
Precautions during application

1. Inobelle must be applied by a doctor who has been properly trained in the application of the product.
2. Before applying Inobelle, the doctor must adequately explain to the patient the indications, prohibitions and potential side effects associated with the use of the drug.
3. The safety and efficacy of lip augmentation have not yet been established.
4. If Inobelle is injected into a patient with a history of herpes outbreaks, Herpetiformis recurrence may occur.
5. The safety of patients with sensitivity to scar formation, hyperpigmentation and scarring hypertrophic scars has not yet been established.
6. The safety and efficacy of long-term use other than the time specified in the clinical trial clinical trial has not yet been established.
7. If the needle is blocked, do not increase the pressure on the plunger, but stop the injection and replace it
8. The amount injected depends on the area to be corrected. In particular, the injection of excessive volume may cause severe swelling.
9. During one treatment session, a total volume of 2 ml per treatment site is recommended.

Prohibitions

1. The product must not be injected into individuals with hypersensitivity to lidocaine.
2. Do not inject into the eye area.
3. Do not inject into blood vessels.
4. Do not inject in the following cases:
 - a) Patient with a tendency to manifest hypertrophic scarring.
 - b) Patient with a history of streptococcal disease.
 - c) Patient with hypersensitivity to hyaluronic acid.
 - d) Patient with a history of severe allergy and anaphylaxis.
 - e) Patient with coagulation disorders.
 - f) Woman who is pregnant or breastfeeding.
 - g) To minors.
5. Do not inject into skin with inflammation or infection.
6. Do not use at the same time as laser therapy, chemical peeling or exfoliation.

Warnings

1. Make sure the sterilization condition is intact before use.
2. Check the expiration date of Inobelle on the label.
3. Inobelle cannot be re-sterilized and reused because it is a sterilized disposable product.
4. Inobelle must be applied by persons who have received training at a level higher than that of a medical expert or persons with such qualifications.
5. Inobelle must be used in the operating room or in a designated area where sterile conditions are maintained.
6. Inobelle should not be used in areas where clinical safety and efficacy have not been verified.
7. Do not use in combination with a non-standard or unapproved medical device.

Side effects

The doctor must inform the patient that injection of Inobelle immediately or after some time, the following symptoms may occur. The occurrence of such symptoms should be reported to the sales.

1. An inflammatory reaction accompanied by an open wound or pain (red spots and/or swelling, etc.) may
2. persist for about a week after the injection.
3. An abscess and hypersensitivity reaction may occur after hyaluronic acid injection.
4. If the inflammatory reaction persists for more than a week or other side effects occur, you should
5. consult your doctor and receive immediate treatment.
6. After injection of lidocaine (for systemic administration), the following effects have been reported:

a) Shock

Shock may occur after lidocaine injection. If symptoms occur, such as such as low blood pressure, facial pallor, respiratory depression, etc., should be immediately discontinued use of the drug and take appropriate action.

b) Malignant hyperthermia

Rarely, malignant hyperthermia may occur, accompanied by symptoms of unknown origin (such as arrhythmias, tachycardis, change in blood pressure, sudden [change] in body temperature, muscle rigidity, cyanosis, hyperventilation syndrome, sweating, acidosis, hyperkalemia, erythruria, etc.).

If any of the situations occurred while taking this drug, the administration should be stopped immediately and appropriate measures should be taken, such as administering dantrolene sodium hydrate and cooling the body, etc.

Symptoms of intoxication such as tremors and convulsions may occur. If such a situation would occur, the following should be done

stop the injections immediately and inject diazepam or sodium thiopental, etc. These symptoms require caution as they may cause shock or intoxication.

c) Hypersensitivity

Skin lesions such as hives, swelling, etc. may occur.

Lidocaine was initially approved by the FDA as a drug on November 19, 1948, and is a widely used local anesthetic with 65 years of clinical experience in the US since its introduction. Lidocaine is typically injected into the face during surgery and is used on the face, head and neck in concentrations of 0.5 - 2% for injections and 4% for topical use.

The concentration of lidocaine in Inobelle is 0.3%, the same as for other approved dermal fillers. For healthy adults, the individual maximum recommended dose of lidocaine should not exceed 4.5mg/kg (2mg/pound) of body weight, and it is recommended that the maximum total dose not exceed 300mg.

