1. NAME OF THE MEDICINAL PRODUCT

XEOMIN powder for solution for injection 50 units
XEOMIN powder for solution for injection 100 units

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One vial contains 50 or 100 units of Clostridium *Botulinum neurotoxin type A* (150kD), free from complexing proteins, human albumin, sucrose.

3. PHARMACEUTICAL FORM

White to off-white solid
Powder for solution for injection

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

XEOMIN is indicated in adults of 18 years of age or above for the treatment of:
Aesthetic indication:
Upper facial lines in adults:

- Glabellar frown lines
- Lateral periorbital lines (crow's feet)
- Horizontal forehead lines

Neurological indications in adults:

- Cervical dystonia (spasmodic torticollis)
- Blepharospasm and hemifacial spasm
- Post stroke spasticity of the upper limb

4.2 Posology and Method of Administration

4.2.1 Method of Administration

Due to unit differences in the potency assay, unit doses recommended for XEOMIN are not interchangeable with those for other preparations of Botulinum toxin type A.

Comparative clinical study results suggest that XEOMIN and the comparator product containing conventional *Botulinum toxin type A* complex (900 kD) are of equal potency when used in a dose conversion ratio of 1:1.

XEOMIN may only be administered by health care professionals. With suitable qualifications & proven experience in the applications of Botulinum neurotoxin type A.

XEOMIN is reconstituted prior to use with sodium chloride 9 mg/ml (0.9%) solution for injection. It is good practice to perform vial reconstitution and syringe preparation over plastic-lined paper towels to catch any spillage. An appropriate amount of solvent is drawn up into a syringe. A 20-27 G needle is recommended for reconstitution. A short bevel needle is recommended. After vertical insertion of the needle through the rubber stopper the solvent is injected gently into the vial in order to avoid foam formation. The vial must be discarded if the vacuum does not pull the solvent into the vial. Remove the syringe from the vial and mix XEOMIN with the solvent by carefully swirling and inverting/flipping the vial – do not shake vigorously. If needed, the needle used for reconstitution should remain in the vial and the required amount of solution should be drawn up with a new sterile syringe suitable for injection.

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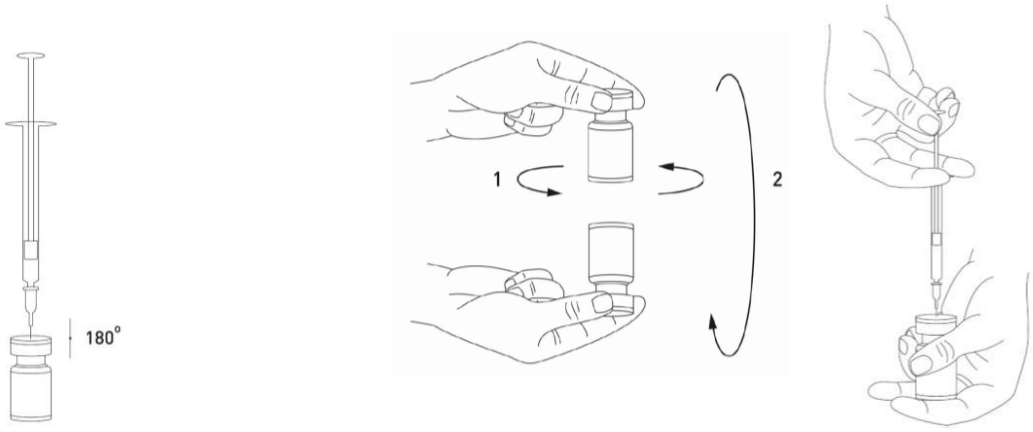

Reconstituted XEOMIN is a clear, colourless solution free of particulate matter.

XEOMIN should not be used if the reconstituted solution has a cloudy appearance or contains floccular or particulate matter.

Reconstituted XEOMIN is intended for intramuscular injection.

Aesthetic indications
Reconstituted XEOMIN is injected using a thin sterile needle (e.g. 30-33 gauge needle/ 0.20-0.30 mm diameter / 13 mm length).

Glabellar frown lines
To reduce the risk of blepharoptosis, injections near the levator palpebrae superioris and into the cranial portion of the orbicularis oculi should be avoided. Injections into the corrugator muscle should be done in the medial portion of the muscle, and in the central portion of the muscle belly at least 1 cm above the bony edge of the eye socket.

Neurological indications
Cervical dystonia (spasmodic torticollis)
A suitable sterile needle (e.g. 25-30 gauge / 0.30-0.50 mm diameter / 37 mm length) is used for injections into superficial muscles, and an e.g. 22 gauge / 0.70 mm diameter / 75 mm length needle may be used for injections into deeper musculature.
Localisation of the involved muscles with techniques such as electromyographic guidance or ultrasound is recommended.

Blepharospasm and hemifacial spasm
After reconstitution, the XEOMIN solution is injected using a suitable sterile needle (e.g. 27-30 gauge / 0.30-0.40 mm diameter / 12.5 mm length).

Post Stroke Spasticity of the upper limb
Reconstituted XEOMIN is injected using a suitable sterile needle (e.g. 26 gauge / 0.45 mm diameter / 37 mm length, for superficial muscles and a longer needle, e.g. 22 gauge / 0.7 mm diameter / 75 mm length, for deeper musculature).
Localisation of the involved muscles with techniques such as electromyographic guidance, nerve stimulation, or ultrasound is recommended.

4.2.2 Posology

Aesthetic indications
Injection volume per injection site: approximately 0.04 to 0.1 ml, depending on dilution.

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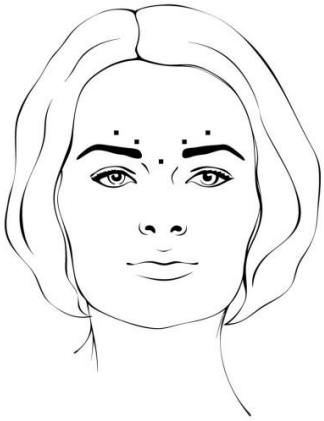
Possible dilutions of XEOMIN for the treatment of aesthetic indications are indicated in the following table:

Table 1: Diluent Volumes for Reconstitution of XEOMIN for the Treatment of Aesthetic Indications

Resulting dose (in units per 0.1 ml)	**Solvent added** (sodium chloride 9 mg/ml (0.9 %) solution for injection)	
	Vial with 50 units	**Vial with 100 units**
4 units	1.25 ml	2.5 ml
5 units	1 ml	2 ml

Repeat treatment should generally be no more frequent than every 3 months.

Glabellar frown lines
Dose per injection sites: 4 units into each of the 5 injection sites (two injections in each corrugator muscle and one injection in the procerus muscle).
Total dose: 20 to 30 units may be given according to the individual needs of the patient.



Improvement in the glabellar frown lines: usually within 2 to 3 days.
Duration of effect: up to 4 months after the injection, however, it may last longer or shorter in individual parties.

Lateral periorbital lines (crow's feet)

3-point injection scheme
Dose per injection sites: 4 units bilaterally into each of the 3 injection sites

- one injection approximately 1 cm lateral from the bony orbital rim
- two injections approximately 1 cm above and below the area of the first injection.

