BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

Contents

1. Device Description

Black Restore™ is a sterile, biodegradable, clear, viscoelastic gel made of non-animal stabilized hyaluronic acid (HA). The HA is crosslinked with BDDE (1,4-butanediol diglycidyl ether) to increase the filler's longevity and maintain facial volume over time.

Composition (per mL):

- Hyaluronic Acid: 22 mg
- Phosphate-buffered saline: q.s. to 1 mL (pH 7.0)

The product is available in a pre-filled syringe with 1 mL of gel, provided with two sterile 27 G½ needles. Each syringe is intended for single use only.

2. Indications and Intended Use

Black Restore™ is intended for:

- Moderate to severe facial wrinkles and folds, such as nasolabial folds.
- Chin augmentation and contouring, providing definition and restoring volume loss.
- Deep dermal to subcutaneous injection to improve facial contours, especially in the mid-face and chin.
- This product is approved for adults aged 21 years and older.

3. Contraindications

The following conditions contraindicate the use of *Black Restore™*:

- Hypersensitivity to hyaluronic acid, including anaphylaxis or other severe allergic reactions.
- Active infection or inflammation at the site of the injection (e.g., herpes simplex, cysts, acne, or unhealed wounds).
- Bleeding disorders or patients on anticoagulant therapy, as these may increase the risk of bleeding or bruising at the injection site.

- Pregnancy or breastfeeding: Safety has not been established for pregnant or breastfeeding women.

4. Warnings

- Intravascular Injection Risk: Accidental injection into blood vessels can result in serious complications, including embolism, ischemia, necrosis, or blindness. Always aspirate before injecting to minimize the risk of vascular occlusion.
- Avoid Injections into Areas with Active Inflammation: Injecting into areas with active inflammation or infection may worsen the condition and delay healing.
- Patients with a History of Severe Allergic Reactions: Individuals with a history of anaphylaxis or multiple severe allergies should avoid this treatment.
- Non-resterilizable Device: The product is for single use only. Do not attempt to sterilize the syringe or needles again.

5. Precautions

- **Single-Use Only**: *Black Restore™* is packaged for single-patient use only. Do not reuse or resterilize. Reusing the product could lead to contamination and potential adverse events.
- **Practitioner Expertise**: Only healthcare practitioners trained in facial anatomy and experienced with dermal filler injections should administer *Black Restore™*. This reduces the risk of complications, such as vascular occlusion.
- **Injection Technique**: Careful attention to injection techniques is critical. Inject the filler into the correct layer (deep dermis or subcutaneous) to avoid superficial lumps or irregularities. Always aspirate before injecting to reduce the risk of intravascular injection.
- **Sterility**: Maintain sterility throughout the procedure. Use sterile gloves and equipment. Do not use the product if the packaging is damaged or compromised. Ensure proper disposal of the syringe and needle after the procedure.
- **Concurrent Treatments**: Avoid performing procedures such as laser treatments, chemical peels, or dermabrasion in the same area before or immediately after the filler treatment, as these could provoke an inflammatory reaction.

- **Immunocompromised Patients**: Use caution when injecting patients who are on immunosuppressive therapy or have conditions affecting their immune response, as they may be more susceptible to infections or prolonged healing times.
- **Pregnancy and Breastfeeding**: The safety of *Black Restore™* has not been established in pregnant or breastfeeding women. Use of the product in these populations is not recommended.
- **Bleeding Disorders**: Patients with bleeding disorders or those taking medications that prolong bleeding (such as aspirin, NSAIDs, or anticoagulants) may experience increased bruising or bleeding at the injection site.
- **Sun and Heat Exposure**: After treatment, patients should avoid excessive sun exposure, tanning beds, and extreme temperatures until any swelling or redness resolves. This helps reduce the risk of inflammation or discomfort.
- **Pre-existing Conditions**: Avoid injecting into areas with active inflammation, infection (such as herpes, cysts, or acne), or where there is a tendency for scarring or hypertrophic reactions. Injection in close proximity to permanent implants should also be avoided, as it could interfere with the outcome or aggravate adverse events.
- **Herpes Reactivation**: Patients with a history of herpes simplex infections may experience reactivation of the virus after dermal filler injections. Prophylactic antiviral therapy may be considered for such patients.
- **Pigmentation Changes**: Post-inflammatory hyperpigmentation may occur, particularly in individuals with darker skin tones (Fitzpatrick IV-VI). Patients should be informed of this possibility prior to treatment.

6. Adverse Reactions

Common Side Effects:

- Localized Reactions: Mild redness, swelling, bruising, tenderness, or itching at the injection site. These effects typically resolve within 1-2 weeks.

- Lumps or Nodules: Small, palpable lumps may form at the injection site. These generally resolve with gentle massage and time.

Severe Risks (rare but serious):

- Vascular Occlusion: Blockage of a blood vessel can lead to tissue ischemia, necrosis, and other serious outcomes. Immediate medical intervention, including the use of hyaluronidase, may be required.
- Infection: If signs of infection such as increased redness, warmth, tenderness, or pus are present, contact a healthcare provider immediately.
- Allergic Reaction: Symptoms such as swelling, hives, or difficulty breathing should be treated as medical emergencies.
- Visual Impairment: Accidental injection near the orbital region may cause vision changes, including blurred vision or blindness.

7.Post-Market Surveillance

Following the market introduction of *Black Restore™* post-market surveillance reports from voluntary submissions and published literature have been collected. These reports most commonly included cases of transient swelling/edema, occurring either immediately or with a delayed onset, up to several weeks after the injection.

