BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

Contents

1.Device Description

Black Velvet™ is a sterile, transparent gel of hyaluronic acid derived from non-animal sources, produced by Streptococcus bacteria, and chemically cross-linked with BDDE (1,4-butanediol diglycidyl ether) to stabilize the product. It is suspended in phosphate-buffered saline at a pH of 7 with a concentration of 15 mg/mL of hyaluronic acid, containing 0.3% lidocaine to reduce discomfort during injection.

2.Intended use

Black Velvet™ is indicated for submucosal implantation for lip augmentation and dermal implantation for the correction of perioral lines (fine wrinkles around the mouth) in patients aged 21 and above.

3.Contraindications

- Severe Allergies: Patients with severe allergies, particularly those with a history of anaphylaxis or multiple severe allergies, should not be treated with *Black Velvet™*.
- Bleeding Disorders: Patients with bleeding disorders should avoid treatment.
- Anatomical Restrictions: Do not inject *Black Velvet ™* into areas other than the dermis or for lip augmentation in the submucosal layer.
- Lidocaine Sensitivity: Avoid in patients with known hypersensitivity to lidocaine or other amide-type anesthetics.

4.Warnings

- Avoid Use in Active Inflammatory Sites: Defer treatment with *Black Velvet ™* in areas where active inflammation is present, such as cysts, rashes, acne, pimples, or other skin eruptions. It is recommended to wait until the inflammatory processes are fully controlled before proceeding with injections in the affected areas.
- Injection Site Reactions: Patients may experience swelling, bruising, pain, or tenderness at the injection site. These reactions are typically mild to moderate and resolve on their own within 18 days. In some cases, a delayed onset of swelling has been observed, occurring as

late as 142 days post-injection. Patients experiencing delayed symptoms should monitor for resolution within 18 days. If swelling persists or worsens, medical attention is advised.

- Vascular Complications: Accidental injection of *Black Velvet™* into blood vessels may result in serious complications, including embolism, ischemia, or infarction. Inject slowly with minimal pressure to reduce the risk of vascular compromise. Intravascular injections may cause vision changes, stroke-like symptoms, or skin blanching. If any of these symptoms arise, cease injection immediately, and provide prompt medical intervention to prevent permanent damage.
- Risk of Necrosis: *Black Velvet™* should never be injected directly into blood vessels. Improper injection near blood vessels, particularly in sensitive areas like the lips, nose, or glabellar region, may cause localized necrosis, scarring, or tissue death. Special caution is advised when treating areas with a history of surgical intervention, as scarring or compromised blood flow can exacerbate these risks.
- Delayed Inflammatory Papules: Patients may rarely develop delayed inflammatory papules post-treatment. These should be evaluated as potential soft tissue infections and treated appropriately. Any delayed onset swelling or papules should be closely monitored and managed under the guidance of a healthcare provider.
- Injection Volume Considerations: Using more than 3 mL of product during a single treatment session increases the risk of adverse reactions. It is advised to limit injections to 3 mL or less and, if necessary, schedule a follow-up treatment to achieve desired correction.
- Vascular Rich Areas: *Black Velvet™* should not be injected into areas rich in blood vessels, such as the glabella or nose, as this increases the risk of vascular embolization and other complications like blindness. These areas require extra caution and expertise when administering injectable fillers.
- Use in Previously Treated Areas: Special care should be taken when injecting *Black Velvet™* into areas that have undergone previous surgical procedures or filler treatments. Pre-existing scar tissue or altered anatomy may increase the risk of vascular compromise or product migration.
- Patient Selection: Patients with certain underlying conditions, such as bleeding disorders, severe allergies, or known hypersensitivity to lidocaine or other amide-type anesthetics, are

not suitable candidates for *Black Velvet™* treatment. Thorough patient screening is essential to ensure the safe administration of the product.

