PROSTROLANE

Natural-B Natural Touch Filler 2 ml

Description

Prostrolane Natural_B is a transparent gel supplied in a glass syringe. The product is for single use only. Prostrolane Natural_B is a sterile medical device, dermal resorbable implant that contains a non-cross-linked Sodium Hyaluronate and peptide complex (Oligopeptide-24, Decapeptide-36, Octapeptide-11, Oligopeptide-34, Oligopeptide-92). Sodium Hyaluronate is non-animal origin and biocompatibility material. Peptide complex consists of 5 kinds peptides that short chain of amino acids linked by peptide bonds. Peptide complex is enhanced the moisturizing effect and delays the degradation of Sodium Hyaluronate. Peptide complex with Sodium Hyaluronate is degradation within 4 weeks. Each carton contains 1 prefilled syringe of 2ml Prostrolane Natural_B and two traceability labels.
(one to be given to the patient, and another to be kept by the doctor in the patient's file)

Composition

PBS(Phosphate Buffered Saline), Sodium Hyaluronate (0.7%)
Peptide Complex (Oligopeptide-24, Decapeptide-36, Octapeptide-11, Oligopeptide-34, Oligopeptide-92)

Indication and Usage

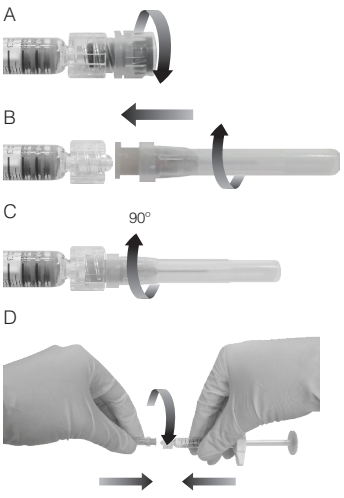
Prostrolane Natural_B is indicated for mid-to-deep dermal implantation for the correction of moderate to severe facial wrinkles and folds, such as nasolabial folds and to restore the shape of the face.
- Site of Application: Face
- Recommended usage volume : 2ml / area (Max usage : 4ml / area)
- Frequency : 1 session / 2 weeks (1 protocol = 2~4 sessions average) (repeat protocol as necessary)

Treatment procedure

Pretreatment Guidelines
Prior to treatment, the patient should avoid taking aspirin, nonsteroidal anti-inflammatory medications, St. John's Wort, or high doses of Vitamin E supplements. These agents may increase bruising and bleeding at the treatment site.
1. It is necessary to counsel the patient and discuss the appropriate indication, risks, benefits and expected responses to the Prostrolane Natural_B treatment. Advise the patient of the necessary precautions before commencing the procedure.
2. Assess the patient's need for appropriate anesthetic treatment for managing comfort, i.e., topical anesthetic, local or nerve block.
3. The patient's face should be washed with soap and water and dried with a clean towel.
Cleanse the area to be treated with alcohol or another suitable antiseptic solution.
4. Sterile gloves are recommended while using Prostrolane Natural_B.
5. Before treatment, press rod carefully until a small droplet is visible at the tip.
6. Prostrolane Natural_B is administered using a thin gauge needle (27G x 13mm or 30G x 13mm) that is sterilized. The sterilized needle is inserted at an approximate angle of 30° parallel to the length of the injected site. Prostrolane Natural_B should be injected into the mid to deep dermis. If Prostrolane Natural_B is injected too superficially this may result in visible lumps and/or bluish discoloration.
7. Inject Prostrolane Natural_B applying even pressure on the plunger rod. It is important that the injection is stopped just before the needle is pulled out of the skin to prevent material from leaking out or ending up too superficially in the skin.
8. Only correct to 100% of the desired volume effect. Do not overcorrect. With cutaneous deformities the best results are obtained if the defect can be manually stretched to the point where it is eliminated. The degree and duration of the correction depend on the character of the defect treated.
9. Typical usage for each treatment session is specific to the site as well as wrinkle severity. Or to apply on the cleared skin surface, to wait for full absorption.
10. After treatment, stick the traceability label on the patient's medical record.

Direction for Assembly

Assembly of 27G or 30G needle(Hypodermic needle) to syringe. For safe use of Prostrolane Natural_B, it is important that the needle is properly assembled. Improper assembly may result in separation of the needle and syringe during injection.



(1) Unscrew the tip cap of the syringe carefully.(A)
(2) Grasp the narrow part of the needle shield loosely; mount the needle on the Luer-Lock (B) by turning it clockwise until you feel counter-pressure. Grasp the wider part of the needle shield firmly.
(3) Press and turn the needle shield 90° (a quarter turn). The quarter turn is necessary to lock the needle onto the syringe.
(4) Pull off the needle shield.
(5) Use the thumb and forefinger to hold firmly around both the glass syringe barrel and the Luer-Lock adapter. Grasp the needle shield with the other hand. To facilitate proper assembly, both push and rotate firmly.