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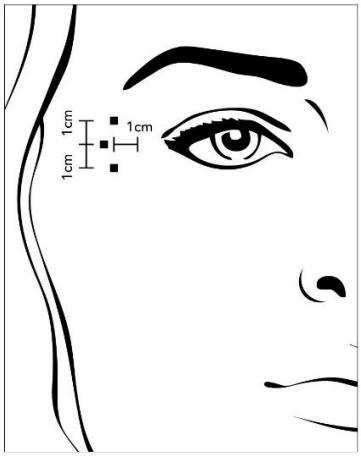
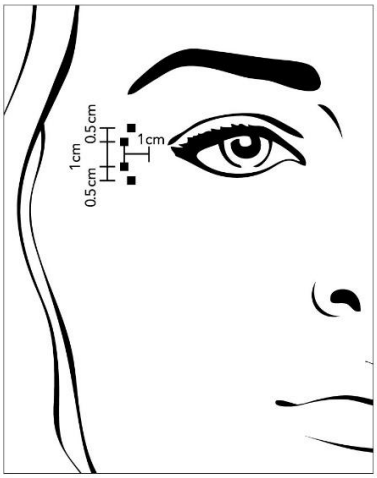


4-point injection scheme
Dose per injection sites: 3 units bilaterally into each of the 4 injection sites

- Mark the 1 cm lateral from the bony orbital rim.
- First two injections approximately 0.5 cm above and below this point
- Two injections approximately 1 cm above and below the first marked point.



Total dose: 24 units (12 units per side) may be given.
Improvement in the lateral periorbital lines: usually within 6 days.
Duration of effect: up to 4 months after the injection, however, it may last longer or shorter in individual patients.

Horizontal forehead lines
Total dose: 10 to 20 units may be given according to the individual needs of the patients.
Dose per injection sites:

- 10 to 20 units into the frontalis muscle in five horizontally aligned injection sites at least 2 cm above the orbital rim
- 2 units, 3 units, or 4 units per injection point, respectively.

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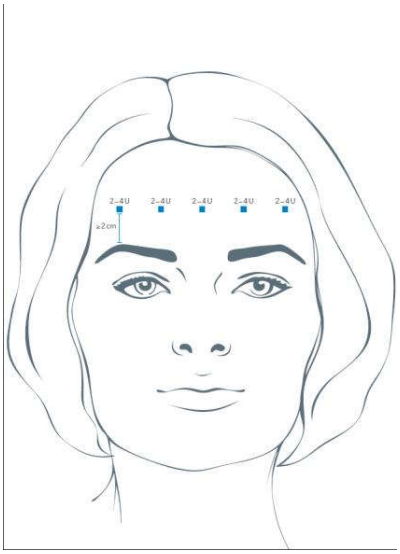

Improvement in the horizontal forehead lines: usually within 7 days.
Duration of effect: up to 4 months after injection, however, it may last longer or shorter in individual patients.

Neurological indications

General

The optimum dose and number of injection sites in the treated muscle(s) should be individualised for each patient and determined by the physician.

Possible dilutions for the treatment of neurological indications are indicated in the following table:

Table 2: Diluent Volumes for Reconstitution of XEOMIN for the Treatment of Neurological Indications

Resulting dose (in units per 0.1 ml)	**Solvent added** (sodium chloride 9 mg/ml (0.9 %) solution for injection)	
	Vial with 50 units	**Vial with 100 units**
40 units	0.125 ml	0.25 ml
20 units	0.25 ml	0.5 ml
10 units	0.5 ml	1 ml
8 units	0.625 ml	1.25 ml
5 units	1 ml	2 ml
4 units	1.25 ml	2.5 ml
2.5 units	2 ml	4 ml
2 units	2.5 ml	5 ml
1.25 units	4 ml	Not applicable

Cervical dystonia ***(spasmodic torticollis)***

Injection volume per injection site: approximately 0.1 to 0.5 ml.
Total dose: should not exceed 200 units per treatment session. Dose: up to 300 units may be given.
No more than 50 units should be given at any single injection site.

XEOMIN is usually injected into the sternocleidomastoid, levator scapulae, splenius capitis, scalenus, and/or the trapezius muscle(s). This list is not exhaustive as any of the muscles responsible for controlling head position may require treatment.

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Median time to first onset of effect: usually within seven days after injection.
Duration of effect: up to 3-4 months, however, it may last significantly longer or shorter.

Treatment intervals and doses should be determined based on the actual clinical need of the individual patient. Improved patient benefit may be achieved by retreating when symptoms return to a clinically significant level of discomfort and severity. Duration of action is dependent on dosing, injection technique, and other variables. Generally the patient should be treated using the lowest effective dose at the longest clinically indicated intervals between injections.

If in individual cases the duration of effect is shorter than 12 weeks, the next injection can be given earlier, upon consideration of the risk-benefit ratio. Repeat treatment should generally be no more frequent than every 6 weeks, and one single injection given earlier than 12 weeks does not indicate a general need for regular earlier re-injection. If an injection interval reduction is necessary, the following recommendations should be followed:
1. Active request from the patient
2. An objective confirmation of the necessity for an injection
3. Absence of adverse reactions to the previous injection

The dose should not be increased when the interval is reduced. In case of intervals reduction below 12 weeks, a close monitoring of adverse reaction should be performed. In a controlled clinical trial XEOMIN has been efficacious and well-tolerated when injected in intervals between 6 and 20 weeks (median: 12 weeks).

<u>Blepharospasm and hemifacial spasm</u>
Initial dose and injection volume per injection site: 1.25 to 2.5 units (0.05-0.1 ml).
Dosing:
- The initial dose should not exceed 25 units per eye.
- Generally, the total dose should not exceed 100 units per treatment session and 50 units per eye

XEOMIN is injected into the medial and lateral orbicularis oculi muscle of the upper lid and the lateral orbicularis oculi muscle of the lower lid. Additional sites in the brow area, the lateral orbicularis oculi muscle and in the upper facial area may also be injected if spasms here interfere with vision.
In cases of unilateral blepharospasm the injections should be confined to the affected eye. Patients with hemifacial spasm should be treated as for unilateral blepharospasm.

Median time to first onset of effect: usually within four days after injection.
Duration of effect: up to 3-4 months, however, it may last significantly longer or shorter in individual patients.

Treatment intervals and doses should be determined based on the actual clinical need of the individual patient. Improved patient benefit may be achieved by retreating when symptoms return to a clinically significant level of discomfort and severity. Duration of action is dependent on dosing, injection technique, and other variables. Generally the patient should be treated using the lowest effective dose at the longest clinically indicated intervals between injections.

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Post stroke spasticity of the upper limb
Injection volume per injection site: approximately 0.2 to 1 ml (can be exceeded to 1.5 ml in selected cases).

The exact dosage and number of injection sites should be tailored to the individual patient based on the size, number and location of involved muscles, the severity of spasticity, and the presence of local muscle weakness.

Table 3: Standard treatment doses per muscle

Clinical Pattern *Muscle*	Units (Range)	Number of Injection Sites per Muscle
Clenched Fist:		
Flexor digitorum superficialis	25-100	2
Flexor digitorum profundus	25-100	2
Flexed Wrist:		
Flexor carpi radialis	25-100	1-2
Flexor carpi ulnaris	20-100	1-2
Flexed Elbow:		
Brachioradialis	25-100	1-3
Biceps	50-200	1-4
Brachialis	25-100	1-2
Pronated Forearm:		
Pronator quadratus	10-50	1
Pronator teres	25-75	1-2
Thumb-in-Palm:		
Flexor pollicis longus	10-50	1
Adductor pollicis	5-30	1
Flexor pollicis brevis/ Opponens pollicis	5-30	1
Internally Rotated/Extended/Adducted Shoulder:		
Deltoideus, pars clavicularis	20-150	1-3
Latissimus dorsi	25-150	1-4
Pectoralis major	20-200	1-6
Subscapularis	15-100	1-4
Teres major	20-100	1-2

No more than 250 units should be administered to the shoulder muscles.

The recommended total dose for upper limb treatment is up to 500 units per treatment session.

Median time to first onset of effect: usually within 4 days after injection.
Maximum effect: usually within 4 weeks.
Duration of effect: up to 12 weeks, however, it may last longer or shorter in individual patients.

