# Juvederm Vista® Ultra

# Juvederm Vista® Ultra XC

# Juvederm Vista® Ultra Plus

# Juvederm Vista® Ultra Plus XC

# Informed Consent Form

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**[Copy for patient]**

# For those who will receive treatment with Juvederm Vista®

## 1. Treatment you will receive

The treatment you will receive is an approach to inject a skin filler with a fine needle under facial skin that has wrinkles or furrows. This procedure can increase the skin volume to smoothen wrinkles and fill up furrows. The products recommended to you include Juvederm Vista® Ultra and Juvederm Vista® Ultra Plus, as well as their variants containing anesthetic agents, Juvederm Vista® Ultra XC and Juvederm Vista® Ultra Plus XC, which are soft tissue fillers containing hyaluronic acid approved by the Ministry of Health, Labour and Welfare for the first time in Japan in March 2014. . These four products are referred to as Juvederm Vista® hereinafter. All of these products have been approved and widely used in the European Union (EU) countries, the United States, Canada, and Australia. In Japan, only doctors who have the designated qualification are allowed to inject the product.

## 2. Ingredients of Juvederm Vista®

The chief ingredient of Juvederm Vista® is hyaluronic acid, created by biotechnology. Since hyaluronic acid is a substance naturally found in the human body, it is absorbed smoothly by skin, and is believed to be safe as a filler. The XC preparations contain lidocaine, an ingredient for reducing pain.

## 3. Effects of Juvederm Vista®

- When injected under the skin, Juvederm Vista® increases the skin volume, and decreases facial wrinkles and furrows for a certain period.
- After one injection, the effect usually persists for 9 to 12 months. Thereafter, the effect gradually disappears with time until the state before the injection is reached. In such cases, the same effect appears when Juvederm Vista® is administered again.

## 4. Adverse reactions to Juvederm Vista®

Most of the adverse reactions observed in 290 subjects treated with Juvederm Vista® (Juvederm Vista® Ultra: 146 subjects/Juvederm Vista® Ultra Plus: 144 subjects) were mild ones, such as transient inflammation at injection site, and were reactions common to the use of skin fillers. Major adverse reactions to Juvederm Vista® Ultra/Juvederm Vista® Ultra Plus were erythema (redness) in 136 subjects (93%)/129 subjects (90%), pain in 131 subjects (90%)/129 subjects (90%), induration (lumps generated deep in the skin) in 129 subjects (88%)/127 subjects (88%), edema (swelling) in 125 subjects (86%)/124 subjects (86%), nodule (small lumps generated between skin surface and subcutaneous tissues) in 115 subjects (79%)/120 subjects (83%), contusion (bruise) in 86 subjects (59%)/87 subjects (60%), pruritus (itching) in 52 subjects (36%)/49 subjects (34%), and discoloration in 48 subjects (33%)/49 subjects (34%). These symptoms are common findings observed in association with the use of skin fillers, and usually disappear within about 1 week after injection.

When the product is injected in areas with thin skin, including the areas around the eyes and nose, between the eyebrows, and forehead, injection into blood vessels by mistake or compression of blood vessels and nerves may induce transient or irreversible visual impairment/blindness, stroke (cerebral ischemia, cerebral hemorrhage, cerebral infarction), necrosis of the wings of the nose, etc., and impairment of facial subcutaneous tissues.

Although systemic reactions to the product are not anticipated, the anesthetic ingredient (lidocaine) contained in the XC preparations may be associated with the following adverse reactions.

Significant adverse reactions (incidence unknown) - shock, consciousness disturbed/tremor/spasm, malignant hyperthermia

Other adverse reactions (incidence unknown) - Central nervous system: sleepiness, anxiety, excitement, blurred vision, dizziness, etc.; Gastrointestinal tract: Nausea/vomiting, etc.

Hypersensitivity: Skin symptoms including urticaria, edema, etc.

Consult with your doctor immediately if these symptoms or any other abnormalities are observed.

## 5. Precautions in treatment with Juvederm Vista®

[Before treatment] *Please ask your doctor about any difficult words, such as symptoms and drug names.

- This product cannot used for those who have a history of hypersensitivity to any of the ingredients in the product or to any amide type local anesthetics.
- This product cannot used for those who have a history of hypersensitivity to gram-positive bacteria-derived protein.
- If you have experienced skin troubles caused by cosmetics containing hyaluronic acid, please let your doctor know.
- Inform your doctor if you are pregnant, breast-feeding , or younger than 18 years (efficacy and safety of Juvederm Vista® in these patients have not been established).
- Consult your doctor if you have a history of anaphylaxis, or have an allergic diathesis, including urticaria.
- Consult your doctor if you have a history of Streptococcal diseases (such as recurrent pharyngalgia and acute rheumatic fever) or acute rheumatic fever associated with cardiac complications (allergic reactions or inflammatory symptoms may occur).
- Consult your doctor if you have a history of autoimmune disease, or if you are receiving immunosuppressive therapy (excessive allergic reaction may occur).
- Consult your doctor if you are predisposed to keloid formation, hypertrophic scarring, or dyschromatosis (keloid formation, hypertrophic scar, or dyschromatosis may develop).
- Consult your doctor if you have hemorrhagic diathesis, or if you are taking non-steroidal anti-inflammatory analgesics including aspirin, or anticoagulants including warfarin (the injection site may be more likely to bruise or bleed).
- Consult your doctor if you are currently receiving or are planning to receive laser therapy, chemical peeling, or other treatment by dermabrasion (inflammation of the injection site may be induced).
- Consult your doctor if you are to be treated with an XC preparation and you have a cardiac conduction defect (lidocaine may exacerbate the symptoms).
- Consult your doctor if you are to be treated with an XC preparation and you have a serious hepatic disorder or serious renal disorder (lidocaine may make you more susceptible to toxic symptoms).
- Consult your doctor if you are to be treated with an XC preparation and you have porphyria (lidocaine may induce acute symptoms including acute abdomen, quadriplegia, and disturbed consciousness).
- Consult your doctor if you are to be treated with an XC preparation and you are taking the following drugs.

Class III antiarrhythmic drugs (amiodarone, etc.), amide type local anesthetics (mepivacaine, bupivacaine, etc.), class I antiarrhythmic drugs (lidocaine, quinidine, etc.)

[After treatment]

- Do not massage the injection site after treatment.
- The treated site may look very swollen for 2 or 3 days, even after injection of the appropriate amount, but it will look natural within one week. However, the site may look excessively swollen or lumps may remain for more than one week if the amount injected is excessive. Please visit the medical institution for a check of the treatment effect about 2 weeks after the treatment. If any abnormality has appeared, please notify your doctor immediately.
- Avoid strenuous exercise, prolonged exposure to sunlight or excessive heat, and alcohol intake for 24 hours after treatment.

## Consent Form for Treatment with Juvederm Vista®

My doctor has provided me with information about the treatment of "facial wrinkles and furrows" and treatment with Juvederm Vista®. I have thoroughly understood the information, and I hereby agree to receive the treatment.

Date of consent: _____ (month) / _____ (day) / _____ (year)

Patient's address: _____

Patient's name: _____

Date of explanation: _____ (month) / _____ (day) / _____ (year)

Name of clinic/hospital: _____

Name of doctor: _____

You can withdraw your consent before or during treatment with the drug without experiencing any inconvenience in further treatment.

**[Copy for doctor]**

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