Additional adverse events, listed in decreasing order of frequency, included:

- Mass formation or induration
- Papules/nodules
- Erythema
- Pain/tenderness
- Short duration of effect
- Bruising or hematoma
- Presumptive bacterial infections and abscess formation
- Inflammation

- Discoloration
- Injection site reactions such as burning sensation, irritation, and warmth
- Ischemia and necrosis due to unintentional intravascular injection or embolization
- Hypersensitivity or angioedema
- Granuloma or foreign body reaction
- Pruritus
- Neurological symptoms such as hypoesthesia, paraesthesia, and facial paralysis
- Ocular symptoms including eye swelling, eye pain, eyelid edema, eyelid ptosis, blurred vision, and visual impairment
- Rash
- Device dislocation
- Blisters or vesicles
- Herpes reactivation symptoms
- Deformity or asymmetry
- Discharge
- Atrophy or scarring
- Urticaria
- Capillary disorders such as telangiectasia
- Dermatitis
- Acne
- Device extrusion
- Non-dermatological events including chills, discomfort, dizziness, headache, malaise, nausea, and fever
- Other dermatological events including skin pain

When required, treatments for these adverse events included interventions such as ice application, massage, warm compress, nitroglycerin paste, corticosteroids, antibiotics, antihistamines, analgesics, antiviral agents, diuretics, aspiration or incision, drainage, surgery, or enzymatic degradation with hyaluronidase.

Serious adverse events have been rare but reported. The most commonly reported serious adverse events included:

- Infection or abscess formation
- Mass or induration, including granulomas
- Ischemia or necrosis
- Ocular disorders

Vascular occlusion and visual disturbances, including blindness, have been reported in association with unintentional intravascular injection or embolization. Prompt recognition and intervention are crucial in such cases to prevent permanent damage. Treatments may include the use of anticoagulants, vasodilators, hyaluronidase, corticosteroids, and other supportive measures.

All post-marketing events should be reported to Pol Tech at 021-284208.

8. Clinical Studies

Several clinical trials evaluated the safety and effectiveness of *Black Restore™* in improving facial volume, correcting chin retrusion, and reducing the appearance of nasolabial folds. The studies involved 300 adult patients, monitored over a 12-month period.

Key Findings:

- Nasolabial Folds: 87% of patients showed visible improvement in nasolabial fold depth after 6 months, with 75% maintaining improvement after 12 months.
- Chin Augmentation: 90% of patients experienced significant chin volume restoration, with improvements lasting up to 1 year.
- Patient Satisfaction: 85% of patients reported high satisfaction with their facial appearance after treatment, particularly with the natural-looking results.

9. Instructions for Use

A. Preparing for Injection:

1. Inspect the syringe for any defects before use. Ensure the product is within its expiration date.
2. Disinfect the treatment area using an antiseptic solution.
3. Use the provided 27 G½ sterile needle. Assemble the needle securely on the syringe by twisting it gently but firmly into place.

B. Injection Techniques:

1. Nasolabial Folds:
    - Use a linear threading or fanning technique. Inject the filler into the mid-to-deep dermis.
    - After injection, gently massage the area to ensure even distribution of the product.
    - Post-Injection Care: Gently massage the area after injection to ensure even distribution of the filler and smoothness
2. Chin Augmentation:
    - For chin contouring, use a bolus technique with injections placed in the subcutaneous or supraperiosteal plane. Careful aspiration before injection is necessary to avoid vascular complications.
    - Post-Injection Care: Gently massage the area after injection.
3. Layering Technique: In deeper wrinkles or areas requiring more volume, layer the product in small aliquots to prevent overfilling and ensure smooth integration.

C. Post-Injection:

- Apply light pressure to minimize bruising and swelling. Use a cold compress if necessary.
- Dispose of the syringe and needle immediately after use, following medical waste disposal protocols.

D. Safety Guidelines:

1. Blanching: If blanching occurs during injection, stop immediately and massage the area until the skin returns to its normal color. This could indicate vascular occlusion.
2. Patient Instructions: Advise the patient to avoid strenuous exercise, excessive sun exposure, or heat for 24 hours post-treatment to minimize swelling and discomfort.

10. Post-Treatment Care

Immediate Care:

- Use a cold compress to reduce swelling, but do not apply ice directly to the skin.
- Avoid touching or massaging the treated area for at least 6 hours post-injection.

24-48 Hours Post-Treatment:

- Avoid exposure to intense heat (e.g., saunas, sunbathing) and strenuous physical activity for 48 hours.
- Refrain from consuming alcohol or blood-thinning medications, as these may exacerbate bruising.
- Maintain hydration to enhance the effects of hyaluronic acid.

Follow-Up:

- Results are typically visible immediately, but the final results will be clearer after swelling subsides, usually within 1-2 weeks.
- Patients may require follow-up treatments or touch-ups every 6-12 months to maintain optimal results.

When to Seek Medical Help:

Seek immediate medical attention if you experience any of the following:

- Sudden vision changes or blindness.

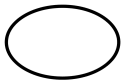
- Severe, unexplained pain in the treated area.
- Signs of infection: Fever, worsening redness, swelling, or pus at the injection site.
- Pale or discolored skin, which may indicate vascular occlusion.

11. Storage and Handling

- Store at room temperature between 2°C and 25°C .
- 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

12. 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	Lot code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
REF	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.

Manufactured by:

Pol Tech. Tehran, Iran

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