Repeat treatment should generally be no more frequent than every 12 weeks. Treatment intervals should be determined based on the actual clinical need of the individual patient.

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4.2.3 Paediatric Population

XEOMIN has not been studied in the paediatric population and is therefore not recommended in the paediatric age group.

4.3 Contraindications

- Hypersensitivity to the active substance or to any of the excipients.
- Generalized disorders of muscle activity (e.g. myasthenia gravis, Lambert-Eaton syndrome).
- Infection or inflammation at the proposed injection sites.

4.4 Special Warnings and Precautions for Use

General
Prior to administering XEOMIN the physician must familiarise himself/herself with the patient's anatomy and any alterations to the anatomy due to prior surgical procedures.

Care should be taken to ensure that XEOMIN is not injected into a blood vessel.

XEOMIN should be used with caution:
- if bleeding disorders of any type exist
- in patients receiving anticoagulant therapy or other substances in anticoagulant doses.
- in patients with amyotrophic lateral sclerosis
- in patients with other diseases which result in peripheral neuromuscular dysfunction
- in targeted muscles which display pronounced weakness or atrophy.

Aesthetic indications
If proposed injection sites are marked with a pen, the product must not be injected through the pen marks, otherwise a permanent tattooing effect may occur.

Glabellar frown lines
To reduce the risk of blepharoptosis, injections near the levator palpebrae superioris muscle and into the cranial portion of the orbicularis oculi muscle should be avoided. Injections into the corrugator muscle should be done in the medial portion of the muscle, and in the central portion of the muscle belly at least 1 cm above the bony edge of the eye socket.

Lateral periorbital lines (Crow's feet)
Injections too close to the zygomaticus major muscle should be avoided to prevent lip ptosis.

Horizontal forehead lines
Paralyzing of lower muscle fibers by injecting XEOMIN near the orbital rim should be avoided to reduce the risk of brow ptosis.

Neurological indications
For the treatment of cervical dystonia and post-stroke spasticity of the upper limb XEOMIN should be injected carefully when injected at sites close to sensitive structures, such as the carotid artery, lung apices and oesophagus.

Cervical dystonia ***(Spasmodic torticollis)***
Patients should be informed that injections of XEOMIN for the management of cervical dystonia may cause mild to severe dysphagia with the risk of aspiration or dyspnoea.

Patients with pre-existing swallowing or breathing difficulties may be more susceptible to these

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complications. In most cases, this is a consequence of weakening of muscles in the area of injection that are involved in breathing or swallowing. When distant effects occur, additional respiratory muscles may be involved.

Treatment of cervical dystonia with botulinum toxins may weaken neck muscles that serve as accessory muscles of ventilation. This may result in critical loss of breathing capacity in patients with respiratory disorders who may have become dependent upon these accessory muscles. There have been post-marketing reports of serious breathing difficulties, including respiratory failure, in patients with cervical dystonia treated with botulinum toxin products.

Patients with smaller neck muscle mass and patients who require bilateral injections into the sternocleidomastoid muscles have been reported to be at greater risk of dysphagia. In general, limiting the dose injected into the sternocleidomastoid muscle may decrease the occurrence of dysphagia.

Patients treated with botulinum toxin may require immediate medical attention should they develop problems with swallowing, speech or respiratory disorders. These reactions can occur within hours to weeks after injection with botulinum toxin.

Blepharospasm and hemifacial spasm
Injections near the levator palpebrae superioris should be avoided to reduce the occurrence of ptosis. Diplopia may develop as a result of *Botulinum neurotoxin type A* diffusion into the inferior oblique. Avoiding medial injections into the lower lid may reduce this adverse reaction.

Reduced blinking following injection of botulinum neurotoxin products into the orbicularis muscles can lead to corneal exposure, persistent epithelial defect and corneal ulceration, especially in patients with cranial nerve disorders (facial nerve).

Careful testing of corneal sensation in eyes previously operated upon, avoidance of injection into the lower lid area to avoid ectropion, and vigorous treatment of any epithelial defect should be employed. This may require protective drops, ointment, therapeutic soft contact lenses, or closure of the eye by patching or other means.

Because of its anticholinergic effects, XEOMIN should be used with caution in patients at risk of developing narrow angle glaucoma.

To prevent ectropion, botulinum toxin products should not be injected into the medial lower eyelid area.

Ecchymosis easily occurs in the soft tissues of the eyelid. Immediate gentle pressure at the injection site can limit that risk.

Post-stroke spasticity of the upper limb
New onset or recurrent seizures have been reported, typically in patients who are predisposed to experiencing these events. The exact relationship of these events to Botulinum neurotoxin injection has not been established.

Local and Distant Spread of Toxin Effect
The recommended dosages and frequencies of administrations of Xeomin should not be exceeded. Extensive or inappropriate doses outside the recommended dosage range may lead to an increased risk of adverse effects.

Undesirable effects may occur from misplaced injections of *Botulinum neurotoxin type A* that temporarily paralyse nearby muscle groups.

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There have been reports of undesirable effects that might be related to the spread of the toxin to sites distant from the injection site (see section 4.8).

Patients treated with therapeutic doses may experience excessive muscle weakness.

When treating neurological indications some of these can be life threatening and there have been reports of death. Dysphagia has also been reported following injection to sites other than the cervical musculature.

In general, patients or caregivers should be advised to seek immediate medical care if swallowing, speech or respiratory disorders occur.

Pre-existing Neuromuscular Disorders
Patients with neuromuscular disorders may be at increased risk of excessive muscle weakness particularly when treated intramuscularly. The *Botulinum neurotoxin type A* product should be used under specialist supervision in these patients and should only be used if the benefit of treatment is considered to outweigh the risk.

Patients with a history of aspiration or dysphagia should be treated with extreme caution when treated for neurological indications.

The treatment for aesthetic indications with XEOMIN is not recommended for patients with a history of dysphagia or aspiration.

Hypersensitivity Reactions
Hypersensitivity reactions have been reported with Botulinum neurotoxin products. If serious (e.g. anaphylactic reactions) and/or immediate hypersensitivity reactions occur, appropriate medical therapy should be instituted.

Antibody Formation
As with all therapeutic proteins, there is a potential for immunogenicity. Too frequent doses may increase the risk of antibody formation, which can result in treatment failure even if the product is being used to treat other indications.

Risk of ptosis in patients treated with Xeomin for glabellar lines
Do not exceed the recommended dosage and frequency of administration of Xeomin. In order to reduce the complication of ptosis the following steps should be taken:
- Avoid injection near the levator palpebrae superioris, particularly in patients with larger brow depressor complexes.
- Corrugator injections should be placed at least 1cm above the bony supraorbital ridge.

Human albumin and transmission of viral diseases
This product contains a small amount of human albumin. The risk of transmission of viral infection or prion-related infection such as Creutzfeldt-Jakob disease (CJD) cannot be excluded with absolute certainty following the use of human blood or blood products.

With physician prescription only / HARUS DENGAN RESEP DOKTER

4.5 Interaction with Other Medicinal Products and Other Forms of Interaction

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Co-administration of XEOMIN and aminoglycoside antibiotics or other agents interfering with neuromuscular transmission, e.g., tubocurarine-type muscle relaxants, should only be performed with caution as these agents may potentiate the effect of the toxin.

4.6 Fertility, Pregnancy and Lactation

Pregnancy
There are no adequate data from the use of *Botulinum neurotoxin type A* in pregnant women.
Studies in animals have shown reproductive toxicity.
The potential risk for humans is unknown.
XEOMIN should not be used during pregnancy unless the potential benefit justifies the risk.

Breastfeeding
It is not known whether *Botulinum neurotoxin type A* is excreted into the human breast milk.
The use of XEOMIN during lactation is not recommended.

