Botulinum Toxin Type A

【IBOT】Botox（Botox®）100 IU/Vial *ATC Code：M03AX01*

【IRBOT】Botox（Botox®）100 IU/Vial *ATC Code：M03AX01*

【IPBOT】整外專用 Botox（Botox®）100 IU/Vial *ATC Code：M03AX01*

**中 文 名：** 保妥適乾粉注射劑 《愛力根》

**適 應 症：** ※眼瞼痙攣、半面痙攣、局部肌肉痙攣、斜視、痙攣性斜頸、小兒腦性麻痺引起之肌肉痙攣、上臉部皺紋(皺眉紋、抬頭紋、魚尾紋)、原發性腋窩多汗症、成人上肢痙攣。※成人脊髓病變所引起的逼尿肌過動而導致尿失禁。※成人尿失禁、尿急與頻尿等膀胱過動症。※成人慢性偏頭痛的預防性治療。※成人病人之下肢痙攣。

藥理分類： Neuromuscular Blocker Agent, Toxin; Ophthalmic Agent, Toxin.

用法用量： Note:

- The lowest recommended dose should be used when initiating treatment (regardless of indication).
- In adults treated for more than one indication, the maximum cumulative dose should be ≤ 400 units/3 months for Botox.

**Bladder dysfunction:** Intra-detrusor:

Note:

- Prophylactic antimicrobial therapy (excluding aminoglycosides) should be administered 1 to 3 days prior to, on the day of, and for 1 to 3 days following onabotulinumtoxinA(Botox) administration to decrease risk of urinary tract infection (UTI).
- Discontinue antiplatelet therapy at least 3 days prior to administration.

**Detrusor overactivity** associated with neurologic condition:

- 30 injections of 1 mL (recommended concentration: ~6.7 units/mL) for a total dose of 200 units/30 mL (maximum: 200 units);
- for the final injection, ~1 mL of sterile NS should be injected to ensure that the remaining medication in the needle is delivered to the bladder;
- may consider re-treatment with diminishing effect but no sooner than 12 weeks from previous administration (median time until second treatment in studies: 42 to 48 weeks).

**Overactive bladder:**

- 20 injections of 0.5 mL (recommended concentration: 10 units/mL) for a total dose of 100 units/10 mL (maximum: 100 units);
- for the final injection, ~1 mL of sterile NS should be injected to ensure that the remaining medication in the needle is delivered to the bladder;
- may consider re-treatment with diminishing effect but no sooner than 12 weeks from the previous administration (median time until second treatment in studies: ~24 weeks)

**Blepharospasm:** IM:

- Botox: Initial dose: 1.25 to 2.5 units injected into the medial and lateral pretarsal orbicularis oculi of the upper lid and lateral pretarsal orbicularis oculi of lower lid.
- Dose may be increased up to twice the previous dose if the response from the initial dose lasted ≤ 2 months; maximum dose per site: 5 units.
- Tolerance may occur if treatments are given more often than every 3 months, but the effect is not usually permanent. Cumulative dose: US labeling: ≤ 200 units in 30-day period

**Cervical dystonia:** IM:

- For dosing guidance, the mean dose is 236 units (25th to 75th percentile

range 198 to 300 units) divided among the affected muscles in patients previously treated with botulinum toxin (maximum: ≤ 50 units/site).

- Initial dose in previously untreated patients should be lower. Sequential dosing should be based on the patient's head and neck position, localization of pain, muscle hypertrophy, patient response, and previous adverse reactions.
- The total dose injected into the sternocleidomastoid muscles should be ≤ 100 units to decrease the occurrence of dysphagia.

**Chronic migraine:** IM:

- Administer 5 units/0.1 mL per site. Recommended total dose is 155 units once every 12 weeks.
- Each 155 unit dose should be equally divided and administered bilaterally, into 31 total sites as described below (refer to prescribing information for specific diagrams of recommended injection sites):
  Corrugator: 5 units to each side (2 sites)
  Procerus: 5 units (1 site only)
  Frontalis: 10 units to each side (divided into 2 sites/side)
  Temporalis: 20 units to each side (divided into 4 sites/side)
  Occipitalis: 15 units to each side (divided into 3 sites/side)
  Cervical paraspinal: 10 units to each side (divided into 2 sites/side)
  Trapezius: 15 units to each side (divided into 3 sites/side)

