



BOTULINUM TOXIN TYPE A · DAEWOONG, KOREA

NABOTA®

prabotulinumtoxinA
900 kDa neurotoxin complex

Daewoong Pharmaceutical's MFDS-registered botulinum toxin type A, supplied as vacuum-dried powder in 50, 100 and 200 Unit vials.

NABOTA 50 U

NABOTA 100 U

NABOTA 200 U



One Daewoong active, three market names

Daewoong Pharmaceutical Co., Ltd.

Republic of Korea. Daewoong makes the drug substance and fills the vials, including the US-licensed product.

2013

MFDS approval in Korea

2014

NABOTA launched in Korea

INN prabotulinumtoxinA · US name prabotulinumtoxinA-xvfs · ATC M03AX01

Market name	Licence holder / marketer	Pack identity
NABOTA®	Daewoong Pharmaceutical	Korean / export carton: 50, 100, 200 U per vial
JEUVEAU®	Evolus, Inc. (US Licence 2070)	US carton only: 100 U, NDC 72301-595-10
NUCEIVA®	Evolus Pharma B.V. (EU MAH); Evolus in UK and Canada	EU 50 U and 100 U; Canada 100 U (DIN 02480158)

Same manufacturer and same INN family, but a different tradename, carton, approval number and indication set in each market.

Three vial strengths



NABOTA 50 U

Units per vial · launched 2015
Daewoong colour code: purple



NABOTA 100 U

Units per vial · launched 2014
Daewoong colour code: green



NABOTA 200 U

Units per vial · launched 2015
Daewoong colour code: orange

All three are official Daewoong SKUs (50, 100 and 200 Units / vial). The US Jeuveau carton exists in 100 U only; the EU Nuceiva carton in 50 U and 100 U. The 200 U strength appears on Daewoong materials, not on the US or EU labels.

What is in a 100 Unit vial

Component	Per 100 U vial
Botulinum toxin type A neurotoxin complex	100 Units
Human serum albumin (HSA)	0.5 mg
Sodium chloride	0.9 mg
Preservative	None
Presentation	Sterile vacuum-dried powder

Milligram amounts are documented for the 100 U label only; they are not extrapolated to 50 U or 200 U. The EU label lists the same two excipients for 50 U and 100 U.

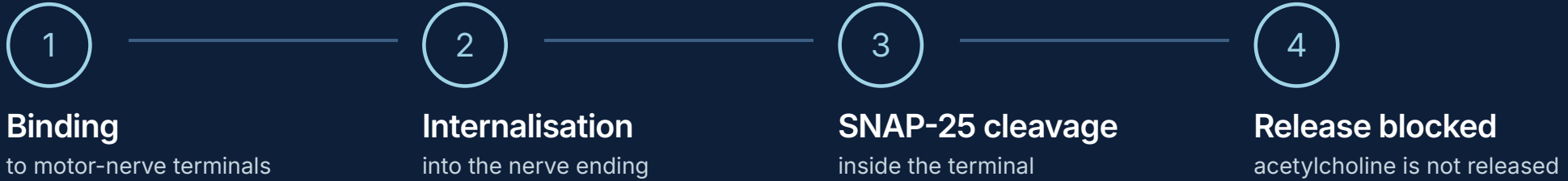
Units are not interchangeable

One Unit corresponds to the calculated mouse intraperitoneal LD50 against the licence holder's reference standard. Units cannot be converted into Units of any other botulinum toxin.

Two formulation generations

The final commercial formulation of the US Phase III programme is vacuum-dried (not freeze-dried) with a specified HSA supply. The earlier Korean comparison trial (Won 2015) used the original formulation. Appearance (New Zealand data sheet): white to yellowish vacuum-dried powder.

How prabotulinumtoxinA works



The result is partial chemical denervation of the treated muscle. Label class: acetylcholine release inhibitor and neuromuscular blocking agent. 900 kDa complex produced by fermentation of *Clostridium botulinum*.

Illustrative diagram, not to scale.

