

Revision 06

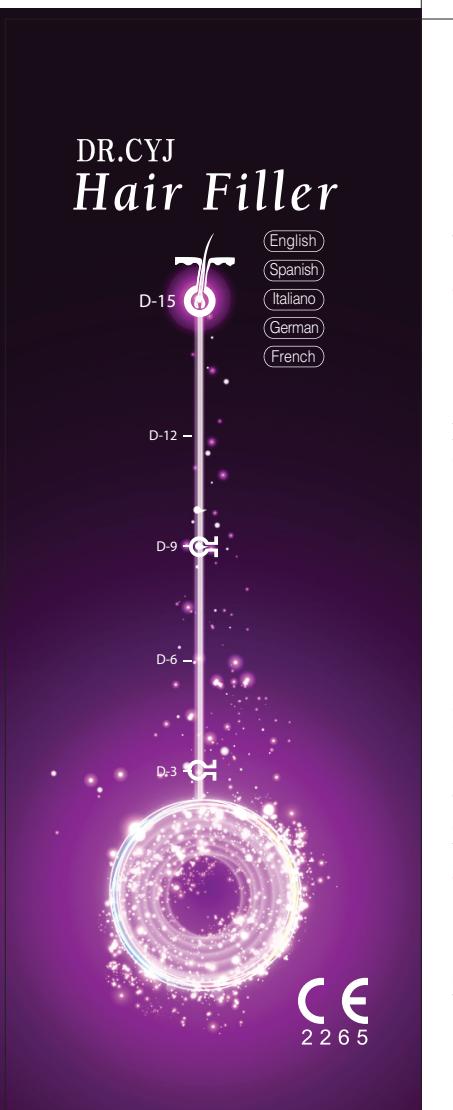
품명 : DR,CYJ Hair Filler 공용 설명서

구분 : 케어젠

변경사항 : 용어 변경

(Description: solution → gel)

변경일 : 2022.03.08

**English**

Instruction for use

Description
DR,CYJ Hair Filler is a clear, transparent and low viscosity gel supplied in a sterilized single syringe. The product is for single use only. DR,CYJ Hair Filler is an unique product non-animal, 0.7% Hyaluronic Acid and peptide complex. Each product contains 1 syringe of 1ml DR,CYJ Hair Filler. The volume of each syringe is shown on the packaging box.

Composition
Hyaluronic Acid(0.7%) Phosphate Buffered Saline, Decapeptide-71, Octapeptide-2, Decapeptide-18, Oligopeptide-54, Octapeptide-11, Decapeptide-10

Intended purpose
DR,CYJ Hair Filler is injected into dermis layer at the site of the damaged scalp in need of implantation for the treatment of subcutaneous tissue damage caused by chemical, physical and traumatic effects of wounded scalp.

Precautions
(a) Preparation
- Do not drink alcohol 7 days before the treatment
- If you are taking medication or have specific experience in the particular drug reactions, consult your physician before the treatment

- For an accurate treatment, clean the area of treatment.
- Check the sterilization date of product
- Check INSTRUCTION FOR USE.

(b) Usage Procedure
① Determine the site of injection, and clean the injection area.

② Do not inject directly until a small droplet is visible at the tip of the needle.

③ Use a thin gauge (30~32Gauge) needle with DR,CYJ Hair Filler. The needle is inserted at an approximate angle of 30° parallel to the surface of the scalp. It should be injected into the superficial or medium.

④ Inject DR,CYJ Hair Filler by applying even pressure on the plunger rod.

Contraindications
• Do not administer to patients with ascertained individual hypersensitivity to the product components or in case of infection or diseases in the area of the injection site.

• Do not inject intravascularly. Do not use DR,CYJ Hair Filler in patients presenting an inflammation/irritation of the hair scalp. Adverse events may occur more commonly in patients with already existing hair inflammation/irritation.

• Patients with pain duration may present following wounded scalp introduction.

• Redness, swelling, edema, hematoma, itching and slight pain at the injection area can occur following treatment and generally subside over 72 hours.

• Do not administer to the patient to the patient by the practitioner. All side effects other than those described above or persisting for more than one week must be reported to the practitioner by the patient. In turn, the practitioner should inform the product's manufacturer. Patients should bring any skin abnormalities, skin disease, infections or sequelae of streptococcal infections. Patients taking immunosuppressants, undergoing corticosteroid therapy, with autoimmune disease history.

• Not recommended to people with above condition.

• Not recommended to use during pregnancy or breastfeeding.

• Do not use in children under the age of 18 years.

• DR,CYJ Hair Filler is a clear, colorless gel without particulates.

• After use, syringes and needles should be handled as potential biohazards. Disposal should be in accordance with accepted medical practice and applicable local, state and federal requirements.

Warnings

• The syringe is intended for single use only.

• Do not use DR,CYJ Hair Filler after the expiration date printed on the box.

• The expiration date refers to valid when product is stored properly in its original package.

• Check sterilization of product.

• Keep out of reach of children.

Storage condition

Store between 2°C ~ 25°C. Away from sunlight. Make sure there are no visible signs of damage to the packaging before use.

Shelf life

24 months under recommended conditions.

Spanish

Instrucciones de uso

Descripción
DR,CYJ Hair Filler es una gel clara, transparente y de baja viscosidad suministrado en una jeringa estéril. El producto es para un solo uso. DR,CYJ Hair Filler es un producto único de origen no animal, 0.7% de Ácido hialurónico y complejo de péptidos. Cada producto contiene 1 jeringa de 1 ml de DR,CYJ Hair Filler.

