

BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

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1. Device Description

Black Origin™ is an innovative formulation based on hyaluronic acid (HA), a naturally occurring polysaccharide that plays a vital role in maintaining tissue hydration by effectively binding large amounts of water. *Black Origin™* combines both high molecular weight (H-HA) and low molecular weight (L-HA) hyaluronic acid in a specially buffered physiological solution, delivering dual benefits for skin hydration and rejuvenation.

The HA in *Black Origin™* is produced through a biofermentation process that ensures high purity and is free from chemical modifications, resulting in excellent biocompatibility and minimal risk of adverse reactions. The other components include sodium chloride, sodium phosphate, and water for injection, making it a safe and well-tolerated option for enhancing skin health.

Black Origin™ is specifically designed to target facial areas, particularly the malar-zygomatic and sub-malar regions, helping redefine contours and improve skin laxity. This advanced treatment effectively counters the natural aging process, which often leads to reduced hydration, weakened collagen structure, and loss of skin elasticity.

The combined viscoelastic and hydrating properties of HA, along with its ability to maintain optimal HA levels in the skin, help rehydrate and rejuvenate the skin, creating an ideal environment for combating signs of aging. This includes improvements in skin tone, elasticity, and the repair of minor scars. Additionally, *Black Origin™* supports dermal cell proliferation, migration, and structural organization.

Injected intradermally, *Black Origin™* works directly within the dermal layer rather than the superficial epidermis, providing targeted rejuvenation from within while protecting dermal cells from oxidative stress. This unique approach ensures long-lasting results for individuals seeking to restore or maintain youthful, healthy-looking skin.

2. Intended use

Black Origin™ is intended for the treatment of facial areas, specifically the malar-zygomatic and sub-malar regions, to redefine facial contours and improve skin laxity. It is designed to address the signs of skin aging, such as reduced hydration, loss of elasticity, and weakened collagen structure. By enhancing skin hydration and promoting tissue remodeling, *Black Origin™* effectively rejuvenates the skin, providing a more youthful appearance. The product is suitable for individuals seeking preventive and corrective aesthetic treatments to counteract aging and improve overall skin quality..

3. Contraindications

- *Black Origin™* should not be used in conjunction with treatments such as laser resurfacing or medium/deep chemical peels.
- It must not be injected intravenously, into muscles, tendons, or for breast augmentation.
- *Black Origin™* should not be administered to inflamed or infected areas, or in patients with active skin inflammation (e.g., acne or rashes) in the treatment area.
- The product is contraindicated for patients with a history of hypersensitivity to hyaluronic acid or any of its components.
- It is also not recommended for use in pregnant or breastfeeding women.
- *Black Origin™* is intended for single-use only and must not be resterilized or reused to avoid contamination risks.

4. Warnings

- The contents of the pre-filled syringe are sterile; however, the external surface is not. Handle the syringe carefully to maintain aseptic conditions during use.
- Do not use *Black Origin™* if the packaging is damaged or has been previously opened, or if it is past the expiry date.
- Only inject into healthy, intact skin. Avoid areas with active inflammation or infection.
- Do not inject into veins, muscles, tendons, or use for breast augmentation.
- Do not mix *Black Origin™* with other products or medications, as it may lead to adverse reactions.
- *Black Origin™* is intended for single use only and must not be resterilized or reused to prevent contamination.
- Once opened, use *Black Origin™* immediately and discard any remaining product after use.
- Keep the product out of reach of children.
- The presence of an air bubble in the syringe does not affect product quality or safety.
- After treatment, patients should avoid UV exposure and use SPF 50 sunscreen to protect the treated area for 3-5 days, ensuring optimal results and minimizing the risk of side effects

5. Precautions

- Do not mix *Black Origin™* with disinfectants containing quaternary ammonium salts or chlorhexidine, as this may cause a precipitate to form.
- The product should only be used by healthcare professionals trained in the appropriate injection techniques to minimize the risk of adverse effects.
- Patients with a history of autoimmune disease or those receiving immunotherapy should be treated with caution, as safety in these populations has not been established.
- Ensure that the injection site is thoroughly cleaned and disinfected before use to prevent infection.
- Avoid applying excessive pressure or massage to the treated area immediately after injection, as this may affect the distribution of the product.

6. Side-effects and possible adverse events

- During treatment with *Black Origin™*, some patients may experience mild side effects such as pain, warmth, redness, or swelling at the injection site, sometimes accompanied by itching. These symptoms typically resolve on their own within a few days but can persist for up to 10 days. Applying ice to the treated area can help alleviate these symptoms.
- In rare cases, patients may experience hardening or small nodules at the injection site. Extremely rare side effects, as reported in the literature, include skin discoloration at the injection site, tissue necrosis, abscess formation, granulomas, or hypersensitivity reactions.
- If severe adverse events occur, patients should seek immediate medical attention. It is crucial that *Black Origin™* is administered by a qualified healthcare professional to minimize the risk of these events.

7. Instruction for use

1. Carefully remove the syringe from its packaging, ensuring that aseptic conditions are maintained throughout the procedure.
2. Unscrew the cap from the syringe tip while holding the luer-lock firmly to avoid contamination. Avoid touching the opening.
3. Attach a 27-33G sterile needle to the luer-lock mount by twisting it until slight resistance is felt, ensuring an air-tight seal to prevent leakage.
4. Inject *Black Origin™* at room temperature using strict aseptic techniques.
5. Identify the injection points based on the patient's needs, focusing on the malar-zygomatic and sub-malar regions:

- Zygomatic protrusion: Ensure that the injection point is at least 2 cm away from the lateral canthus (outer corner) of the eye.
- Nasal base: Draw a line connecting the nostril to the tragus and another perpendicular line starting from the pupil. Locate the injection point at the intersection of these lines.
- Tragus: Stay at least 1 cm anterior to the inferior margin of the tragus.
- Chin: Draw a vertical line in the center of the chin, then draw a perpendicular line one-third from the top of the vertical line. Move 1.5 cm towards the oral commissure from the intersection point to locate the injection site.
- Mandibular angle: Inject 1 cm above the mandibular angle.

6. Administer 0.2 ml of product per injection point using the bolus technique, ensuring that the injection is made into the dermal or subcutaneous layer.
7. Gently massage the treated area to aid product distribution and optimize results.
8. Each syringe is intended for single use; discard any remaining product after treatment.
9. Follow the post-treatment recommendations, including avoiding UV exposure and applying SPF 50 sunscreen for 3-5 days to protect the treated area.

8. Storage and Handling

- Store at room temperature up to 25°C , away from heat sources
- Do not freeze the product or expose it to excessive heat or direct sunlight.
- Do not use the product if the packaging is damaged or if the expiration date has passed.
- Each syringe is for single use only and must be discarded immediately after use.
- To place an order, contact Pol Tech Central Office: 021-284208

9. Glossary Symbols

Symbol	Symbol Title	Explanatory Text
	Manufacturer	Indicates the medical device manufacturer
	Use-by date	Indicates the date after which the medical device is not to be used.

	Lot code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	Consult instructions for use	Indicates that important information regarding safety, usage, and precautions is contained in the documentation, and this information should be reviewed before using the product.
	Sterilized using steam	Indicates a medical device that has been sterilized using steam.
	Single sterile barrier system	Indicates a single sterile barrier system. The packaging system for a sterile medical device is composed of one or more sterile barriers.
	Do not re-use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
	Caution	Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.

	Temperature limit	indicates the recommended storage temperature range for a medical device or product.
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Manufactured by:

Pol Tech. Tehran, Iran

Phone: 021-284208