Fertility
There are no clinical data from the use of *Botulinum neurotoxin type A*. In an animal study no adverse effects on male or female fertility were detected.

4.7 Effects on Ability to Drive and Use Machines

XEOMIN has a minor or moderate influence on the ability to drive and use machines.

Patients should be counselled that if asthenia, muscle weakness, vision disorders, dizziness or drooping eyelids occur, they should avoid driving or engaging in other potentially hazardous activities.

4.8 Undesirable Effects

Usually, undesirable effects are observed within the first week after treatment and are temporary in nature. They may be related to the active substance, the injection procedure, or both.

Undesirable effects independent from indication
Application related undesirable effects
As it is expected for any injection procedure localized pain, inflammation, paraesthesia, hypoaesthesia, tenderness, swelling/oedema, erythema, itching, localized infection, haematoma, Bleeding and/or bruising may be associated with the injection of XEOMIN.

Needle related pain and/or anxiety may result in vasovagal responses, including transient symptomatic hypotension, anxiety, nausea, tinnitus and syncope.

Undesirable effects of the substance class Botulinum toxin type A
Localised muscle weakness is one expected pharmacological effect of Botulinum toxin type A.

Toxin spread
When treating neurological indications side effects related to spread of toxin distant from the site of administration have been reported very rarely to produce symptoms consistent with Botulinum toxin effects (exaggerated muscle weakness, dysphagia, and aspiration pneumonitis with fatal outcome in some cases).

Undesirable effects such as these cannot be completely ruled out with the use of XEOMIN in aesthetic indications.

Hypersensitivity reactions

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Serious and/or immediate hypersensitivity reactions including anaphylaxis, serum sickness, urticaria, soft tissue oedema, and dyspnoea have been rarely reported. Some of these reactions have been reported following the use of conventional *Botulinum toxin type A* complex either alone or in combination with other agents known to cause similar reactions.

Post-marketing experience with XEOMIN
Flu-like symptoms and hypersensitivity reactions like swelling, oedema (also apart from injection site), erythema, pruritus, rash (local and generalised) and dyspnoea have been reported.

Undesirable effects dependent on indication

Based on clinical experience information on the frequency of adverse reactions for the individual indications is given below. The frequency categories are defined as follows: very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100), rare (≥1/10,000 to <1/1,000); very rare (<1/10,000); unknown (cannot be estimated from the available data).

Glabellar frown lines

Table 4: Adverse reactions based on clinical experience with glabellar frown lines

Body System	Adverse Reaction	
General disorders and administration site conditions:	Uncommon:	injection site bruising, influenza like illness, (local) tenderness, fatigue, injection site pain, discomfort (heavy feeling of eyelid/eyebrow)
Musculoskeletal and connective tissue disorders:	Common:	Mephisto sign
	Uncommon:	facial asymmetry (brow asymmetry), muscle spasms (above eyebrows)
Nervous system disorders:	Common:	headache
Eye disorders:	Uncommon:	eyelid oedema, vision blurred, eyelid ptosis
Skin and subcutaneous tissue disorders:	Uncommon:	pruritus, brow ptosis
Infections and infestations:	Uncommon:	nasopharyngitis
Vascular disorders:	Uncommon:	haematoma

Lateral periorbital lines (crow's feet)

Table 5: Adverse reactions based on clinical experience with Lateral periorbital lines

Body System	Adverse Reaction	
General disorders and administration site conditions:	*Common:*	injection site haematoma
Eye disorders:	*Common:*	eyelid oedema, dry eye

Upper facial lines

Table 6: Adverse reactions based on clinical experience with upper facial lines

Body System	Adverse Reaction

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General disorders and administration site conditions:	*Common:*	injection site haematoma, injection site pain, injection site erythema, discomfort (heavy feeling of frontal area)
Eye disorders:	*Common:*	eyelid ptosis, dry eye
Nervous system disorders:	*Very common:*	headache
	Common:	hypoaesthesia
Skin and subcutaneous tissue disorders:	*Common:*	brow ptosis
Musculoskeletal and connective tissue disorders:	*Common:*	facial asymmetry, Mephisto sign (lateral elevation of eyebrows)
Gastrointestinal disorders:	*Common:*	nausea

Cervical dystonia ***(Spasmodic torticollis)***
The management of cervical dystonia may cause dysphagia with varying degrees of severity with the potential for aspiration which may require medical intervention. Dysphagia may persist for two to three weeks after injection, but has been reported in one case to last five months.
Dysphagia appears to be dose-dependent.

Table 7: Adverse reactions based on clinical experience with cervical dystonia

Body System	Adverse Reaction	
Gastrointestinal disorders:	Very common	dysphagia
	Common:	dry mouth, nausea
General disorders and administration site conditions:	Common:	injection site pain, asthenia
Musculoskeletal and connective tissue disorders:	Common:	neck pain, muscular weakness, myalgia, musculoskeletal stiffness, muscle spasms
Nervous system disorders:	Common:	headache, presyncope, dizziness
	Uncommon:	speech disorder
Infections and infestations:	Common:	upper respiratory tract infection
Respiratory thoracic and mediastinal disorders:	Uncommon:	dysphonia, dyspnoea
Skin and subcutaneous tissue disorders:	Common:	hyperhidrosis
	Uncommon:	rash

Blepharospasm

Table 8: Adverse reactions based on clinical experience with blepharospasm

Body System	Adverse Reaction	
Nervous system disorders:	Uncommon:	headache, facial paresis
Eye disorders:	Very common:	eyelid ptosis
	Common:	Dry eyes, vision blurred, visual impairment,
	Uncommon:	Diplopia, lacrimation increased
Gastrointestinal disorders:	Common:	dry mouth
	Uncommon:	Dysphagia
General disorders and	Common:	injection site pain

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administration site conditions:	Uncommon:	fatigue
Musculoskeletal and connective tissue disorders:	Uncommon:	muscular weakness
Skin and subcutaneous tissue disorders:	Uncommon:	rash

Hemifacial spasm
Similar adverse reactions as for blepharospasm can be expected with hemifacial spasm.

Post-stroke spasticity of the upper limb

Table 9: Adverse reactions based on clinical experience with upper limb spasticity

Body System	Adverse Reaction	
Gastrointestinal disorders:	Common:	dry mouth
	Uncommon:	dysphagia, nausea
General disorders and administration site conditions:	Uncommon:	asthenia
Musculoskeletal and connective tissue disorders:	Uncommon:	muscular weakness, pain in extremity, myalgia
Nervous system disorders:	Uncommon:	headache, hypoaesthesia

Reporting of Undesirable effects
If any undesirable effects are experienced, the individual should consult their doctor, pharmacist, or nurse. This includes any undesirable effects that may not be listed in the leaflet. Undesirable effects can also be reported directly (as detailed below).

Indonesia	Pharmacovigilance/MESO Nasional BPOM RI Website: e-Meso BPOM or PT Pyridam Farma, Tbk Pharmacovigilance Team Email: pv.safety@pyfa.co.id

4.9 Overdose

Symptoms of overdose
Increased doses of *Botulinum neurotoxin type A* may result in pronounced neuromuscular paralysis distant from the injection site with a variety of symptoms. Symptoms may include general weakness, ptosis, diplopia, breathing difficulties, speech difficulties, paralysis of the respiratory muscles or swallowing difficulties which may result in aspiration pneumonia. Symptoms of overdose are not immediately apparent post-injection.

Measures in cases of overdose
In the event of overdose the patient should be medically monitored for symptoms of excessive muscle weakness or muscle paralysis. Symptomatic treatment may be necessary. Respiratory support may be required if paralysis of the respiratory muscles occurs.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic Properties

Pharmacotherapeutic group: other muscle relaxants, peripherally acting agents
ATC code: M03AX01

Botulinum neurotoxin type A blocks cholinergic transmission at the neuromuscular junction by

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inhibiting the release of acetylcholine from peripheral cholinergic nerve terminals.

