



Main Ingredient

Clostridium botulinum Toxin Type A

Dosage Form

Freeze-dried white powder for reconstruction with sterile, Preservative-free 0.9% sodium chloride solution

Indication

Temporary improvement in the appearance of moderate to severe glabellar lines associated with corrugator and/or procerus muscle activity, as well as crow's feet lines associated with orbicularis oculi muscle activity in adult patients aged 19 – 65 years old.

• Storage and Shelf life

Unopened vial of HUTOX® should be stored in a refrigerator (2 to 8 $^{\circ}$ C) for up to 36 months.

Dosage & Administration by Indication

1. Glabellar Lines

Reconstitute HUTOX Inj. 100 unit with 0.9% preservative-free, sterile saline to make 100 U/2.5 mL(4U/0.1 mL). Using a 30 gauge needle, inject a dose of 0.1 mL into each of 5 sites, 2 in each corrugators muscle and 1 in procerus muscle, for a total of 20 U.

2. Crow's Feet

Reconstitute HUTOX Inj. 100 unit with 0.9% preservative-free, sterile saline to make 100 U/2.5 mL(4U/0.1 mL). Using a 30 gauge needle, inject a dose of 0.1 mL into each of 6 sites, 3 in each orbicularis oculi muscle, for a total 24 U.



• Dilution Table

Dilution Added (Preservative-free, sterile 0.9% saline)	Resulting Dose (U/0.1mL)
1.0 mL	10.0 U
2.0 mL	5.0 U
4.0 mL	2.5 U
8.0 mL	1.25U

 $^{^\}star$ These dilutions are calculated for an injection volume of 0.1 mL. Administering increased or decreased dose is also possible.

• Clinical Trial Timeline

Hutox Inj. 100Unit (900kDa)

: On-going clinial trials of expanded indications.

Glabellar Lines	: Indication Approved.
Crow's Feet Lines	: Indication Approved.
Upper Limb Spasticity	: Completed clinical study Phase I (2020. 05. 11). Clinical study Phase III in progress.
Benign Masseteric Hyperthrophy	: Completed clinical study Phase II (2021. 10. 20). IND (Phase III) submitted on Aug. 2022.