

NEURONOX® INJECTION

Clostridium botulinum toxin type A (50/100/200 units)

What is in this leaflet

1. What Neuronox® Injection is used for
2. How Neuronox® Injection works
3. Before you use Neuronox® Injection
4. How Neuronox® Injection
5. While you are using it
6. Side effects
7. Storage and disposal of Neuronox® Injection
8. Product description
9. Manufacturer and Product Registration Holder
10. Date of revision

What Neuronox® Injection is used for

No	Indication	Remarks
1	Blepharospasm	for the treatment uncontrolled contractions of the eye muscles/eye lids and surrounding facial are resulting from dry eyes for people 18 years of age and older.
2	Paediatric cerebral palsy	indicated for the treatment in children 2 age and older for lack of flexibility of upward bending motions of ankle joint which due to impairment in the are of the brain.
3	Glabellar Wrinkles	for the treatment for wrinkless that appear between eyebrows which refer as frown lines in adult over the age of 18 and below of the age 65
4	Muscle spasticity	Upper limb spasticity associated with stroke in people 20 years of age and older

How Neuronox® Injection works

The active ingredient in this medicine is Clostridium botulinum toxin type A. Botulinum toxin has the neurotransmitter effect as blocker to prevent acetylcholine which makes the muscle contract due to dystonia. This generates the treatment for overactive smooth muscles or abnormal activity of glands.

Before you use Neuronox® Injection

- When you must not use it

Do not use Neuronox® Injection if:-

- you are hypersensitive to Clostridium botulinum toxin type A or other ingredients of this product.

- you have systemic neuromuscular junctional disorder
- you have respiratory dysfunction
- you are or think you may be pregnant, planning to become pregnant or if you are breastfeeding.

- Before you start to use it

You should check with your doctor if :-

- you are immune-compromised patients
- you have any other health problems.

- Taking other medicines

There are a few medicines which may not take with Neuronox® Injection. It is important to tell your doctor or pharmacist about all the medicines that you are taking, including those obtained without doctor's prescription.

How to use Neuronox® Injection

- How much to use

Injection.

No	Indication	Remarks
1	Blepharospasm	Injected using a sterile 27-30 gauge needle. Initial recommended dose 1.25 – 2.5U (0.05ml to 0.10ml volume at each site)
2	Paediatric cerebral palsy	Injected using a sterile 26-30 gauge needle
3	Glabellar Wrinkles	Injected using a 30 gauge needle with reconstituted make up 4U/0.1 with 0.90% non-preserved sterile saline.
4	Muscle spasticity	The dosage and number of injection should be tailored to the individual based on the size, the number and location of muscles involved the severity of spasticity, presence of local muscle weakness and the patient's response to previous treatment.

- When to use it

Use Neuronox® Injection when needed and according to your doctor's prescription.

- How long to use it

It is important to take Neuronox® Injection as long as your doctor prescribes.

- If you forget to use it

Do not take extra dose to make up for a missed dose. Just take your next dose at usual time.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it

- Things you must do

Take Neuronox® Injection exactly the way as prescribed.

- Things you must not do

Do not share your medicines with others even if they have same diagnosis as you.

- Things to be careful of

If you experience any side effects, consult your doctor or pharmacist for advice.

Side effects

Like all medicines, Neuronox® Injection can cause side effects, although not everybody gets them. The side effects are hypersensitivity reactions, neuromuscular disorder, and dysphagia. If any of side effect happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital.

Any other effects not listed above may also occur in some people. Please refer to your doctor or pharmacist if you experience any other symptoms while taking this medication.

You may report any side effect or adverse drug reaction directly to the National Centre for Adverse Drug Reaction Monitoring by calling 03-78835550, or visiting the website portal.npra.gov.my (Consumers→Reporting)

Storage and disposal of Neuronox® Injection

- Storage

Store at freezer (below -5°C) or refrigerator (2 -8°C).

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

A lyophilized white powder for injection in a colourless transparent vial

- Ingredient(s)

- Active Ingredient

- Clostridium botulinum toxin type A.

- Inactive Ingredients

- Human Serum albumin 20%
- Sodium chloride

- MAL number

MALXXXXXXXXXA

Manufacturer

Medytox Inc.

78, Gangni 1-gil Ochang-eup, Cheongwongu,
Cheongju-si Chungcheongbuk-do,
Republic of Korea.

Product Registration Holder

Sunward Pharmaceutical Sdn. Bhd.
No. 9,11 & 17, Jalan Kempas 4, Taman
Perindustrian Tampoi Indah, 81200
Johor Bahru, Johor, Malaysia.

Date of revision

28/02/2017

Serial Number