This inhibition occurs according to the following sequence:
- heavy chain of neurotoxin binding to cholinergic nerve terminals
- internalisation of the neurotoxin within vesicles into the nerve terminal
- translocation of the light-chain of the neurotoxin molecule into the cytosol of the nerve terminal
- enzymatic cleavage of SNAP25, a presynaptic target protein essential for the release of acetylcholine

Complete recovery of endplate function/impulse transmission after intramuscular injection normally occurs within 3-4 months as nerve terminals sprout and reconnect with the muscle endplate and the presynaptic neurotransmitter release mechanism becomes functional again.

5.2 Pharmacokinetic Properties

General characteristics of the active substance
Classic kinetic and distribution studies cannot be conducted with *Botulinum neurotoxin type A* because the active substance is applied in such small quantities (picograms per injection) and binds rapidly and irreversibly to the cholinergic nerve terminals.

Native Botulinum toxin is a high molecular weight complex which, in addition to the neurotoxin (150 kD), contains other non-toxic proteins, like haemagglutinins and non-haemagglutinins. In contrast to conventional preparations containing the *Botulinum toxin type A* complex, XEOMIN contains pure (150 kD) neurotoxin because it is free from complexing proteins.

Distribution of the active substance in patients
Human pharmacokinetic studies with XEOMIN have not been performed for the reasons detailed above.

5.3 Preclinical Safety Data

Non-clinical data revealed no special hazard for humans based on conventional studies of cardiovascular safety pharmacology.

The findings made in repeat-dose toxicity studies conducted with XEOMIN were mainly related to its pharmacodynamic action.

In a chronic study in rats XEOMIN was injected into the salivary gland. The weight of the injected submandibular salivary gland was reduced at all dose levels, and salivary gland acinar atrophy was seen at the highest dose of 40 LDU/kg after four repeated injections of XEOMIN at 8 weeks intervals in rats. No evidence of local intolerability was noted.

Reproductive toxicity studies with XEOMIN performed in rats and rabbits did neither show adverse effects on male or female fertility nor direct effects on embryo-foetal or on pre- and postnatal development.

However, administration of XEOMIN at dose levels exhibiting clear maternal toxicity was associated with an increased number of abortions in an embryotoxicity study in rabbits and with slightly decreased fetal bodyweights in an embryotoxicity study in rats.

In a post-weaning juvenile toxicity study in rats, atrophy of the testicular germinal epithelium and hypospermia were observed at the highest dose tested (30 units/kg/adm) without any impact on male fertility. When males and females were paired at 14 weeks of age, mating performance was reduced in

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high dose males possibly due to the limb weakness or the markedly lower body weight. In the absence of any effect on the mean number of corpora lutea, preimplantation loss was increased at 10 units/kg/adm and above. Whether this finding was a male or female mediated effect could not be conclusively clarified.

No genotoxicity or carcinogenicity studies have been conducted with XEOMIN.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

1 mg Human albumin
4.7 mg Sucrose

6.2 Incompatibilities

XEOMIN must not be mixed with other medicinal products except those mentioned in section 6.6.

6.3 Shelf-life

Unopened vial: 3 years
Reconstituted solution: Chemical and physical in-use stability has been demonstrated for 24 hours at 2°C to 8°C.

6.4 Special Precautions for Storage

Do not store above 30 °C
For storage conditions of the reconstituted XEOMIN, see section 6.3.

6.5 Nature and Contents of Container

Vial: type 1 glass
Stopper: bromobutyl rubber
Tamper-proof seal: aluminium

Box, 1 vial @ 50 units
Box, 1 vial @100 units

6.6 Special Precautions for Disposal and other Handling

Procedure to follow for a safe disposal of vials, syringes and materials used
Any unused vials, residual reconstituted solution in the vial and/or syringe should be inactivated by adding one of the following solutions: 70% ethanol, 50% isopropanol, diluted sodium hydroxide solution (0.1 N NaOH), or diluted sodium hypochlorite solution (at least 0.1% NaOCl).

Used vials, syringes, and materials should not be emptied and should be discarded into appropriate containers and disposed of in accordance with local requirements.

Recommendations should any incident occur during the handling of Botulinum toxin
Any spills of the product must be wiped up: either using absorbent material impregnated with any of the above listed solutions in case of the powder, or with dry, absorbent material in case of reconstituted product.

The contaminated surfaces should be cleaned using absorbent material impregnated with any of the

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above listed solutions, then dried.

If a vial is broken, proceed as mentioned above by carefully collecting the pieces of broken glass and wiping up the product, avoiding any cuts to the skin.

If the product comes into contact with skin, rinse the affected area abundantly with water.

If product gets into the eyes, rinse thoroughly with plenty of water or with an ophthalmic eyewash solution.

If product comes into contact with a wound, cut or broken skin, rinse thoroughly with plenty of water and take the appropriate medical steps according to the dose injected.

7. MARKETING AUTHORISATION HOLDER

Registered by:
PT. PYRIDAM FARMA Tbk.
Jakarta, Indonesia

Manufactured by:
Merz Pharma GmbH & Co. KGaA
Am Pharmapark
D-06861 Dessau-Roßlau, Germany

Released by:
Merz Pharma GmbH & Co. KGaA, Reinheim, Germany

8. MARKETING AUTHORISATION NUMBER(S)

Registration number: DKI1691300444A1

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

25 October 2021

10. DATE OF REVISION OF THE TEXT

April 2025

11. DRUG CATEGORY

Ethical

Pada proses pembuatannya bersinggungan dengan bahan bersumber babi.

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XEOMIN®(ZEE-oh-min)

Clostridium Botulinum neurotoxin type A (150kD), bebas dari pengompleks protein

Informasi Produk untuk Pasien

Apa yang ada di brosur ini?

Brosur ini akan menjawab beberapa pertanyaan umum tentang XEOMIN.

Brosur ini tidak memiliki informasi yang lengkap. Jika Anda ingin tahu lebih lanjut tentang XEOMIN, berkonsultasilah kepada dokter Anda atau apoteker.

Semua obat memiliki risiko dan manfaat. Dokter Anda telah menimbang segala risiko dengan manfaat yang diharapkan dari penggunaan obat ini.

Jika Anda ragu dalam menggunakan XEOMIN, berkonsultasilah kepada dokter atau apoteker Anda.

Simpan brosur ini.

Anda mungkin membutuhkan untuk dibaca lagi.

Untuk apa XEOMIN digunakan?

XEOMIN digunakan pada orang dewasa untuk pengobatan :

- garis-garis kerutan di antara alis mata (garis glabelar).
- garis-garis kerutan periorbital (crow's feet)
- garis-garis kerutan di dahi

XEOMIN juga digunakan pada orang dewasa untuk pengobatan :

- *Twisted neck* (*spasmodic torticollis*)
- Spasme kelopak mata (*blepharospasm*) dan spasme yang mempengaruhi satu sisi wajah (spasme hemifacial)
- Peningkatan tekanan otot / kaku otot yang tidak terkontrol pada punggung, lengan atau tangan (kelumpuhan pada tubuh bagian atas pasca-stroke)

Obat ini mengandung *Clostridium Botulinum neurotoxin* tipe A (150kD), bebas dari protein pengompleks. Obat ini termasuk golongan relaksan otot perifer.

XEOMIN diinjeksikan ke dalam otot, kemudian memblok jalur sinyal dari saraf ke otot. Hal ini akan menyebabkan otot mengalami penurunan kemampuan untuk berkontraksi.

Tanyakan dokter Anda, mengapa XEOMIN diberikan untuk Anda.