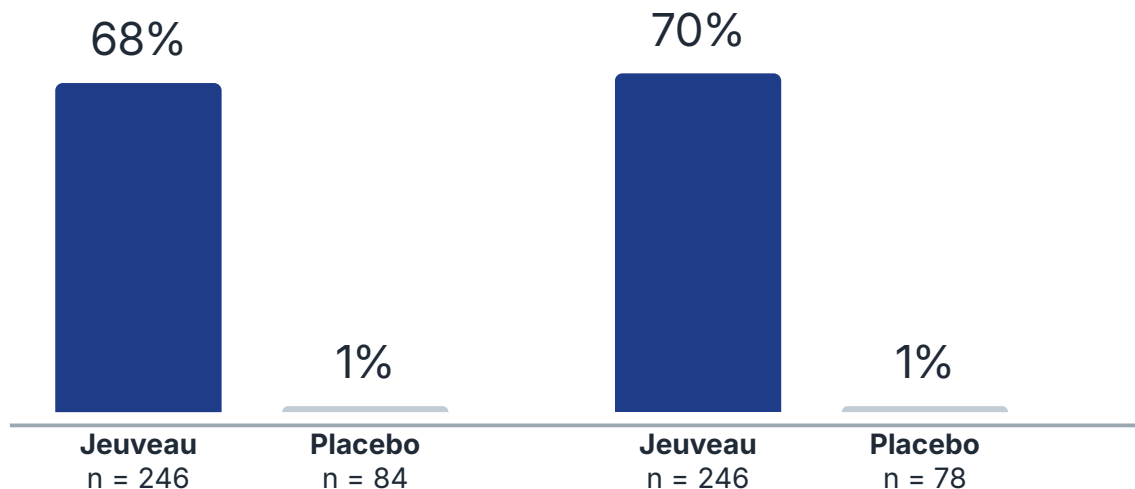
HI PURE™ TECHNOLOGY · MANUFACTURER AND PATENT CLAIM

Patents KR 10-1339349 (2013) and US 9,512,418 B2 (issued 6 Dec 2016): acid precipitation plus anion-exchange chromatography. The patent specification reports HPLC purity of 98.38% (primary) and 98.99% (secondary) and claims type A protein of at least 98% purity. This is a patent claim, not a label specification; no independent lot assay is documented.

US pivotal trials EV-001 and EV-002

EV-001 · NCT02334423

EV-002 · NCT02334436



ENDPOINT

Investigator and subject independently agree on a ≥ 2 -grade improvement on the 4-point glabellar line scale at maximum frown, Day 30. Single 20 U dose, randomised 3:1, double-blind, placebo-controlled.

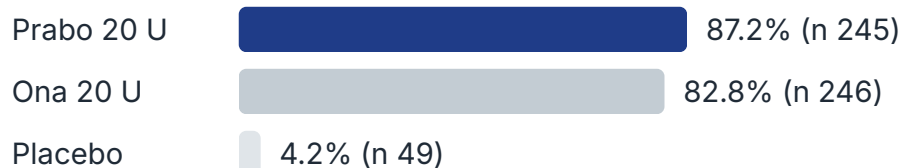
PUBLISHED TO ONE DECIMAL

Beer 2019: 67.5% vs 1.2% and 70.4% vs 1.3%; differences 66.3% and 69.1% (both $p < 0.001$). No serious adverse event was study-drug related.

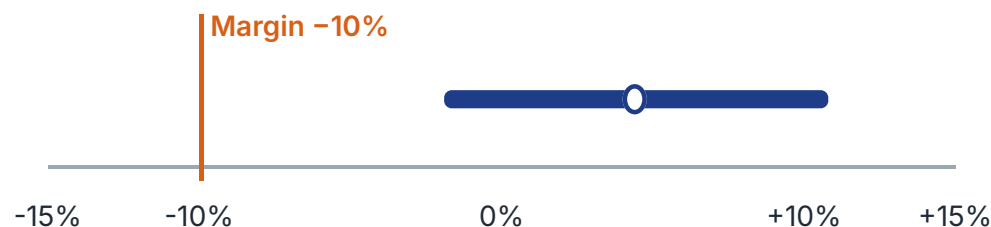
Total randomised 654 (492 Jeuveau, 162 placebo); enrolment 330 and 324. Mean age 51 years (range 18–81); 68 subjects (10%) aged 65+; 91% women; 84% White. Trials ran on the US Jeuveau product.

Two glabellar head-to-head trials

EVB-003 · EUROPE / CANADA · RZANY 2020



Investigator GLS 0 or 1 at maximum frown, Day 30. Difference 4.4% (95% CI -1.9 to 10.8): non-inferior.



95% CI of the difference vs the non-inferiority margin

DESIGN

150-day, multicentre, double-blind, single-dose Phase III; active and placebo control; 5:5:1; 540 enrolled; adults with moderate-to-severe lines and important psychological impact. 5 serious adverse events: prabo 3 (1.2%), ona 1 (0.4%), placebo 1 (2.0%), none study-drug related.

WON 2015 · KOREA · ORIGINAL FORMULATION

268 randomised 1:1, 20 U each. Week-4 responders 93.89% vs 88.64%. Lower limit of 97.5% one-sided CI -1.53%, above the -15% margin: not inferior. Adverse events similar, mostly mild.