**Spasticity (focal):** IM:

- Individualize dose based on patient size, extent, and location of muscle involvement, degree of spasticity, local muscle weakness, and response to prior treatment.
- In clinical trials used to support the FDA-approved labeling, total doses up to 400 units (Botox) were administered as separate injections typically divided among selected muscles; may repeat therapy at ≥ 3 months with appropriate dosage based upon the clinical condition of patient at time of re-treatment. Single session doses of ≤ 1,200 units (off-label dose) have been reported;
- however, safety and efficacy of routine use of doses >500 units has not been evaluated (Francisco, 2004).
- Single site doses of ≤ 400 units (off-label dose) in a lower limb (off-label use) have been reported (*Nalysnyk, 2013*).
- Suggested guidelines for the treatment of upper limb spasticity. The lowest recommended starting dose should be used and ≤ 50 units/site should be administered. Note: Dose listed is total dose administered as individual or separate intramuscular injection(s):
  Adductor pollicis: 20 units (1 site)
  Biceps brachii: 100 to 200 units (divided into 4 sites)
  Flexor digitorum profundus: 30 to 50 units (1 site)
  Flexor digitorum sublimes: 30 to 50 units (1 site)
  Flexor carpi radialis: 12.5 to 50 units (1 site)
  Flexor carpi ulnaris: 12.5 to 50 units (1 site)
  Flexor pollicis longus: 20 units (1 site)
- Suggested guidelines for the treatment of stroke-related upper limb spasticity: Canadian labeling: Note: Dose listed is total dose administered as individual or separate intramuscular injection(s):
  Adductor pollicis: 20 units (1 to 2 sites)

Biceps brachii: 100 to 200 units (up to 4 sites)
Flexor digitorum profundus: 15 to 50 units (1 to 2 sites)
Flexor digitorum sublimes: 15 to 50 units (1 to 2 sites)
Flexor carpi radialis: 15 to 60 units (1 to 2 sites)
Flexor carpi ulnaris: 10 to 50 units (1 to 2 sites)
Flexor pollicis longus: 20 units (1 to 2 sites)

**Strabismus:** IM:

Note: Several minutes prior to injection, administration of local anesthetic and ocular decongestant drops are recommended.

- Initial dose: Vertical muscles and for horizontal strabismus < 20 prism diopters: 1.25 to 2.5 units in any one muscle Horizontal strabismus of 20 to 50 prism diopters: 2.5 to 5 units in any one muscle Persistent VI nerve palsy ≥ 1 month: 1.25 to 2.5 units in the medial rectus muscle Re-examine patients 7 to 14 days after each injection to assess the effect of that dose.
- Subsequent doses for patients experiencing incomplete paralysis of the target may be increased up to twice the previous administered dose.
- The maximum recommended dose as a single injection for any one muscle is 25 units.
- Do not administer subsequent injections until the effects of the previous dose are gone.

**Primary axillary hyperhidrosis:**

- **Intradermal**: 50 units/axilla. Injection area should be defined by standard staining techniques. Injections should be evenly distributed into multiple sites (10 to 15), administered in 0.1 to 0.2 mL aliquots, ~1 to 2 cm apart.
- May repeat when clinical effect diminishes.

**Cosmetic uses:**

**Reduction of glabellar lines:** Adults: IM:

- An effective dose is determined by gross observation of the patient's ability to activate the superficial muscles injected. The location, size, and use of muscles may vary markedly among individuals.
- Inject 0.1 mL (4 units) dose into each of five sites, two in each corrugator muscle and one in the procerus muscle for a total dose 0.5 mL (20 units) administered no more frequently than every 3 to 4 months.

**Reduction of lateral canthus lines:**

**US labeling:** Adults: IM: Inject 0.1 mL (4 units) into 3 injection sites per side (6 total injection points) in the lateral orbicularis oculi muscle for a total dose of 0.6 mL (24 units) administered no more frequently than every 3 months.

**Canadian labeling:** Adults: IM: Inject 2 to 6 units into each of 1 to 3 injection sites, lateral to the lateral orbital rim.

**Reduction of forehead lines** (Canadian labeling; not in US labeling): IM:

Inject 2 to 6 units into each of four sites in the frontalis muscle every 1 to 2 cm along either side of forehead crease and 2 to 3 cm above eyebrows for total dose of 24 units.

禁　　忌：1.本品禁止用於已知對配方中的任何成份過敏者。

2.禁止用於重症肌無力或 Eaton Lambert 症候群病人。

3.禁止用於建議注射部位有感染現象存在時。

4.對於罹患尿道感染的病患，以及未定期進行乾淨間歇性導尿(CIC)的急性尿滯留及排尿後餘尿量超過 200 mL 的病患而言，不應投與 BOTOX®。

懷 孕 期：　對於 BOTOX 用於懷孕女性的影響並無充分且經過明確對照的研究，故應避免

BOTOX 用於孕婦；又於懷孕期使用本藥或病人 於使用本藥期間受孕，則應告知病人可能的風險，包括流產或胎兒畸形。

授 乳 期： BOTOX 不建議使用於哺乳婦。未知本藥是否分泌於人類乳汁。

配　　製： 建議使用生理食鹽水注射液。請輕柔注入稀釋液以免產生泡沫。

安 定 性： 新配製後溶液需儲存於冰箱(2-8℃)，應於 72 小時內使用。

儲　　存： 真空乾燥製品可儲存於 2-8 ℃冷藏、或-5 ℃至-20 ℃冷凍。