XEOMIN tidak bersifat adiktif.

XEOMIN hanya tersedia dengan resep dari dokter.

XEOMIN telah diuji untuk keamanan dan efektifitas pada orang dewasa. Tidak dianjurkan untuk digunakan pada anak-anak.

Sebelum Anda menggunakan XEOMIN

Kapan Anda tidak boleh menggunakan XEOMIN?

Jangan gunakan XEOMIN jika Anda memiliki jenis alergi berikut :

- tiap obat yang mengandung *Botulinum neurotoxin* tipe A
- tiap bahan yang tercantum di akhir brosur ini

Jangan gunakan XEOMIN jika Anda memiliki kondisi berikut :

- gangguan umum dari aktivitas otot (misalnya *myasthenia gravis, Lambert-Eaton Syndrome*)
- infeksi atau peradangan pada tempat suntikan

Jangan gunakan XEOMIN setelah tanggal kadaluarsa yang tercantum pada kemasan atau jika kemasan robek atau jika kemasan dalam kondisi tidak bagus.

Jika Anda tidak yakin apakah Anda harus mulai menggunakan XEOMIN,

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berkonsultasilah kepada dokter Anda.

Sebelum Anda mulai menggunakan XEOMIN

Beritahukan kepada dokter Anda jika Anda memiliki kondisi alergi terhadap obat lain, makanan, pengawet, atau pewarna.

Efek samping yang mungkin terjadi akibat penyuntikan Botulinum neurotoksin type A pada tempat yang tidak tepat adalah melumpuhkan sementara otot-otot di sekitarnya. Sangat jarang adanya laporan efek samping yang mungkin terkait dengan penyebaran Botulinum neurotoksin yang jauh dari tempat penyuntikan untuk menghasilkan gejala yang konsisten terhadap efek Botulinum neurotoksin type A (misalnya kelemahan otot yang berlebihan, kesulitan menelan atau menelan makanan atau minuman tanpa disengaja ke saluran pernafasan). Pasien yang menerima dosis yang disarankan mungkin mengalami kelemahan otot yang berlebihan.

Jika dosisnya terlalu tinggi atau penyuntikan terlalu sering, risiko pembentukan antibodi bisa meningkat. Pembentukan antibodi dapat menyebabkan kegagalan pengobatan dengan Botulinum neurotoksin type A, apapun alasan penggunaannya.

Beritahukan dokter Anda jika Anda memiliki atau pernah memiliki kondisi kesehatan berikut :

- gangguan pendarahan tipe apapun
- pengobatan dengan bahan yang mencegah darah dari penggumpalan (misalnya coumarin, heparin, asam asetilsalisilat, clopidogrel)
- kesulitan menelan
- kesulitan bernafas
- kelemahan otot atau penurunan volume otot pada otot tempat suntikan
- amyotrophic lateral sclerosis (ALS), yang dapat menyebabkan penurunan otot secara umum gangguan pada mata (misalnya glaucoma), terutama jika Anda melakukan pengobatan untuk *blepharospasm*
- menderita atau pernah menderita kejang
- setiap penyakit yang mengganggu interaksi antara saraf dan otot skeletal (disfungsi neuromuskular perifer)
- masalah dengan injeksi Botulinum neurotoksin type A di masa lalu
- menjalani operasi

Twisted neck (spasmodic torticollis)
Setelah injeksi, Anda mungkin mengalami kesulitan menelan yang ringan sampai parah. Hal ini dapat menyebabkan masalah pada pernapasan dan Anda mungkin memiliki risiko lebih tinggi untuk menghirup zat asing dari cairan. Zat asing di paru-paru Anda bisa menyebabkan radang atau infeksi (pneumonia). Dokter Anda akan memberi Anda perawatan medis khusus jika diperlukan (misalnya dalam bentuk nutrisi buatan).

Kesulitan menelan bisa berlangsung hingga dua sampai tiga minggu setelah penyuntikan, salah satu pasien diketahui memiliki durasi hingga lima bulan.

Spasme kelopak mata (blepharospasm) dan spasme yang mempengaruhi satu sisi wajah (spasme hemifacial)
Beritahu dokter Anda jika Anda

- menjalani operasi mata. Dokter Anda akan mengambil tindakan pencegahan tambahan.
- beresiko terkena penyakit yang disebut *narrow angle glaucoma*. Penyakit ini dapat menyebabkan tekanan pada mata bagian dalam untuk membuka dan dapat menyebabkan kerusakan pada saraf optik Anda. Dokter Anda akan tahu jika Anda berisiko.

Selama perawatan, pendarahan kecil mungkin terjadi pada jaringan lunak kelopak mata. Dokter Anda dapat membatasi ini dengan cara memberikan tekanan lembut pada tempat suntikan sesegera mungkin.

Setelah Anda menerima injeksi XEOMIN pada otot mata Anda, tingkat kedip Anda akan berkurang. Hal ini dapat menyebabkan pemaparan yang berkepanjangan pada bagian depan transparan mata (kornea). Paparan ini dapat menyebabkan kerusakan permukaan dan pembengkakan (kornea ulserasi).

Peningkatan tekanan otot / kaku otot yang tidak

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terkontrol pada punggung, lengan atau tangan (kelumpuhan pada tubuh bagian atas pasca stroke)

XEOMIN dapat digunakan untuk perawatan peningkatan tekanan otot / kaku otot yang tidak terkontrol pada tubuh bagian atas pada pasien pasca stroke, seperti pundak, siku, lengan atau tangan. XEOMIN efektif dikombinasikan dengan metode terapi umum. XEOMIN seharusnya digunakan bersamaan dengan metode terapi lainnya.

Hal ini bukan berarti bahwa obat ini dapat meningkatkan kemampuan gerak sendi di mana otot di sekitarnya telah kehilangan kemampuan untuk meregangkan.

Beritahukan dokter Anda jika Anda sedang hamil atau berencana untuk hamil.

XEOMIN tidak boleh digunakan selama kehamilan, kecuali jika dokter Anda memutuskan bahwa kebutuhan dan manfaat pengobatan dapat membenarkan risiko yang mungkin timbul pada janin.

Beritahukan dokter Anda jika Anda sedang menyusui.

XEOMIN tidak disarankan jika Anda sedang menyusui.

Beritahu dokter Anda jika Anda berusia dibawah 18 tahun.

Penggunaan XEOMIN pada anak-anak dan remaja belum diteliti dan oleh karena itu tidak disarankan untuk pasien berusia di bawah 18 tahun.

Beritahu dokter Anda jika Anda menyetir.
Anda seharusnya tidak mengemudi atau terlibat dalam aktivitas berbahaya lainnya jika kelopak mata menurun, kelemahan (asthenia), kelemahan otot, pusing, atau gangguan penglihatan terjadi. Jika ragu mintalah saran dari dokter Anda.

Jika Anda belum memberitahukan dokter Anda tentang kondisi di atas, beritahukan dokter Anda sebelum Anda diberikan XEOMIN.

Penggunaan obat-obat lainnya

Beritahukan dokter atau apoteker Anda jika Anda menggunakan obat-obat lainnya, termasuk obat tanpa resep dari dokter

XEOMIN mungkin dapat berinteraksi dengan obat-obat lainnya yang menyebabkan relaksasi otot atau berpengaruh pada system pernafasan.

Beritahukan dokter Anda jika Anda menggunakan obat-obat lainnya, terutama jika Anda :

- baru mendapatkan suntikan antibiotik
- menggunakan relaksan otot
- menggunakan obat flu atau alergi
- menggunakan obat tidur
- menggunakan obat pengencer darah

Obat-obat ini dapat dipengaruhi oleh XEOMIN atau mempengaruhi kerja XEOMIN. Anda mungkin membutuhkan dosis obat yang berbeda atau jenis obat yang berbeda.