5.Precautions

- Sterile Packaging and Use: *Black Velvet™* is packaged for single-patient, single-use only. Do not re-sterilize. If the package is opened or damaged, the product must not be used, as this may compromise sterility and increase the risk of infection. Proper handling of all components is essential to maintain product integrity.
- Patient Counseling: Healthcare providers should thoroughly discuss the potential risks and benefits of soft tissue injections with patients prior to treatment. It is important to ensure that patients understand the signs and symptoms of potential complications, such as infection, inflammation, or vascular occlusion. Patients should be informed about possible post-treatment reactions and when to seek medical attention.
- Qualified Personnel: *Black Velvet™* should only be administered by healthcare professionals who have the appropriate training, experience, and knowledge of the relevant anatomy at and around the injection site. Injections in certain high-risk areas (e.g., near vascular structures) should only be performed by skilled practitioners to minimize the risk of serious complications.
- Anatomical Limits: The safety and efficacy of *Black Velvet™* for use in areas other than lips or perioral lines have not been established in controlled clinical studies. The product should only be injected into approved anatomical areas as directed by healthcare professionals, based on their knowledge of safe and effective use.
- Cannula Injection: The safety and effectiveness of *Black Velvet™* with blunt-tip cannulas have only been evaluated in certain cannula types. The product has been studied with specific blunt-tip cannulas (e.g., DermaSculpt or Softfil), which are between 25G to 27G in gauge and 1.5 inches in length. Other cannulas have not been evaluated, and their use is at the healthcare provider's discretion.
- Patients Under 22 Years: The safety and effectiveness of *Black Velvet™* for lip augmentation in patients under 22 years of age have not been established. Limited data is available for

patients under 36 years of age, and any treatment of younger patients should be approached with caution.

- Immunosuppressive Therapy: Patients receiving immunosuppressive therapy may experience a greater risk of infection or other complications following treatment with Black *Velvet*™. Physicians should carefully evaluate the risk-benefit ratio in such patients and take appropriate precautions to avoid infection.
- Bleeding and Bruising: *Black Velvet ™* may cause bruising or bleeding at the injection site. Patients who have received anticoagulant, antiplatelet, or thrombolytic therapy in the 3 weeks prior to treatment have not been studied, and special caution is advised when treating these patients.
- Concomitant Treatments: The safety of *Black Velvet ™* in combination with other dermal therapies, such as laser treatments, epilation, or chemical peels, has not been established. If patients have recently undergone any dermal procedures, treatment should be delayed until the skin has healed completely to reduce the risk of adverse events such as inflammation or infection.
- Sun and UV Exposure: Patients should minimize exposure to excessive sunlight, UV lamps, and extreme cold until any initial swelling or redness has resolved. These environmental factors can aggravate post-injection reactions and should be avoided for a minimum of 24-48 hours post-procedure.
- Herpes Reactivation: Patients with a history of herpes simplex virus (HSV) infections in the area to be treated may be at risk of reactivating herpes outbreaks following injections of Black *Velvet* ™. Prophylactic antiviral therapy may be considered to reduce the likelihood of herpes reactivation.
- Handling Biohazardous Waste: After use, syringes, needles, and cannulas should be handled as biohazardous waste and disposed of in accordance with accepted medical practice and local, state, and federal regulations.
- Product Appearance: *Black Velvet ™* is a clear, colorless gel. If the product appears cloudy, separated, or shows any signs of physical compromise, do not use the syringe. Notify the manufacturer for further instructions. Glass syringes are fragile and should be handled carefully to avoid breakage.

- Use with Local Anesthetics: *Black Velvet ™* contains lidocaine. When used in conjunction with other amide-type local anesthetics (e.g., additional dental blocks or topical lidocaine), be cautious of potential additive effects, particularly in patients with conditions such as epilepsy, impaired cardiac conduction, or renal or hepatic dysfunction.

6.Postmarketing Surveillance

The adverse event reports received from post-marketing surveillance of *Black Velvet ™* have provided additional insights into the product's safety profile. These reports come from both voluntary submissions and the medical literature.

The most commonly reported adverse events include:

- Swelling, pain/tenderness, erythema, and bruising at the injection site.
- Hypersensitivity reactions, such as angioedema (rapid swelling), often occurring within a few days after injection. In most cases, these symptoms were resolved with corticosteroid treatment or hyaluronidase administration.
- Infections/abscesses, sometimes appearing up to three weeks after the procedure. These were treated effectively with antibiotics, corticosteroids, or hyaluronidase.

Serious Adverse Events

Serious complications related to *Black Velvet ™* have been rare, but reports include:

- Ischemia/necrosis, caused by vascular occlusion. This serious complication has been reported following accidental intravascular injection. Symptoms include blanching, tissue death, and ulcers at or near the injection site.
- Blindness: In very rare cases, vascular occlusion following injections near the glabella, nose, or periorbital area resulted in blindness or vision abnormalities. These events occurred when the filler inadvertently entered blood vessels supplying the eye. Treatments for these incidents included anticoagulants, epinephrine, steroids, and hyaluronidase.

Delayed Reactions

- Delayed-onset inflammation: In some cases, inflammation near the injection site was reported days or even weeks after treatment. These reactions were often linked to bacterial or viral infections, vaccinations, or dental procedures. Most cases resolved either on their own or with medical treatment.

