Masport®

Clostridium Botulinum Toxin Type A

Embrace your Skin
Laugh at Wrinkles
with Masport®

mdpc
Biotechnology and Biopharmaceutics
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MASPORT® recognizing and setting treatment targets

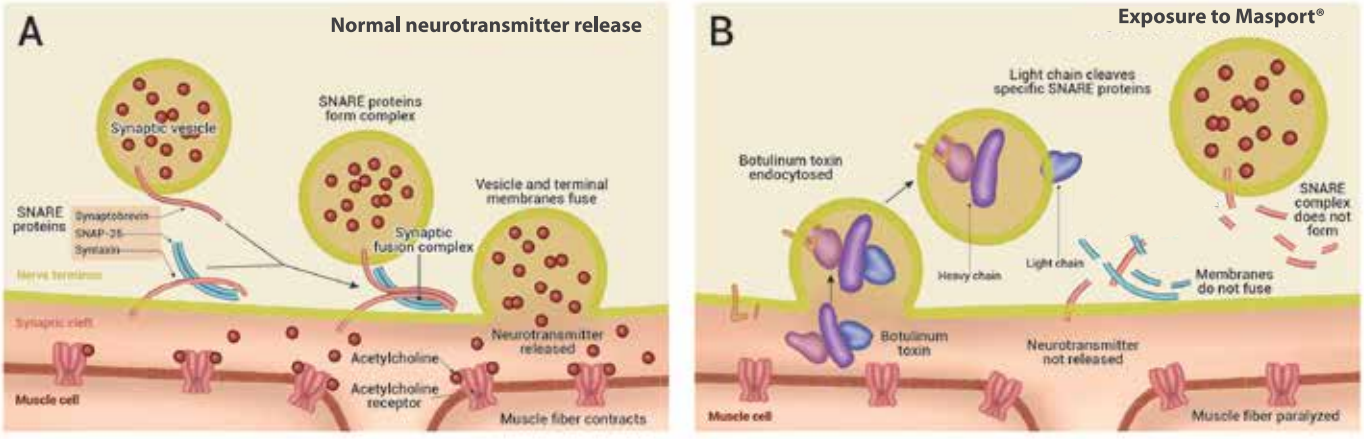
Product general information

MASPORT® is a sterile, highly purified and lyophilized Botulinum toxin type A (BTX-A)-haemagglutinin complex, intended for intramuscular injection (IM). It is used for treatment of disorders due to muscles spasms.

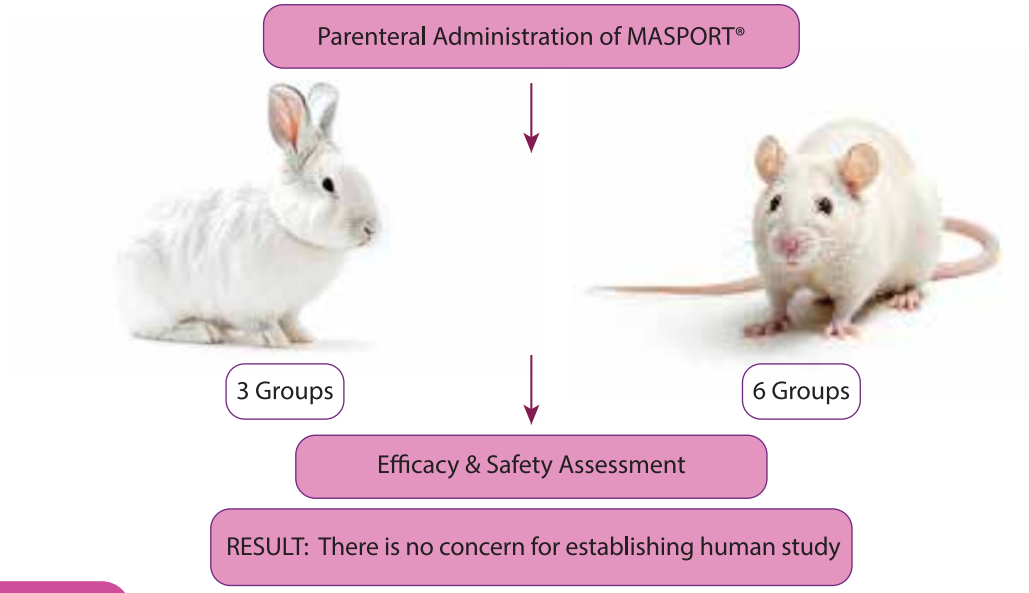
Each package contains one vial of MASPORT® in form of 500, 300 or 150 IU lyophilized vial and one vial solvent (sterile preservative-free sodium chloride 0.9% solution). MASPORT® also contains human albumin and lactose as excipients, and it doesn't contain any antimicrobial preservative.