El volumen de cada jeringa está indicado en la caja de embalaje.

Composición
Ácido hialurónico (0.7%) Tampón fosfato salino, Decapeptide-28, Oligopeptide-71,Octapeptide-2, Decapeptide-18, Oligopeptide-54, Octapeptide-11, Decapeptide-10

Destinación d'uso
DR,CYJ Hair Filler viene inyectado en el estrato dérmico a nivel del cuero cabelludo dañado que necesita de implante para el tratamiento de los disturbios del tejido subcutáneo causados por los efectos químicos, físicos y traumáticos del cuero cabelludo herido.

Propósito previsto
DR,CYJ Hair Filler se inyecta en la capa de la dermis en el sitio del cuero cabelludo dañado que necesita de implante para el tratamiento del daño del tejido subcutáneo causado por los efectos químicos, físicos y traumáticos del cuero cabelludo herido.

Precauciones
(a) Preparación
- No beber alcohol 7 días antes del tratamiento

- Si estás tomando medicación o tiene experiencia específica de reacciones a los medicamentos, consulta con su médico antes de iniciar el tratamiento

- Para un tratamiento preciso, limpia el área de tratamiento.

- Comprueba la fecha de caducidad del producto

- Comprueba las INSTRUCCIONES DE USO.

(b) Uso

① Determinar la ubicación, y limpiar el área de inyección.

② Para la inyección, presiona la barra con cuidado hasta que una pequeña gota sea visible en la punta de la aguja.

③ Utilice un calibre de agua fino (30 ~ 32 Gauge) con DR,CYJ Hair Filler. La jeringa se inserta en un ángulo apropiado de 30 ° paralelo a la superficie del cuero cabelludo. Se debe inyectar en la dermis superficial o media.

④ Inyectar DR,CYJ Hair Filler aplicando una presión uniforme sobre el vástago del émbolo.

Contraindicaciones

• No administrar a pacientes con hipersensibilidad comprobada a los componentes del producto o en caso de padecer infecciones o enfermedades en la piel de deyección de la inyección.

• Inyección por vía intravascular. No usar DR,CYJ Hair Filler en pacientes que presenten inflamación/ irritación del cuero cabelludo.

• Los efectos adversos pueden ocurrir con mayor frecuencia en pacientes con inflamación / irritación del cuero cabelludo.

• Inyección de agua caliente o media.

• Inyección DR,CYJ Hair Filler aplicando una presión uniforme sobre el vástago del émbolo.

Contraindicaciones

• No somministrare ai pazienti con ipersensibilità individuale comprovata ai componenti del prodotto o in caso di infiezioni o malattie nelle zone della pelle da iniezione.

• Non iniettare per via intravascolare. Non utilizzare DR,CYJ Hair Filler nei pazienti che presentano una inflamazione / irritazione del cuo capelli.

• I risultati avversi possono verificarsi con maggiore frequenza in pazienti con inflamazione / irritazione del cuo capelli.

• Iniezione di acqua calda o media.

• Iniezione DR,CYJ Hair Filler applicando una pressione uniforme sulla canna del pistone.

Contraindication

• Nicht an Patienten mit festgestellter individueller Überempfindlichkeit gegen die Produktkomponenten oder bei Infektionen oder Erkrankungen im Bereich der Injektionsstelle verabreichen.

• Nicht intravaskular injizieren. DR,CYJ Hair Filler nicht an Patienten mit einer Kopfhautentzündung/-reizung verabreichen.

• Un erwünschte Ereignisse können häufiger bei Patienten mit bestehender Haarenzündung/-reizung auftreten.

• Eine überzeitige Transfusionsdauer kann vorübergehende Schmerzen von Kurz Dauer aufzeigen.

• Rötungen, Schwellungen, Ödeme, Hämatome, Juckreiz und leichte Schmerzen im Injektionsbereich nach der Behandlung auftreten und im Allgemeinen über 72 Stunden abnehmen.

• Die potentiellen Risiken müssen dem Patienten am Ersttermin mitgeteilt werden. Alle anderen als oben beschriebenen Nebenwirkungen, die länger als eine Woche andauern, müssen vom Patienten dem Arzt gemeldet werden. Im Gegenzug sollte der Arzt den potentiellen Risiken des Produktes so bald wie möglich darüber informieren.

• Allergie gegen einen Inhaltsstoffe

Patienten mit Hautveränderungen, Hauterkrankungen, Infektionen oder Folgen von Strepptokokkeninfektionen.

Patienten, die Immunsuppressive einnehmen und sich eine Kortikosteroide unterziehen, mit Autoimmunerkrankungen in der Vorgeschichte.

• Nicht empfohlen für Personen mit oben genannten Erkrankungen.

• Nicht während der Schwangerschaft oder Stillzeit empfohlen.

• Nicht empfohlen für Kinder oder Minderjährige unter 18 Jahren.

• DR,CYJ Hair Filler ist ein transparentes, farbloses Gel ohne Partikel.

Verwenden Sie die Spritze nicht, wenn der Inhalt der Spritze eine Verfärbung, ein Geruch oder eine Veränderung der Textur aufweist.

• No use if the syringe or needle is broken or damaged.

• Do not use DR,CYJ Hair Filler if the package is open or damaged.

• Check sterilization of product.

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