Non-inferiority only: no superiority and no unit interchangeability. A 2022 male post-hoc of EVB-003 did not reach significance.

Repeat dosing, antibodies and other trials

922

subjects in open-label repeat-dose trials EV-004 and EV-006 (NCT02184988, NCT02428608): 20 U up to 80 U total, median 3 treatments; adverse-event profile similar to single-dose trials.

2 + 2

of 1,414 treated subjects: 2 had pre-existing and 2 treatment-emergent antibodies. Assay comparisons across products may mislead.

Onset and duration as labelled: signs within 2–3 days, peak within 4 weeks, recovery normally within 12 weeks (EU); denervation typically from day 2, rising over two weeks (New Zealand); each treatment lasts about three to four months (Singapore).

Study	Design · n	Role
Nam 2015	Korea Phase III vs onabotulinumtoxinA, post-stroke upper-limb spasticity · 197 (99 / 98)	Wrist-flexor MAS –1.44 vs –1.46 at week 4, within 0.45 margin; supports the Korean indication only
Masseter Phase 3	Double-blind 48 U vs placebo plus extension · 180 core, 114 extension	Largest masseter-thickness change at 12 weeks; no serious event reported; Korean indication only
Song (Phase IV)	Single-arm Korean onset study · small (44 enrolled)	Manufacturer-adjacent; not the pivotal programme

Adverse reactions at $\geq 1\%$

Reaction	Jeuveau, N = 492	Placebo, N = 162
Headache	 57 (12%)	 21 (13%)
Eyelid ptosis	 8 (2%)	0 (0%)
Upper respiratory tract infection	 13 (3%)	 1 (1%)
White blood cell count increase	 6 (1%)	0 (0%)

EV-001 and EV-002 combined, n (%). A 0% placebo value means no case was reported in that arm.

Boxed warning · class

Distant spread of toxin effect. Effects of all botulinum toxin products may spread from the treatment area hours to weeks later. Swallowing and breathing difficulties can be life threatening; deaths have been reported. Jeuveau is not approved for spasticity or any condition other than glabellar lines.

Contraindications and warnings

US label

Hypersensitivity to any botulinum toxin preparation or any formulation component.
Infection at the proposed treatment site.

EU label (stricter)

Hypersensitivity to the active substance or excipients. Generalised disorders of muscle activity (e.g. myasthenia gravis, Eaton-Lambert syndrome). Infection or inflammation at the site.

NABOTA label (SG / NZ style)

Also lists neuromuscular junction disorders (MG, LEMS, ALS) and pregnant or nursing women and women of childbearing potential.

Warnings to observe: serious adverse events with unapproved use; hypersensitivity (anaphylaxis, serum sickness, urticaria, soft-tissue oedema, dyspnoea); cardiovascular events including arrhythmia and myocardial infarction, some fatal; pre-existing neuromuscular disorders; dysphagia and breathing difficulty; dry eye and other eye effects; a remote theoretical viral/CJD risk from albumin (no case identified). **Interactions:** aminoglycosides and other neuromuscular-transmission agents, anticholinergics, other botulinum toxins, muscle relaxants. **Age:** paediatric use not established; EU not recommended over 65; US trials had 68 subjects aged 65+. **Pregnancy:** US data insufficient; EU not recommended, not for breast-feeding.

Labelled indications differ by market

Indication	Korea · NABOTA	US · Jeuveau	EU / UK / Canada · Nuceiva
Glabella lines, adults (EU: under 65, with psychological impact)	Labelled	Labelled	Labelled
Lateral canthal lines	Labelled	Not labelled	Not labelled
Blepharospasm associated with dystonia	Labelled	Not labelled	Not labelled
Upper-limb spasticity after stroke (Korea, 7 Dec 2015)	Labelled	Not labelled	Not labelled
Benign masseteric hypertrophy (MFDS, 25 Aug 2023)	Labelled	Not labelled	Not labelled

The common aesthetic regimen across labels is a 20 Unit glabellar treatment; retreatment no more often than every three months (US). Masseter appears on the Singapore label and the 2023 MFDS announcement, not on Daewoong's current English page. Korean-only uses are never presented as US approvals. Preparation and treatment technique follow the pack leaflet.

Storage by label



Unopened: 2–8 °C on every label; US and NZ add do not freeze, and the US label adds original carton, protected from light. Reconstituted product must be clear, colourless and free of particles.