MASPORT® mechanism of action

Clostridium Botulinum type A toxin blocks peripheral cholinergic transmission at the neuromuscular junction by a presynaptic action at a site proximal to release of acetylcholine. The action of toxin involves an initial binding step whereby the toxin attaches rapidly and with high avidity to the presynaptic nerve membrane. Intramuscular injection of MASPORT® at therapeutic doses produces partial chemical denervation of the muscle resulting in a localized reduction in muscle activity.



Preclinical study



Clinical trial

Clinical trial phase I & II

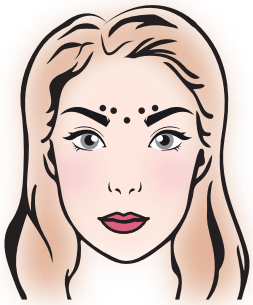
Safety and efficacy study of IM administration of botulinum toxin type A MASPORT® (produced by Masoondarou Company) in healthy volunteers was conducted at Razi Hospital with IRCT registration code: IRCT201201154536N2.

Drug administration method

1 vial 500 IU of MASPORT® was diluted with 2.5 ml 0.9% NaCl for each group. The solution was injected at 5 points (0.1 ml per injection site) in 4 seperated groups.

	Unit of toxin per group	Reconstituted Drug (ml)	Normal Saline (ml)	U/0.5 ml
Reconstitute one vial by 2.5 ml Normal saline	1st:10	0.1	0.9	10
	2nd:20	0.2	0.8	20
	3rd:40	0.4	0.6	40
	4th:60	0.6	0.4	60

Between 3 to 5 injection sites

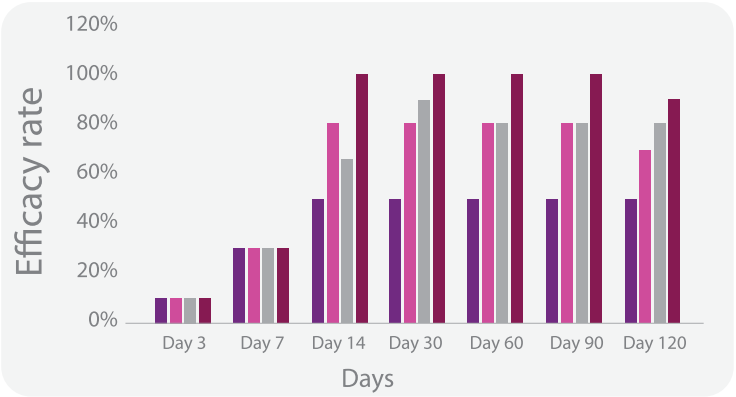


Clinical outcome assessment based on Glabellar Line Severity Scale (GLSS)

- Efficacy was assessed by investigator and also by Subject Global Assessment of Change (SGA) at 30 days after injection.
- The occurrence and duration of adverse effects were recorded throughout the study.

No glabellar lines	Mild glabellar lines	Moderate glabellar lines	Severe glabellar lines	Very Severe glabellar lines
0	1	2	3	4

Efficacy



Safety Results

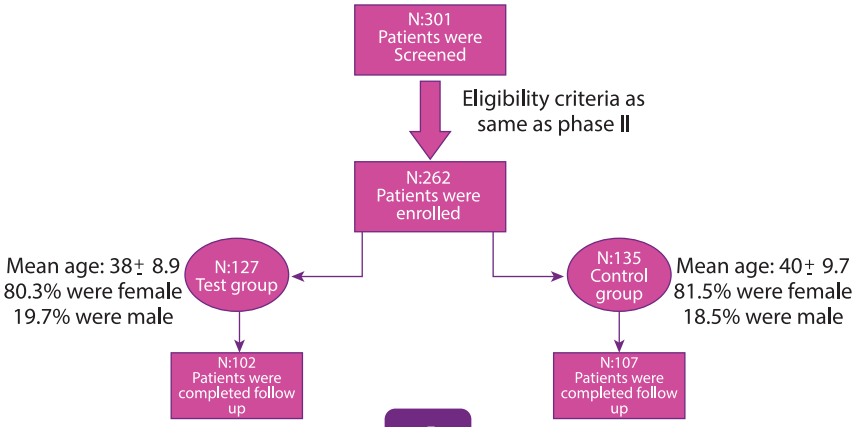
Type of adverse event	1st group		2nd group		3rd group		4th group		Total	
	prevalence rate		prevalence rate		prevalence rate		prevalence rate		prevalence rate	
	No.	%	No.	%	No.	%	No.	%	No.	%
Headache	0	0%	0	0%	1	33.3%	0	0%	1/12	8.3%
Pain in Face	0	0%	0	0%	0	0%	0	0%	0	0%
Flu Syndrome	0	0%	0	0%	0	0%	0	0%	0	0%
Pain at Injection Site	1 mild	33.3%	0	0%	0	0%	0	0%	1/12	8.3%
Edema at Injection Site	0	0%	0	0%	0	0%	0	0%	0	0%
Injury accidental	0	0%	0	0%	0	0%	0	0%	0	0%

