PRESCRIPTION ONLY MEDICINE

KEEP OUT OF REACH OF CHILDREN

This medical device contains 0.3% lidocaine hydrochloride and 24% Sodium Hyaluronate

Disposable sterilized medical device. Do not re-use

CE 2265

QTFill PLUS

Model Name

QTFILL PLUS FINE	1.0ml Needle 2 X 30G * 1/2"
QTFILL PLUS DEEP	1.0ml Needle 2 X 27G * 1/2"
QTFILL PLUS Sub-Q	1.0ml Needle 2 X 25G * 1/2"

This product is a bio-material for tissue restoration.
Syringe is filled with 0.3% Lidocaine hydrochloride with a derivative of cross-linked sodium hyaluronate originated from bacterial fermentation gel. It is intended to be used for facial tissue augmentation for mid-to-deep dermal implantation for the correction of moderate to severe facial wrinkles and Nasolabial folds. The addition of lidocaine provides a pain relieving effect during treatment.

Product Name : Cross-linked Hyaluronic Acid injectable gel with Lidocaine
Manufacture number : See exterior package
Manufactured date : See exterior package
Expiry date : See exterior package
Shelf life : Two years (24 months)
Storage : Room temperature(2℃~25℃), avoid light and freezing
Package unit : 1 pre-filled-syringe and 2 Needles / 1 box

COMPOSITION

Sodium hyaluronate, cross-linked 24 mg
Lidocaine hydrochloride 3 mg
Phosphate buffer pH 6.8 – 7.5 q.s. 1.0 mL
One syringe contains 1.0 mL of Cross-linked Hyaluronic Acid injectable gel with Lidocaine.

Application and Indication of each models

QTFILL PLUS FINE is indicated to be used for lip defects or volume enhancement.
QTFILL PLUS DEEP is indicated to be used for mid to deep dermis injection for correction of scars or deep wrinkles or facial tissue augmentation.
QTFILL PLUS Sub-Q is intended to be used for a facial tissue augmentation for mid to deep dermal implantation for the correction of moderate to severe facial wrinkles and folds.

Directions for the use

1) Warning and contraindications:

① Patients who are hypersensitive to lidocaine or amide-type local anesthetics should not use.
② Injection to intradermal or upper part of periosteum.
③ Do not resterilize at the time of use.
④ Avoid injecting to blood vessel which is likely to cause occlusion of blood vessels (tissue necrosis due to it).
⑤ Avoid using by mixing with other products.
⑥ Do not re-use.
⑦ Check and see if sterile condition is not damaged before use.
⑧ Check the effective period on the label of the product.
⑨ Prohibit using to below groups.
- Patients should be more than 21-years-old.
- Patients who are known to be hypersensitive to hyaluronic acid.
- Women who are pregnant or breastfeeding.
- Patient who showed anaphylaxis to raw materials of filler
- Patient who has history of serious allergy or anaphylaxis
- Patient who has bleeding disorder in past or present time.
- Patients who are taking thrombolytic agents or anticoagulants
- Patients who have received anticoagulants, antiplatelet drugs, vitamin E or NSAIDs within 2 weeks.
- Patients who have used topical agents (steroids and retinoids: medicines only, excluding cosmetics) on the facial region within one month
- Patients who have had experience in being subject to calcium hydroxyapatite (CaHA) around the nasolabial folds or have got filler infections such as collagen, or hyaluronic acid (HA)
- Patients who have received acne treatment, dermabrasion, skin resurfacing, wrinkle correction treatment or cosmetic surgery (e.g., face lifting surgery, etc.) on the facial region within 6 months.
- Patients who use cosmetic products to correct winkles within six months.
- Patients who have a history of autoimmune disorder or who have received immunotherapy.
- Patients with a history of streptococcal infections on the facial region.
- Patients with inflammatory and/or infectious diseases (such as acne or herpes) around nasolabial folds.
- Patients with wounds, scars, and skin disorders that may affect the evaluation of efficacy around nasolabial folds.

⑩ Do not inject into inflammatory or infected skin
⑪ Do not use with laser treatment, chemical peeling or peeling.
⑫ This product is used to temporarily improve the facial wrinkles of adults and is prohibited to be used by minors.

2) Precautions for use

① Comply with general precautions at the time of injection to intradermal or upper part of periosteum.
② Always be careful because danger of infection is intrinsic.
③ There should be sufficient anatomic knowledge on the part where injection is made.
④ Avoid injecting to the part where permanent implant was made.
⑤ Until disappearance of edema or sense of heat at the part where injection is done, the patient shall not expose the part where injection is made to sizzling heat or extreme coldness.
⑥ Avoid using to patient who anticipate to have more result than effect of treatment.
⑦ For the case where this product is injected to the part where it is being treated with other filler, there is no verified result.
⑧ Doing make-up within 12 hours after the injection is prohibited. Long-term exposure to sunlight, UV, gel or sauna (sweating bathroom) is prohibited for 2 weeks after the injection.
⑨ Severe side-effect such as blindness, etc. may happen in case of injection into blood vessel, and therefore, using it to the eye contours (eye circle or eyelids) where its injection into blood vessel is highly likely is prohibited. Special attention shall be paid at the time of using.
⑩ There was no established result on safety and effectiveness for the case of using for a long period beyond the time which is established by clinical research.
⑪ There was no established result on safety and effectiveness about lip broadening treatment.
⑫ Injection to patient who has history of herpetic eruption may lead to the recurrence of it.
⑬ No safety is guaranteed to patient who tend to develop keloid scarring, hyperpigmentation and hypertrophic scarring.
⑭ This operation shall be carried out by doctor who is sufficiently trained for such operation.
⑮ Doctor shall sufficiently explain to patient about indications, contraindications and potential side-effects before injection.

