha, puxando-a com firmeza com uma mão, enquanto segura no corpo da seringa com a outra mão. (fig. 5).
- Затем снимите предохранительный колпачок с иглы, потянув за него одной и держа другой цилиндр шприца. (рис. 5).
- Daha sonra, bir elinizle şırınganın gövdesini tutarken, diğeri elinizle sıkıca çekerek, iğnenin korumasını çıkarın. (resim. 5).