Key points conclusion

- Therapeutic effects were observed in all four doses of 10, 20, 40 and 60 units. The efficacy rate is dose-dependent and dose of 60 units leads to best and most complete efficacy.
- No serious adverse events occurred, and the reported events were transient .

Clinical Trial Phase III

A phase III, double-blind, randomized, comparative clinical trial was conducted at Razi Hospital, which is a dermatology reference hospital in Iran. The study took place between June and September 2013. The objective of this study was to compare the efficacy and safety of a new botulinum toxin type A (MASPORT® [abobotulinum toxin A], Masoondarou Co.) with DYSPORT® for the treatment of glabellar lines.



Clinical Outcome Assessment

- Efficacy was assessed by investigator and also by Subject Global Assessment of Change (SGA) at 30 days after injection.
- The occurrence and duration of adverse effects were recorded throughout the study.

Responders:

The responders were defined as persons with +2 grades improvement from baseline for both investigator and patient assessment.

Condition	Intervention/ Treatment
Glabellar Lines	Subjects with moderate-to-severe glabellar lines received either a fixed dose of 50 units of MASPORT® or DYSPORT®, 5 evenly distributed injections of 10 units: in the midline procerus, infero medial and superior middle aspect of corrugator muscle

Efficacy

- **MASPORT® , at a dose of 50 units, is equally effective and safe compared to its biosimilar counterpart DYSPORT®.**

Safety

Reported adverse effects in either treatment group

Adverse effect	Percentage	
	MASPORT® (%)	DYSPORT® (%)
Headache	8.57	8.15
Drowsiness	1.90	2.22
Drooping eyelids	2.86	2.96
Rhinorrhea	1.90	1.48
Headache associated with Rhinorrhea	2.86	1.48
Headache associated with Drooping eyelids	0	0.74

P value= 0.91

- **Reported side effects have generally been minimal and transient and did not require intervention.**

Indications and usage

MASPORT® is an acetylcholine release inhibitor and a neuromuscular blocking agent indicated for disorders including:

Primary hyperhidrosis

Urinary incontinence

Glabellar lines

Cervical dystonia

Blepharospasm & hemifacial spasm

Lower Limb Spasticity

Equinovarus foot

Plantar flexed foot/ankle

Flexed toes

Upper Limb Spasticity

Flexed elbow

Clenched fist

Flexed wrist

Dosage and administration

MASPORT® reconstitution volumes and final concentrations; recommended by manufacturer

MASPORT Vial	Required solvent per each vial	Final dose concentration (U / 0.1 mL)
MASPORT®500	2.5 ml	20
MASPORT®300	1.5 ml	20
MASPORT®150	1 ml	15

Use in specific populations

Pregnancy: There are no adequate clinical studies in pregnant women, Botulinum Toxin should only be used during pregnancy if the potential benefit justifies the potential risk to the fetus.

Lactation: There are no data on the presence of Botulinum Toxin in human or animal milk, the effects on the breastfed child or the effects on milk production.

Pediatric use: Botulinum Toxin is not recommended for use in pediatric patients less than 18 years of age for the treatment of cervical dystonia, glabellar lines, blepharospasm and hemifacial spasm, primary hyperhidrosis and urinary incontinence and also in children < 2 years for the treatment of upper and lower limb focal spasticity.

Onset and Duration of Action of Masport®

The therapeutic effects of Masport® start in one week after injection and during 4 weeks reach to peak. The toxin inhibitory effect lasts for about 4 - 6 months.