Dokter Anda memiliki informasi lainnya tentang obat yang harus dihindari selama menggunakan XEOMIN.

Bagaimana menggunakan XEOMIN?

XEOMIN hanya dapat diberikan oleh dokter yang memiliki pengetahuan spesialis yang sesuai untuk pengobatan menggunakan Botulinum neurotoksin type A.

XEOMIN yang sudah dilarutkan ditujukan untuk penyuntikan kedalam otot (penggunaan intramuskular).

Ikuti semua petunjuk yang diberikan oleh dokter Anda dengan hati-hati.

Petunjuk yang ada mungkin berbeda dengan informasi dalam brosur ini.

Berapa banyak dan berapa lama XEOMIN digunakan?

Dokter Anda akan menentukan dosis yang tepat untuk digunakan, tergantung kondisi kesehatan Anda dan akan memberitahu Anda seberapa sering Anda akan memerlukan perawatan dengan XEOMIN.

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Garis kerutan vertikal antara alis mata (garis glabellar)

Saat melakukan perawatan garis vertikal di antara alis mata (garis glabellar) dosis total yang biasa digunakan adalah 20 unit dibagi menjadi 5 tempat suntikan. Dosis total dapat ditingkatkan oleh dokter hingga 30 unit jika dibutuhkan sesuai kebutuhan individu pasien, dengan interval paling sedikit 3 bulan antara setiap perawatan.

Garis kerutan periorbital (garis crow's feet)
Untuk pengobatan garis kerutan periorbital (garis crow's feet) dokter Anda akan menyuntikkan dosis standar 24 unit (12 unit per mata). 4 atau 3 unit akan diterapkan secara bilateral ke masing-masing dari 3 atau 4 tempat suntikan.

Pengurangan garis kerutan periorbital yang terlihat saat tersenyum maksimal sebagian besar terjadi dalam 6 hari. Efeknya bertahan hingga 4 bulan setelah injeksi, namun bisa bertahan lebih lama atau lebih pendek. Interval antara perawatan tidak boleh kurang dari 3 bulan.

Garis kerutan di dahi
Saat perawatan garis kerutan di dahi, dokter Anda akan menggunakan dosis dalam kisaran 10 hingga 20 unit sesuai dengan kebutuhan individu pasien. Dosis total 10 hingga 20 unit akan disuntikkan ke dalam lima tempat injeksi yang sejajar secara horizontal (masing-masing 2 unit, 3 unit, atau 4 unit per titik injeksi).

Pengurangan garis kerutan dahi biasanya terjadi dalam 7 hari. Efeknya bertahan hingga 4 bulan setelah injeksi, namun bisa bertahan lebih lama atau lebih pendek. Interval antara perawatan tidak boleh kurang dari 3 bulan.

Twisted neck (spasmodic torticollis)
Periode antara sesi perawatan tidak boleh lebih pendek dari 6 minggu. Dosis yang direkomendasikan untuk satu tempat suntikan tunggal adalah hingga 50 unit, dan jumlah dosis yang direkomendasikan per sesi perawatan adalah hingga 200 unit. Dosis hingga 300 unit mungkin diberikan oleh dokter Anda.

Spasme kelopak mata (blepharospasm) dan spasme yang mempengaruhi satu sisi wajah (spasme hemifacial)
Periode antara sesi perawatan tidak boleh lebih pendek dari 6 minggu. Perawatan bisa diulang jika diperlukan. Dosis awal yang dianjurkan adalah sampai 25 unit per mata, dan dosis total yang direkomendasikan dalam sesi perawatan lanjutan adalah hingga 100 unit per sesi dan 50 unit per mata. Jika Anda menderita spasme di satu sisi wajah (spasme hemifacial), dokter Anda akan mengikuti rekomendasi pengobatan untuk spasme kelopak mata yang terbatas pada satu sisi wajah.

Peningkatan tekanan otot / kaku otot yang tidak terkontrol pada punggung, lengan atau tangan (kelumpuhan pada tubuh bagian atas pasca stroke)

Dosis yang direkomendasikan bisa mencapai 500 unit untuk setiap sesi pengobatan. Periode antara setiap sesi pengobatan setidaknya 12 minggu.

Jika Anda mengalami overdosis

Segera hubungi dokter Anda jika Anda diberikan jumlah XEOMIN yang terlalu banyak. Tetap hubungi meskipun Anda tidak merasakan tanda-tanda ketidaknyamanan atau keracunan.

Jika Anda merasakan gejala overdosis, segera hubungi layanan gawat darurat atau mintalah kerabat Anda untuk melakukannya, dan pergilah ke rumah sakit. Pengawasan medis hingga beberapa hari dan bantuan ventilasi mungkin diperlukan.
Gejala-gejala overdosis antara lain :

- keletihan secara umum
- kelopak mata menurun
- penglihatan dobel
- kesulitan bernafas dan kelumpuhan otot pernafasan
- kesulitan berbicara
- kesulitan menelan yang dapat menyebabkan pneumonia

Diskusikan segala kekuatiran Anda dengan dokter Anda.

Suntikan berulang dengan XEOMIN

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Jika Anda tidak melakukan aktivitas dalam jangka waktu lama, aktivitas apapun harus dimulai secara bertahap setelah injeksi XEOMIN. Hubungi dokter Anda dan segera dapatkan bantuan medis jika Anda mengalami hal berikut:

- kesulitan dalam bernapas, menelan atau berbicara
- gatal-gatal, pembengkakan termasuk pembengkakan wajah atau tenggorokan, mengi, terasa samar dan sesak napas (kemungkinan gejala reaksi alergi parah).

Selama Anda menggunakan XEOMIN

Hal-hal yang harus Anda lakukan

Jika Anda akan menggunakan obat baru lainnya, beritahukan dokter Anda atau apoteker bahwa Anda menggunakan XEOMIN.

Beritahukan dokter lainnya, dokter gigi, dan apoteker yang mengobati Anda jika Anda sedang menggunakan XEOMIN.

Jika Anda akan menjalani operasi, beritahukan ahli bedah atau ahli obat bius bahwa Anda menggunakan XEOMIN. XEOMIN dapat mempengaruhi kerja obat lain yang digunakan selama operasi.

Jika Anda menjadi hamil selama menggunakan XEOMIN, segera beritahukan dokter Anda.

Simpan semua jadwal pertemuan dengan dokter Anda supaya perkembangan Anda dapat diperiksa.

Efek samping

Segera beritahukan dokter Anda atau apoteker jika Anda merasa tidak nyaman ketika menggunakan XEOMIN.

XEOMIN menolong orang-orang dengan kondisi otot overaktif (misalnya *cervical dystonia, blepharospasm*, spasme hemifacial, spastisitas tungkai atas, garis kerutan glabellar, garis kerutan crow's feet atau garis kerutan di dahi), tetapi obat ini menimbulkan efek samping yang tidak diinginkan pada beberapa orang. Semua obat memiliki efek samping. Kadang-kadang efeknya serius, kebanyakan tidak. Anda mungkin membutuhkan perhatian medis jika Anda mengalami beberapa efek samping dari obat ini.

Saat melakukan perawatan indikasi neurologis, efek samping seperti kelemahan otot yang berlebihan atau kesulitan menelan mungkin disebabkan oleh relaksasi otot yang jauh dari tempat penyuntikan XEOMIN. Kesulitan menelan dapat menyebabkan inhalasi benda asing yang mengakibatkan radang paru-paru dan dalam beberapa kasus, menyebabkan kematian. Efek samping seperti ini tidak bisa sepenuhnya dikesampingkan dengan penggunaan XEOMIN dalam indikasi estetika.