Contraindications

Prostrolane Natural_B must not be used:
- for the combination with peeling, laser treatment or ultra-sound,
- if the patient has cutaneous disorder, inflammation or infection at the treatment site or near to this site,
- in the case of patients have a known hypersensitivity to hyaluronic acid, with a history of severe allergy or anaphylactic shock,
- in case of the patients with autoimmune diseases,
- Due to possible interactions with other filling implants, which have not been researched, it is inadvisable to use Prostrolane Natural_B into sites in the presence of other filling implants.
- in pregnancy, breast-feeding mother, and in children or minors under 18 ages
- for patients with bleeding disorders, skin color disorders

Warnings and Side Effects

• Avoid applying on skin products other than those advised by doctor.
• The doctor must inform the patient of possible local reactions related to the implantation of this resorbable device.
• Should any inflammatory reaction or any other side effect not disappear within a week, the patient must inform the clinician about it immediately.
• The doctor is requested to report any notable side effect related to the Prostrolane Natural_B to Caregen Co., Ltd. through the website, www.caregen.co.kr by fax at +82-31-452-3869.
• Defer use of Prostrolane Natural_B at specific sites in which an active inflammatory process (Skin eruptions such as cysts, pimples, rashes, or hives) or infection is present until the process has been controlled.
• Prostrolane Natural_B is packaged for single patient use. Do not re-sterilize. Do not use if package is opened or damaged.
• Do not use Prostrolane Natural_B after the expiry date printed on the package.
• Prostrolane Natural_B should not be mixed with other products before implantation of the device.
• Do not inject into blood vessels.
• Do not inject into eyelids.

Precautions

• In case of allergic risk, a test should be done before the first injection. The test results must be attached to the patient's medical record.
• Health care practitioners are encouraged to discuss all potential risks of injection with their patients prior to treatment and ensure that the patients are aware of signs and symptoms of potential complications.
• In order to minimize the risks of potential complications, the product should only be used by health care practitioners who have appropriate training, experience, and who are knowledgeable about the anatomy at and around the site of injection.
• Minimize the risks of potential complications, the product should only be used by health care practitioners who have appropriate training, experience, and who are knowledgeable about the anatomy at and around the site of injection.
• As with all transcutaneous procedures, Prostrolane Natural_B implantation carries a risk of infection. Standard precautions associated with injectable materials should be followed.
• Prostrolane Natural_B filler injection may cause hyperpigmentation at the injection site.
• Bruising or bleeding may occur at injection sites.
• Prostrolane Natural_B is a transparent gel without particulates. In the event that the content of a syringe shows signs of separation and/or appears cloudy, do not use the syringe. Glass is subject to breakage under a variety of unavoidable conditions.
Care should be taken with the handling of the glass syringe and with disposing of broken glass to avoid laceration or other injury.
• Prostrolane Natural_B should not be mixed with other products before implantation of the device. Patients should minimize exposure of the treated area to excessive sun, UV lamp exposure and extreme cold weather at least until any initial swelling and redness resolved.
• After use, syringes and needles should be handled as potential biohazards. Disposal should be in accordance with accepted medical practice and applicable local, national requirements.

Treatment Techniques

1. Prostrolane Natural_B can be injected by a number of different techniques that depend on the treating physician's experience and preference, and patient characteristics.
2. Serial puncture involves multiple, closely spaced injections along wrinkles or folds. Although serial puncture allows precise placement of the filler, it produces multiple puncture wounds that may be undesirable to some patients.
3. Linear threading is accomplished by fully inserting the needle into the middle of the wrinkle or fold and injecting the filler along the track as a "thread." Although threading is most commonly practiced after the needle has been fully inserted and is being withdrawn, it can also be performed while advancing the needle ("push-ahead" technique).
4. Serial threading is a technique that utilizes elements of both approaches.
5. Cross-hatching consists of a series of parallel linear threads injected at intervals of five to ten mm followed by a new series of threads injected at right angles to the first set to form a grid. This technique is particularly useful in facial contouring when coverage of the treatment region needs to be maximized.
6. The correct injection technique is crucial for the final result of the treatment. Dissection of the sub-epidermal plane with lateral movement of the needle, rapid flows (≤ 0.25 mL/min), rapid injection or high volumes may result in an increase in short-term episodes of bruising, swelling, redness, pain, or tenderness at the injection site.
7. When the injection is completed, the treated site should be gently massaged so that it conforms to the contour of the surrounding tissues. If an overcorrection has occurred, massage the area firmly between your fingers or against an underlying superficial bone to obtain optimal results.
8. If so called "blanching" is observed, i.e., the overlying skin turns a whitish color, the injection should be stopped immediately and the area massaged until it returns to a normal color.
9. If the wrinkle needs further treatment, the same procedure should be repeated until a satisfactory result is obtained. Additional treatment with Prostrolane Natural_B may be necessary to achieve the desired correction.
10. If the treated area is swollen directly after the injection, an ice pack can be applied on the site for a short period. Ice should be used with caution if the area is still numb from anesthetic to avoid thermal injury.
11. Patients may have mild to moderate injection site reactions, which typically resolve in a few days.

Storage condition

Store between 2℃ ~ 25℃. Protect from freezing and sunlight. Make sure there are no visible signs of damage to the packaging before use.

Shelf life

2 years under recommended conditions.

Manufactured by Caregen Co., Ltd.

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	Do not reuse
	Use by
STERILE	Sterilized using steam or dry heat
LOT	Lot number
	Date of manufacture
	Attention, see instruction for use
CE 2265	CE Mark and identification number of Notified Body
	Manufacturer
	Don't use if packages is damaged
EC REP	Authorised representative in the EC
	Consult instructions for use
STERILIZE	Do not re-sterilize
	Keep away from sunlight
2℃ 25℃	Temperature limitation

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