Day 1

The day of injection

Weeks 2-3+

2-3 weeks after injection

Patient should return for evaluation of success of injection

Weeks 12+

After 12 weeks or longer

Another dose can be injected if it is needed

Contraindication

MASPORT® is contraindicated in individuals with known allergy to any botulinum toxin product such as MYOBLOC®, DYSPORT® and BOTOX®.

- Allergy to cow`s milk protein or any of the components in the formulation of MASPORT®.
- Individuals with neuromuscular; cardiac and pulmonary disorders.
- Infection at the proposed injection site.

Studies & Publications:

To gain more information about the use of MASPORT® in other indications, you can refer to the following articles:

1. Hedayat, K., & Ehsani, A. H. (2024). A Phase III Clinical Study of the Efficacy and Safety of Botulinum Toxin Type A (MASPORT) with DYSPORT for the Treatment of Glabellar Lines. Aesthetic plastic surgery, 48(3), 324–332. https://doi.org/10.1007/s00266-023-03766-5

2. Bazargan, A. S., Tabavar, A., Roohaninasab, M., Ali, Z. N., Tavana, Z., Montazeri, S. S. M., & Jafarzadeh, A. (2023). Evaluation of the effect of botulinum toxin injection in aggravating or improving seborrheic dermatitis symptoms: A prospective, single-arm clinical trial. Skin research and technology : official journal of International Society for Bioengineering and the Skin (ISBS) [and] International Society for Digital Imaging of Skin (ISDIS) [and] International Society for Skin Imaging (ISSI), 29(10), e13478. https://doi.org/10.1111/srt.13478

3. Yaghoobi Notash, A., Sadeghian, E., Heshmati, A., & Sorush, A. (2022). Effectiveness of Local Botulinum Toxin Injection for Perianal Pain after Hemorrhoidectomy. Middle East journal of digestive diseases, 14(3), 330–334. https://doi.org/10.34172/mejdd.2022.291

4. Khademi, M., Roohaninasab, M., Goodarzi, A., Seirafianpour, F., Dodangeh, M., & Khademi, A. (2021). The healing effects of facial BOTOX injection on symptoms of depression alongside its effects on beauty preservation. Journal of cosmetic dermatology, 20(5), 1411–1415. https://doi.org/10.1111/jocd.13990

5. Farashi, F., Ghoncheh, M., Ghasemian Moghaddam, M. R., & Soroosh, Z. (2024). Evaluation of people's satisfaction with botulinum toxin injection for facial rejuvenation based on age. Journal of cosmetic dermatology, 23(7), 2380–2385. https://doi.org/10.1111/jocd.16289

6. Ghazavi, M., Rezaii, S., Ghasemi, M., Azin, N., & Reisi, M. (2023). Botox injection in treatment of sialorrhea in children with cerebral palsy. American journal of neurodegenerative disease, 12(3), 97–102.

7. Salimi, H., Hosseini, J., Sharifian, R., Fallah Karkan, M., Namiranian, N., Injinari, N., Ahmadi Basiri, E., Abouei, S., Samadaeegelehkolaee, K., & Mirjalili, A. (2024). The Effect of Botulinum Toxin (Masport) Injection Following Internal Urethrotomy of Bulbar Urethral Stricture: A Pilot Study. American journal of men's health, 18(4), 15579883241271279. https://doi.org/10.1177/15579883241271279

8. Nazari Rad, M. , Akhondian, J. , Alamdaran, S. A. , Rezaeian, A. , khakshour, A. , Abbasi Shaye, Z. and Sayedi, S. J. (2023). The Effects of Botulinum Toxin Type A on Reducing Sialorrhea in Children with Cerebral Palsy: A Self-Controlled Clinical Trial. Journal of Pediatric Perspectives, 11(12), 18406-18412. doi: 10.22038/ijp.2023.75995.5385

9. Pazyar, N., Ashoori, S., Mahdianrad, A., & Seyedtabib, M. (2024). Comparison of the effect of intra-dermal injection of botulinum toxin and normal saline in the treatment of facial skin pores. Journal of family medicine and primary care, 13(5), 1797–1803. https://doi.org/10.4103/jfmpc.jfmpc_1327_23

10. Moradi, S., Khazaeli, D., Dadfar, M. and Bakhtiari, N. (2022). Efficacy of Intracavernosal Injections of 50-Unit Versus 100-Unit Doses of AbobotulinumtoxinA (Masport®) in Vasculogenic Erectile Dysfunction with Phosphodiesterase Type 5 Inhibitors Resistant. Journal of Nephro-Urol Mon, 14(1): e119131. doi: 10.5812/numonthly.119131

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