Parameter	US · Jeuveau	EU · Nuceiva	NZ · NABOTA 100 U
Unopened	2–8 °C, carton, protect from light, do not freeze	2–8 °C	2–8 °C, do not freeze
Shelf life	36 months from manufacture	30 months (50 U, 100 U)	36 months
After reconstitution	Within 24 h at 2–8 °C; do not freeze	In-use stability 72 h at 2–8 °C; microbiologically use at once, normally ≤24 h	Up to 24 h at 2–8 °C; do not freeze

Korean registration: use within 24 hours after dilution, keep refrigerated at 2–8 °C. Further stability plots in the 2018 Daewoong brochure are manufacturer data on file and do not change these limits.

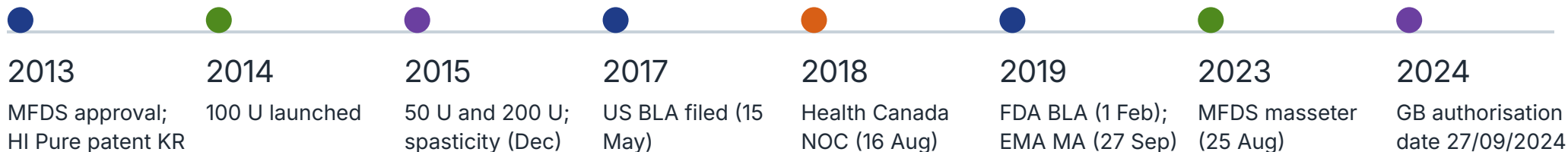
Regulatory status by carton

Carton	Market / authority	Documented status	Scope · reference
NABOTA 50 / 100 / 200 U	Korea · MFDS	Approved 2013	Glabellar + Korean indications above
NABOTA 100 U	New Zealand · Medsafe; Singapore · HSA	Registered	Glabellar (NZ, under 65); SIN16680P
NABOTA 50 / 100 / 200 U	US · FDA	Not FDA-approved	Only the Jeuveau carton is US-licensed
JEUVEAU 100 U	US · FDA	BLA approved	BLA 761085, 1 Feb 2019; glabellar, adults
NUCEIVA 50 / 100 U	EU · EMA; GB · MHRA	Marketing authorisation	EU/1/19/1364, 27 Sep 2019; PLGB 55681/0002
NUCEIVA 100 U	Canada · Health Canada	NOC 2018	DIN 02480158, 16 Aug 2018
All cartons	EU · CE marking	Not applicable	A medicine, not a CE-marked device

Units: never interchangeable with any other botulinum toxin (every label).

From Korea to three Western regulators

US path: BLA filed 15 May 2017, complete response 15 May 2018, resubmitted 2 August 2018, approved 1 February 2019, marketed from 13 February 2019.
US Patent 9,512,418 issued 6 December 2016. Paediatric studies waived.



EU legal basis: Directive 2001/83/EC Art. 8.3, centralised (EMA/H/C/004587); batch release by Evolus Pharma B.V.; drug substance by Daewoong. UK status is a national GB authorisation for a prescription-only medicine, separate from the EU licence.

What a NABOTA carton is and is not

CORRECT

- NABOTA is Daewoong's MFDS-registered botulinum toxin type A.
- The same manufacturer supplies the US product sold as Jeuveau.
- Nuceiva is the Evolus / Daewoong name in the EU, UK and Canada; it is a medicine.
- PrabotulinumtoxinA was non-inferior to onabotulinumtoxinA in two glabellar trials.

NOT CORRECT

- "NABOTA is FDA approved" or an FDA 50 U / 200 U vial.
- A CE-certified NABOTA or a CE-marked Nuceiva.
- Units interchangeable 1:1 with BOTOX, or "better than BOTOX".
- HI Pure purity as a label specification.

OPEN EVIDENCE GAPS

No independent lot assay of HI Pure purity · milligram excipients documented for the 100 U label only · the 200 U dilution appears only in the manufacturer leaflet · masseter not yet on Daewoong's English product page.

Every pack leaflet, local authorisation and the clinician's training take precedence over this overview.



ABOUT YAKSU MEDI

Yaksu Medi is a Korea-based B2B wholesale supplier of Korean medical aesthetic products. Clinics and distributors buy NABOTA botulinum toxin type A wholesale from Korea through us, in Daewoong's 50 U, 100 U and 200 U cartons, alongside Korean HA fillers and skin boosters.



Genuine NABOTA
Daewoong cartons from authorised Korean channels.



Worldwide wholesale
All three strengths for clinics and distributors abroad.



Cold-chain shipping
2–8 °C packing with DDP delivery options.



Documentation support
Product and shipping papers to help with import.

Looking for a Korean aesthetic wholesale supplier of prabotulinumtoxinA? Ask for current NABOTA 50 U, 100 U and 200 U pricing, lead times and cold-chain options for your country.

yaksumedi.com · info@yaksukorea.com



NABOTA® · Daewoong, Korea