Healthcare providers are encouraged to report any adverse reactions associated with *Black Velvet ™* to the manufacturer, as this helps to build a more comprehensive safety profile and ensure ongoing monitoring of the product's performance.

7.Clinical Studies

Study Design

A randomized, evaluator-blinded, no-treatment-controlled clinical study was conducted to evaluate the safety and effectiveness of *Black Velvet ™* for lip fullness augmentation and the treatment of perioral rhytids (fine lines around the mouth). The study enrolled 221 subjects. Subjects were randomized in a 3:1 ratio to receive either *Black Velvet ™* or no treatment, ensuring a robust comparison between treatment and control groups.

An additional group of 40 subjects, all younger than 35 years of age, seeking lip augmentation, was enrolled but not randomized. These subjects were evaluated separately and were not included in the main analysis. The subjects in the treatment group were allowed to return for a touch-up treatment 2 weeks after the initial injection if necessary.

Primary and Secondary Endpoints

The primary endpoint was the improvement in lip fullness as assessed by the Medicis Lip Fullness Scales (MLFS) and the Global Aesthetic Improvement Scale (GAIS). Both scales were used to evaluate lip enhancement, symmetry, texture, and patient satisfaction. Subjects also self-assessed the aesthetic improvement in their lips at various time points throughout the study.

The secondary endpoints included the treatment of perioral rhytids and other safety measures such as adverse event reporting, lip texture, firmness, and movement.

Study Population

The study aimed to recruit a diverse sample of patients, including a minimum of 30 participants with Fitzpatrick skin types IV, V, or VI. These skin types represent individuals with darker complexions, ensuring the product's efficacy and safety across a wide range of skin tones. All subjects were aged 21 or older, with some younger participants enrolled in the non-randomized portion of the study.

Results

1. Lip Fullness Improvement:
    - The results showed that 76.7% of subjects treated with *Black Velvet ™* demonstrated a significant improvement in lip fullness at Week 8, as assessed by blinded evaluators using the MLFS. This improvement was sustained at subsequent visits, with 73.1% at Week 12, 68.3% at Week 16, and 64% at Week 20. By Week 24, 58.8% of subjects still showed enhanced lip fullness.
    - In comparison, the no-treatment group showed minimal change, with only 11.9% of subjects showing any improvement by Week 8, and 20% by Week 24.
2. Perioral Rhytids:
    - Subjects also demonstrated improvement in the appearance of upper perioral rhytids. 57.6% of subjects treated for both rhytids and lips showed improvement by Week 24, compared to 22.8% for those treated for lips alone.
    - The no-treatment group showed minimal to no improvement in this area throughout the study duration.
3. Self-Assessment and Satisfaction:
    - The subjects' self-assessment results aligned with the evaluator-assessed outcomes. At Week 2, 97.7% of subjects reported being pleased with their lip improvement. This percentage slightly decreased over time but remained high, with 76.5% of subjects still reporting satisfaction at Week 24.
4. Re-Treatment Decisions:
    - By Week 24, 76% of subjects opted to undergo re-treatment, indicating high satisfaction with the aesthetic results and a willingness to maintain the outcome. The

majority of subjects who did not opt for re-treatment reported no need for further enhancement.

Safety Profile

The safety assessment revealed that *Black Velvet™* was well-tolerated across all patient demographics. The most common side effects included swelling, bruising, and pain at the injection site, which typically resolved within 2 weeks. There were no significant differences in the incidence of adverse events between subjects with darker skin tones and those with lighter complexions.

- Delayed-Onset Reactions: A small number of subjects reported delayed-onset swelling occurring between 21 and 142 days post-treatment. These reactions were mild and resolved within 18 days without additional treatment.

8.Instruction for use

Directions for Assembly

For safe and effective use of Black *Velvet* ™, it is essential to properly assemble the needle or blunt cannula.

Syringe with a White Cap:

- Hold the syringe at the ribbed part of the white closure system (luer-lock adapter).
- With your other hand, grasp the cap at the end of the closure system and gently tilt it back and forth until the cap disconnects and can be pulled off (breaking the seal).
- Do not rotate.
- Do not touch the syringe tip to maintain sterility.

Syringe with a Transparent Cap:

- Carefully unscrew the tip cap of the syringe.

Assembly of Needle to Syringe

- Use your thumb and forefinger to hold both the glass syringe barrel and the luer-lock adapter firmly.
- With the other hand, grasp the needle shield (or the hub if using a cannula).
- To ensure proper assembly, push and rotate the needle or cannula firmly into place.

