

### Description

Prostrolane Blanc\_B is a transparent gel supplied in a glass syringe. The product is for single use only. Prostrolane Blanc\_B is a sterile medical device, dermal resorbable implant that contains a non-cross-linked Sodium Hyaluronate and peptide complex (Oligopeptide-92, Octapeptide-11, Feruloyl Oligopeptide-33, Valprooyl Oligopeptide-33). Sodium Hyaluronate is non-animal origin and biocompatibility material. The Role of Sodium Hyaluronate in the skin is to deliver peptide, hydrate the skin by holding in water, and to act as a cushioning agent. Peptide complex consists of 4 kinds peptides that short chain of amino acids linked by peptide bonds. The role of the peptide complex is enhanced the moisturizing effect, improve the appearance of photo-aged skin and delays the degradation of Sodium Hyaluronate. Peptide complex with Sodium Hyaluronate is degradation within 4 weeks. Each carton contains 1 pre-filled syringe of 2ml Prostrolane Blanc\_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-92, Octapeptide-11, Feruloyl Oligopeptide-33, Valprooyl Oligopeptide-33)

### Indication and Usage

Prostrolane Blanc\_B is indicated for dermal implantation for the treatment of sun damaged and photo-aged wrinkled ageing skins.  
 - Site of Application: Face, neck  
 - Recommended usage volume : 2ml / area (Maximum: 4ml / area)  
 - Frequency : 1 session / 2 weeks (1 protocol = 2-4 sessions average ) (repeat protocol as necessary)

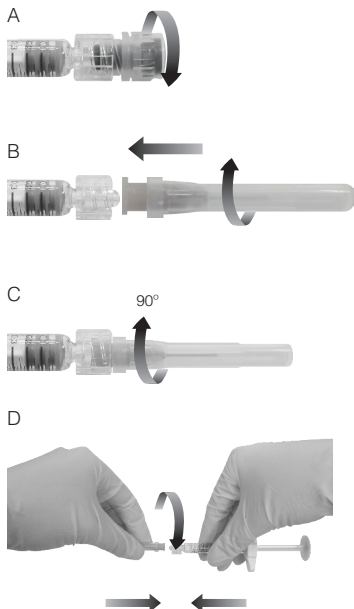
### Treatment procedure

**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 Blanc\_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 Blanc\_B.
5. Before treatment, press rod carefully until a small droplet is visible at the tip.
6. Prostrolane Blanc\_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 Blanc\_B should be injected into the mid to deep dermis. If Prostrolane Blanc\_B is injected too superficially this may result in visible lumps and/or bluish discoloration.
7. Inject Prostrolane Blanc\_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.
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 Blanc\_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 Blanc\_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 Blanc\_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

- 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 Blanc\_B to Caregen Co., Ltd. through the website, [www.caregen.co.kr](http://www.caregen.co.kr) by fax at + 82-31-452-3869.
- Defer use of Prostrolane Blanc\_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 Blanc\_B is packaged for single patient use. Do not re-sterilize. Do not use if package is opened or damaged.
- Do not use Prostrolane Blanc\_B after the expiry date printed on the package.
- Prostrolane Blanc\_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 Blanc\_B implantation carries a risk of infection. Standard precautions associated with injectable materials should be followed.
- Prostrolane Blanc\_B filler injection may cause hyperpigmentation at the injection site.
- Bruising or bleeding may occur at injection sites.
- Prostrolane Blanc\_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 Blanc\_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.

### Storage condition

Store between 2°C - 25°C. 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



Sterilized using steam or dry heat



Lot number



Date of manufacture



Attention, see instruction for use



CE Mark and identification number of Notified Body



Manufacturer



Don't use if packages is damaged



Authorised representative in the EC



Consult instructions for use



Do not re-sterilize



Keep away from sunlight



Temperature limitation

# PROSTROLANE

Blanc-B 2ml



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