

# **Botox Vista<sup>®</sup> Injection 50 Units Informed Consent Form**

[For patient]

# For those who will receive treatment with Botox Vista®

## 1. Treatment you will receive

Frown lines or crow's feet lines for which you will receive treatment appear on the skin because the corrugator and procerus muscles in the case of frown lines, or the orbicularis oculi muscles in the case of crow's feet lines contract strongly with various facial expressions. The treatment you will receive aims at reducing frown lines or crow's feet lines by weakening the contractile power of the muscles causing the wrinkles. We recommend the injection of a drug called Botox Vista® Injection 50 Units (referred to as Botox Vista® hereafter). Botox® was first approved as a drug in the United States in 1989. At present, it has been approved and used widely in 91 countries, including United States, United Kingdom, Germany, and France. In Japan, it was approved in January 2009 for the indication of "frown lines in adults less than 65 years of age," and in May 2016 for the additional indication of "crow's feet lines in adults less than 65 years of age." This is the only drug approved in Japan for the indications above and can only be administered by certified physicians.

## 2. Ingredient of Botox Vista®

Botox Vista® is a drug that contains botulinum toxin type A (natural protein) as active agent, which is produced from *Clostridium botulinum*. There is no risk of infection with *Clostridium botulinum* because *Clostridium botulinum* is not injected. Results of various studies have shown that an extremely small amount of this protein relaxes the muscles when it is injected directly into strained muscles, and therefore, it has come to be used as a drug.

## 3. Effects of Botox Vista®

- ◆ A chemical transmitter called acetylcholine is released between nerves and muscles to convey nerve stimuli to muscles, thereby inducing muscle contraction. Injection of the drug into the mimetic muscles generating "frown lines or crow's feet lines" inhibits contraction of the muscles, and decreases "frown lines or crow's feet lines" for a certain period.
- ◆ The effect of this drug will start to appear 2 to 3 days after the treatment and usually lasts for 3 to 4 months. The effect will gradually disappear with time, until the original state before you received Botox Vista® treatment. The same effect will appear when you receive another treatment.
- ◆ Since the drug contains protein as main ingredient, in some rare cases antibodies may be produced within your body as the treatment is continued, and the effect may decrease.

## 4. Adverse reactions to Botox Vista®

In use-results surveys for frown lines, adverse drug reactions were reported in 14 (0.89%) out of 1566 subjects included in the safety analysis set. They included eyelid ptosis in 3 subjects (0.19%), injection site pain in 3 subjects (0.19%), and herpes zoster, paraesthesia oral, muscle atrophy, acne, dermatitis allergic, and eczema in 1 subject each (0.06%).

In a clinical study of Botox Vista® 24 Units and 12 Units in crow's feet lines in Japan, adverse events were reported within 90 days after the first treatment in 70 subjects (23.8%) among a total of 294 subjects. None of these adverse events were regarded as adverse drug reactions. In an overseas clinical study of Botox Vista® 24 Units in crow's feet lines, adverse events were reported in 166 subjects (31.6%) among a total of 526 subjects. The most common adverse drug reaction was eyelid oedema, which occurred in 5 subjects (1.0%).

In a Japanese clinical study of simultaneous treatment of crow's feet lines (Botox Vista® 24 Units or 12 Units)

and frown lines (Botox Vista® 20 Units), adverse events were reported within 90 days after the first treatment in 28 subjects (28.0%) among a total of 100 subjects. The most common adverse drug reaction observed in the subjects treated with Botox Vista® 44 Units was eyelid ptosis, which occurred in 4 (8.5%) out of 47 subjects. Similarly, eyelid ptosis occurred in 2 (3.8%) out of 53 subjects treated with Botox Vista® 32 Units. In overseas clinical studies, there were no adverse drug reactions that occurred at a high incidence during simultaneous treatment of crow's feet lines and frown lines. The onset of dyspnoea and myasthenia has been reported after overdose of the drug for another indication.

A death, possibly related to the drug, was reported after the use of the drug for another indication.

The effect of this drug usually remains for 3 to 4 months. Since adverse drug reactions other than those mentioned above may occur, please let your doctor know if any changes occur in your physical condition during the period or if you have any concerns about treatment with this drug.

## 5. Precautions in treatment with Botox Vista®

[Before administration]

- ◆ This product cannot be used in patients with systemic muscle diseases (severe myasthenia, Lambert-Eaton syndrome, amyotrophic lateral sclerosis, etc.).
- ◆ This product cannot be used in pregnant or potentially pregnant women and in lactating women. (Safety in pregnant and lactating women has not been established.)
- ◆ Women of child-bearing potential should use contraceptive measures during treatment with Botox Vista® and for the next two menstrual cycles after the final treatment. Male patients should use contraceptive measures for at least three months.
- ◆ This product cannot be used for those who have previously experienced allergy after this drug treatment, and those who have an allergic diathesis.
- ◆ If you are taking any drugs, inform your doctor. Be sure to let your doctor know if you are taking antibiotics, muscle relaxants, and tranquilizers.
- ◆ Inform your doctor if you have glaucoma or chronic respiratory diseases including asthma.
- ◆ If you are receiving botulinum toxin treatment at another medical institution, be sure to let your doctor know the disorder being treated, date of administration, and the dose.

[After treatment]

- ◆ You can wash your face on the day of injection, but do not massage or strongly rub the injection site.
- ◆ The injection site may feel puffy, lifted or lowered eyebrows, swollen eye area, droopy or heavy eyelids, temporal change of facial expression, or headache with tightening sensation of forehead. Such symptoms usually disappear within 1 week to 1 month, depending on each subject's condition.
- ◆ There may be bruising at the injection site.
- ◆ Caution is required when you drive or operate machinery as sense of exhaustion, muscular weakness, dizziness, and reduced visual acuity may occur.

## Consent Form for Treatment with Botox Vista® Injection 50 Units

My doctor has provided me with information about the treatment of "frown lines and crow's feet lines" and treatment with Botox Vista® Injection 50 Units. 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.

[For doctor]

## For those who will receive treatment with Botox Vista®

### 6. Treatment you will receive

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