Pre-Treatment Guidelines

- Patients should avoid aspirin, nonsteroidal anti-inflammatory drugs (NSAIDs), or high doses of Vitamin E supplements prior to treatment. These agents can increase the risk of bruising and bleeding at the injection site.

Treatment Procedure

1. Counsel the Patient: Discuss the appropriate indication, risks, benefits, and expected responses to the *Black Velvet™* treatment. Ensure the patient understands necessary precautions before proceeding.
2. Assess for Anesthesia: Evaluate the need for anesthesia to manage comfort (e.g., topical anesthetic, local anesthetic, or nerve block).
3. Cleansing: The patient's face should be washed with soap and water, then dried with a clean towel. Cleanse the treatment area with alcohol or another suitable antiseptic solution.
4. Sterile Gloves: Sterile gloves are recommended while injecting Black *Velvet* ™.
5. Priming the Syringe: Before injection, carefully press the plunger rod until a small droplet of the product is visible at the tip of the needle.
6. Aspiration: When using a needle, insert it, then slightly withdraw the plunger rod to ensure the needle is not in a blood vessel before injecting.
7. Needle and Cannula Use:
    - *Black Velvet ™* is administered using a thin gauge needle (30 G x ½"). Alternatively, a blunt-tip cannula (recommended gauge sizes 25-27 G) can be used for lip augmentation. Cannulas are only recommended for lip enhancement, while needles may be used for both lips and perioral lines.
8. Injection Technique:

- Needle Use: Insert the needle at an approximate angle of 30° parallel to the length of the wrinkle, fold, or lip. For rhytids, inject *Black Velvet ™* into the mid-to-deep dermis. For lip augmentation, inject into the submucosal layer, avoiding intramuscular injection. Superficial injections may result in visible lumps or bluish discoloration.
- Cannula Use: For lip augmentation, create an entry point with a sharp needle of appropriate size before using the cannula. Inject slowly. Change the needle or cannula for each new treatment site.

9. Injection Pressure: Apply even pressure on the plunger rod while injecting. Do not apply excessive force. If resistance is encountered, reposition the needle or cannula, or withdraw it fully to check its functionality.
10. End of Injection: Stop the injection just before the needle is withdrawn to prevent leakage or superficial placement of the filler.
11. Avoid Overcorrection: Correct only up to 100% of the desired volume. Do not overcorrect. Best results are achieved when the defect is manually stretched during treatment.
12. Typical Usage: The recommended maximum dose per session is 1.5 mL per lip or 1.0 mL for perioral rhytids correction.

Injection Techniques

1. *Black Velvet™* can be injected using various techniques, depending on the physician's experience and the patient's specific needs:
    - Serial Puncture (A): Multiple, closely spaced injections are made along wrinkles or folds. This technique allows precise placement of the filler but may result in multiple puncture wounds.
    - Linear Threading (B): Fully insert the needle/cannula into the wrinkle or fold and inject the filler along the track. This can be done while advancing the needle or withdrawing it. For lip enhancement, retrograde linear threading is recommended.
    - Serial Threading: Combines elements of both techniques.
2. Blanching: If the skin turns white (blanching), stop the injection and massage the area until the color returns to normal. Blanching could indicate vascular occlusion, and immediate action is required.

3. Massage: After completing the injection, gently massage the treated area to ensure even distribution of the product.
4. Overcorrection: If overcorrection occurs, massage the area firmly between your fingers to flatten out excess filler.
5. Follow-up: If wrinkles or lips require further treatment, repeat the procedure until the desired correction is achieved.

Post-Treatment Care

- If swelling occurs after the procedure, an ice pack can be applied for a short time. Exercise caution with ice packs if the treated area is still numb to avoid thermal injury.
- Mild to moderate injection site reactions are typical and usually resolve within 18 days.

Sterile Needles

- Follow national and institutional guidelines for the use and disposal of sharp medical devices.
- Do not straighten a bent needle; discard and replace it immediately.
- Do not reshield used needles. Dispose of used needles in approved sharps containers.

9.Post-Treatment Care

- Avoid Sun Exposure: Patients should avoid direct sunlight, tanning beds, and extreme heat for at least 24 hours post-treatment to prevent exacerbating swelling and redness.
- Cold Compress: A cold compress may be applied to reduce swelling, but it should not be placed directly on the skin.
- Avoid Physical Exertion: Strenuous activity should be avoided for 24 to 48 hours following the procedure.
- Signs of Complications: Instruct patients to report any signs of unusual swelling, pain, or vision changes immediately.

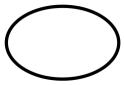
10. Storage and Handling

- Store at room temperature up to 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

11. 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.

Revision Number: 26092024-00

	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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