3) Incompatibility and mutual interaction

Precipitation reaction of hyaluronic acid may be caused by quaternary ammonium salts such as benzalkonium chloride which is sterilants. Accordingly this product shall not be stored with such materials or avoid contact with operation equipment which uses such materials. There was no verification for the case of using this product together with other medicine or equipment.

4) Expected side-effects

① After injection, symptom such as redness, edema, pressure pain and pain, bruise and itchiness may appear and it shall disappear for itself after 1~2 weeks.
② It is necessary to inform the people concerned that immediately or after lapse of a certain period of time, the following symptoms may appear. When such symptom appears it is necessary to report it to the seller.
③ After injection, inflammation(red fever, redness, edema) accompanied by cut wound or pain may persist about a week.
④ After injection of hyaluronic acid, abscess and oversensitive reaction may appear and so due precaution shall be taken.
⑤ If inflammation reaction persists more than a week or other side-effects appear, then heal it through immediate consultation with medical professional.
⑥ The following adverse reactions were reported in lidocaine injections (for systemic administration)

a. Shock
Symptoms such as shock may be observed. If blood pressure reduction, facial pale, abnormal pulse, respiratory depression, etc are observed, immediately discontinue administration and take appropriate action.

b. Malignant high fever
Severe malignant hyperthermia accompanied by unknown vomiting, arrhythmia, blood pressure fluctuations, rapid temperature rise, muscle stiffness, reddening of blood (cyanosis), hyperventilation, sweating, acidosis, hyperkalemia and myoglobinuria may appear infrequently. If these symptoms are accompanied by malignant hyperthermia during administration of this drug, discontinue administration immediately and take appropriate actions such as intravenous administration of trolene sodium, systemic cooling, hyperoxia to pure oxygen, and correction of acid base equilibrium. In addition, this symptom can lead to kidney failure, so the dose should be kept.

c. Central nervous system
- If you have any of these symptoms, stop taking the drug immediately and take appropriate measures such as diazepam or a short-acting time-consuming barbituric acid (thiopental sodium).
- Drowsiness, anxiety, excitement, ignorance, dizziness, nausea, vomiting, etc may appear. Observe carefully to shock or poisoning symptoms and take appropriate actions as necessary.

d. Hypersensitivity
Skin symptoms such as urticaria, edema, etc may appear

e. Because of the rapid rate at which Lidocaine HCl is metabolized, any condition that affects liver function may alter Lidocaine HCl kinetics. The half-life may be prolonged two-fold or more in patients with liver dysfunction. Renal dysfunction does not affect Lidocaine HCl kinetics but may increase the accumulation of metabolites.

Method of use

a. Preparatory requirement before use

1) This product is medical device therefore it shall be used by licensed medical professionals.
2) Before using it the doctor shall provide sufficient explanation to the patient about indications, contraindications and potential side-effects of this product.
3) Before its use it is necessary to check and see if sterilized condition is damaged or not.
4) Check the effective period on the label of the product.

b. Sequence of manipulation and method of use

1) Before use, disinfect the part subjected to injection thoroughly.
2) Carry out partial anesthesia when required.
3) Insert needle to injection syringe.
4) A certain amount of this product is injected into skin where the injection is required according to judgement of medical professional and when required repetitive injection may be made.
5) After injection the part where injection is made shall be shaped by tip of hands.
6) Regular additional injection is required or demanded in order to maintain improved condition.

c. Method of storage and management after use

1) It is disposable and therefore, make sure to dispose of it after use.
2) Never resterilize and use it again.

Distributor: S.THEPHARM Co.,Ltd.
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Manufacturer: S.THEPHARM Co.,Ltd.
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* STP-IFU-004, Rev. 00, 2024-05-21

Picture 1

Picture 2

Picture 3

S.THEPHARM Co.,Ltd.
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EC REP
JaviTech e.K.
Sachsenhausener Straße 16, 65824
Schwalbach am Taunus ,Germany

Do not re-use	Use by
Sterilized using steam or dry heat	Sterilized using ethylene oxide
Lot number	Date of manufacture
Attention, see instructions for use	CE-marked according to Medical Device Regulation
Manufacturer	Don't use if package is damaged
Authorised representative in the European Union	Consult instructions for use
Do not re-sterilize	Keep away from Sunlight
Keep dry	Fragile
Temperature limitation	

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With Lidocaine 1.0ml

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