

REJURAX

100 IU

200 IU

Clostridium Botulinum Toxin Type A



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Product Specifications

Clostridium Botulinum Toxin Type A



REJURAX 100IU

REJURAX 200IU

Classification	Medicine						
Active Ingredient	Clostridium botulinum toxin						
Contents (1 vial)	<table><tr><td>Clostridium Botulinum Toxin Type A</td><td>100 unit / 200 unit</td></tr><tr><td>Human Serum Albumin</td><td>100unit 0.5mg / 200unit 1.0mg</td></tr><tr><td>Sodium Chloride</td><td>100unit 0.9mg / 200unt 1.8mg</td></tr></table>	Clostridium Botulinum Toxin Type A	100 unit / 200 unit	Human Serum Albumin	100unit 0.5mg / 200unit 1.0mg	Sodium Chloride	100unit 0.9mg / 200unt 1.8mg
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Human Serum Albumin	100unit 0.5mg / 200unit 1.0mg						
Sodium Chloride	100unit 0.9mg / 200unt 1.8mg						
Appearance	A white or light yellow lyophilisate contained in a colorless and transparent vial and is a transparent solution when dissolved in saline.						
Effect	Temporary improvement of moderate to severe wrinkle lines (such as glabella lines) in adult patients.						
Mechanism	A temporary reduction in muscle activity for medical and aesthetic use.						
Storage Condition	Store at sealed containers, refrigeration (2~8°C)						
Shelf Life	36 months from manufacturing date						

REJURAX is vacuum-dried botulinum toxin type A product

There are two methods used for the production of botulinum toxin products: vacuum drying and freeze drying.

Vacuum Drying	A method used to remove moisture or solvents from a substance under reduced pressure.
Freeze Drying (Lyophilization)	A dehydration process by freezing the material and then reducing the surrounding pressure to allow the frozen solvents to sublime directly from solid to vapor, bypassing the liquid phase.

Unlike other botulinum toxin products, REJURAX is produced through a vacuum-drying process, certify the highest standards of quality and potency.

	REJURAX	Freeze Drying
Potency Loss	Low	High
Processing Time	Short	Long
Production Efficiency	High	Low
Purity	Very high	High
Damage During Process	Minimized	-
Inactive Protein	Minimized	-
Cake (Appearance)	Hardly visible, firm and uniform	Visible, easily cracked and not uniform

Safety is the top priority for REJURAX, therefore it contains a lower concentration of neurotoxin in comparison with others.

Amount of Neurotoxin in Various Products

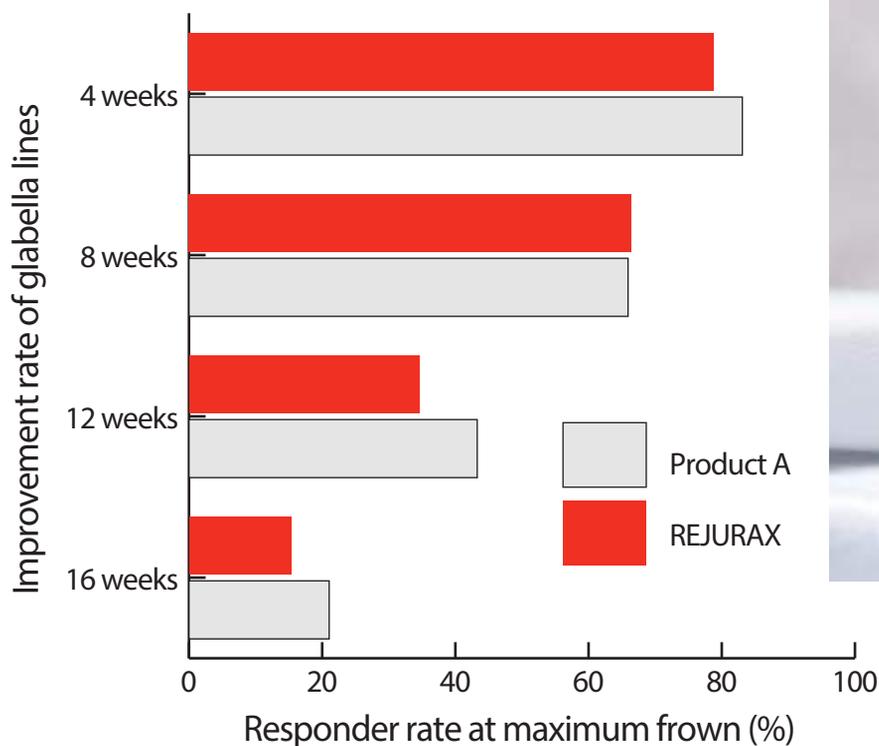
Product	Amount of Neurotoxin (ng/vial)
REJURAX	3.59
Product A	4.38
Product B	3.90
Product C	4.52

Authentic safety begins with purity. By using our purification process, BIENOX boasts an average purity of 99.59% according to SEC-HPLC analysis, surpassing regulatory criteria of 95%.



The structure of Botulinum Toxin Type A of REJURAX was confirmed by SDS-PAGE

Molecular weight of protein subunits constituting botulinum toxin type A complex was confirmed through SDS-PAGE. As a result, same molecular weight as the data expected from REJURAX was confirmed. REJURAX upholds the commitment to safety and reliability through rigorous analysis.



Effectiveness of REJURAX in glabellar lines improvement was verified in clinical trials

The results underscore the efficacy of REJURAX in the treatment of moderate to severe glabellar lines. With 278 participants with moderate to severe glabellar lines, both REJURAX and Product A treatments yielded similar improvement rates in glabellar lines and patient satisfaction levels at 4, 8, 12, and 16 weeks post-injection.

The difference in improvement rate between two groups was not statistically significant which proved that REJURAX is not inferior compared to the control group.

Compared to product A, the patients who received REJURAX treatment were 10 - 15% more satisfied with the results after 16 weeks.

Study Methodology : Multicenter, double-blinded, randomized, parallel-group, active-controlled, phase III clinical study

Study Design : 278 cases with moderate to severe glabellar lines were randomized to BIENOX group (139 cases) and product A group (137 cases) with intramuscular injection of total 20U in 5 sites of glabella lines and evaluated 4, 8, 12, 16 weeks after the injection.

REJURAX is proven to be stable and efficient after time passes

During the 36-month of long-term stability test, REJURAX showed no changes in its physical and chemical properties, meeting all standards set for safety and effectiveness. Potency results also remained consistent throughout the testing period, affirming REJURAX's reliability.



Product	REJURAX
Method	Vacuum Dried
Storage Condition	2~8°C, sealed refrigerator
Test period	36 months
Test Details	Physicochemical characteristics Potency
Results	Passed

Maintaining stability and high potency is important to provide predictable outcomes and minimizing the risk of under or over-treatment. Rigorously controlled during manufacturing process, REJURAX guarantees optimal efficacy and safety.

	Potency test criteria	Results
Korean Pharmacopoeia	Estimated potency : 80~125% of the stated potency Confidence limits (P= 0.95) : 80~125% of the estimated potency	N/A
European Pharmacopoeia	Estimated potency : 80~125% of the stated potency Confidence limits (P= 0.95) : 80~125% of the estimated potency	N/A
REJURAX	Estimated potency : 80~125% of the stated potency Confidence limits (P= 0.95) : 80~125% of the estimated potency	All KP, EP criteria met

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STABILITY, SAFETY, EFFICACY



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