Reaksi alergi dapat terjadi dengan XEOMIN. Reaksi alergi segera yang serius (anafilaksis) atau reaksi alergi terhadap serum dalam produk (serum sickness), yang menyebabkan misalnya sulitnya bernafas (dyspnoea), gatal-gatal (urtikaria) atau pembengkakan pada jaringan lunak (edema), jarang dilaporkan. Beberapa reaksi berikut telah diamati setelah menggunakan kompleks Botulinum toksin tipe A konvensional. Efek samping ini terjadi saat toksin diberikan sendiri atau dikombinasikan dengan produk lain yang diketahui menyebabkan reaksi serupa. Reaksi alergi dapat menyebabkan gejala berikut:

- kesulitan bernafas, menelan atau berbicara karena bengkak pada wajah, bibir, mulut atau tenggorokan
- bengkak pada tangan, kaki atau pergelangan kaki.

Jika Anda memperhatikan ada efek samping ini, segera beritahu dokter Anda atau pergi ke unit gawat darurat di rumah sakit terdekat atau mintalah kerabat Anda untuk melakukannya.

Biasanya, efek samping diamati dalam minggu pertama setelah perawatan dan bersifat sementara. Efek samping mungkin terkait dengan obat, teknik injeksi atau keduanya. Efek samping mungkin terbatas pada area di sekitar tempat suntikan (misalnya kelemahan otot lokal, nyeri lokal,

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pembengkakan, parestesi, berkurangnya rasa sentuhan (hypoaesthesia), nyeri tekan, pembengkakan (umum), pembengkakan jaringan lunak. (edema), kulit kemerahan (eritema), gatal, infeksi lokal, hematoma, perdarahan dan / atau memar).

Penyuntikan menggunakan jarum bisa menyebabkan rasa sakit. Rasa sakit atau kecemasan terhadap jarum dapat menyebabkan pingsan, tekanan darah rendah, mual atau tinnitus.

Garis kerutan vertikal antara alis mata (garis glabellar)
Efek samping berikut dilaporkan dengan XEOMIN:

Umum (dapat mempengaruhi hingga 1 dari 10 orang): Sakit kepala, *mephisto sign*;

Jarang terjadi (dapat mempengaruhi hingga 1 dari 100 orang): Luka pada tempat suntikan, hematoma, kelopak mata / alis mata berasa tebal, alis mata menurun, akumulasi cairan di kelopak mata (edema kelopak mata), gatal (pruritus), seperti sakit influenza, nyeri tekan, kelelahan, nyeri pada tempat suntikan, otot kejang penglihatan kabur, kelopak mata menurun, pembengkakan pada hidung dan tenggorokan (nasofaringitis), wajah tidak simetris (alis tidak simetris)

Garis kerutan periorbital (garis crow's feet)
Efek samping berikut dilaporkan dengan XEOMIN:
Umum (dapat mempengaruhi hingga 1 dari 10 orang): Memar di tempat suntikan, akumulasi cairan di kelopak mata (edema kelopak mata), mata kering

Garis kerutan wajah bagian atas
Efek samping berikut dilaporkan dengan XEOMIN:
Sangat Umum (dapat mempengaruhi lebih dari 1 dari 10 orang): Sakit kepala
Umum (dapat mempengaruhi hingga 1 dari 10 orang): Memar di tempat suntikan, nyeri di tempat suntikan, kulit memerah di sekitar tempat suntikan, ketidaknyamanan (rasa berat di area frontal), kelopak mata turun (eyelid ptosis), mata kering, berkurangnya indra peraba (hypoaesthesia), alis terkulai (brow ptosis), asimetri wajah, tanda Mephisto (mengangkat alis luar), mual

Twisted neck (spasmodic torticollis)
Efek samping berikut dilaporkan dengan XEOMIN:

Sangat umum (dapat mempengaruhi lebih dari 1 dari 10 orang):
Kesulitan menelan (disfagia);

Umum (dapat mempengaruhi hingga 1 dari 10 orang): Mulut kering, mual, nyeri pada tempat suntikan, kelemahan (asthenia), nyeri leher, kelemahan otot, nyeri muskuloskeletal, kekakuan otot, otot kejang, sakit kepala, presyncope, pusing, infeksi saluran pernapasan atas, keringat meningkat (hiperhidrosis);

Jarang terjadi (dapat mempengaruhi hingga 1 dari 100 orang): Gangguan bicara, gangguan suara (disfonia), sesak napas (dyspnoea), ruam

Pengobatan *twisted neck* dapat menyebabkan kesulitan menelan dengan tingkat keparahan yang bervariasi. Hal ini dapat menyebabkan bernafas dengan bahan asing, yang mungkin memerlukan intervensi medis. Kesulitan menelan bisa bertahan selama dua sampai tiga minggu setelah penyuntikan, namun telah dilaporkan dalam satu kasus sampai lima bulan. Kesulitan menelan tampaknya bergantung pada dosis.

Spasme kelopak mata (blepharospasm)
Efek samping berikut dilaporkan dengan XEOMIN:

Sangat umum (dapat mempengaruhi lebih dari 1 dari 10 orang): Kelopak mata menurun (ptosis kelopak mata)

Umum (dapat mempengaruhi hingga 1 dari 10 orang): mata kering, penglihatan kabur, gangguan penglihatan, mulut kering, nyeri pada tempat suntikan;

Jarang terjadi (dapat mempengaruhi hingga 1 dari 100 orang): Ruam, sakit kepala, kelemahan otot wajah (paresis wajah), penglihatan ganda (diplopia), lakrimasi meningkat, kesulitan menelan (disfagia), kelelahan, kelemahan otot

Spasme yang mempengaruhi satu sisi wajah (spasme hemifacial)
Efek samping yang serupa dengan spasme kelopak mata dapat diperkirakan terjadi saat mengobati spasme yang

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mempengaruhi satu sisi wajah (spasme hemifacial).

Peningkatan tekanan otot / kaku otot yang tidak terkontrol pada punggung, lengan atau tangan (kelumpuhan pada tubuh bagian atas pasca stroke)

Efek samping berikut dilaporkan dengan XEOMIN:

Umum (dapat mempengaruhi hingga 1 dari 10 orang): Mulut Kering

Jarang terjadi (dapat mempengaruhi hingga 1 dari 100 orang): Sulit menelan (dysphagia), mual, lemas (asthenia), rasa sakit yang ekstrim, nyeri otot (myalgia), kelelahan, sakit kepala, berkurangnya respon sentuhan (hypoaesthesia)

Jangan kuatir dengan daftar efek samping di bawah ini. Anda mungkin tidak mengalami efek-efek samping tersebut.

Tanyakan dokter Anda untuk menjawab semua pertanyaan Anda.

Ada laporan gejala mirip flu dan reaksi hipersensitivitas, seperti pembengkakan, pembengkakan jaringan lunak (edema), kemerahan, gatal, ruam (lokal dan umum), dan sesak napas.

Beritahukan dokter Anda jika Anda melihat sesuatu yang membuat Anda merasa tidak nyaman.

Efek samping lainnya yang tidak ada di daftar di atas mungkin dialami beberapa orang.

Pelaporan efek samping
Jika Anda mengalami efek samping apapun, konsultasikan dengan dokter, apoteker, atau perawat Anda. Hal ini juga termasuk efek samping yang mungkin tidak tercantum dalam brosur. Anda juga dapat melaporkan efek samping secara langsung (lihat di bawah).

Indonesia
PT Pyridam Farma, Tbk
Pharmacovigilance Team
Email: pv.safety@pyfa.co.id

Deskripsi Produk

Seperti apa produk ini?

Injeksi intramuscular XEOMIN berbentuk serbuk injeksi berwarna putih yang dikeringkan dan dimasukkan ke dalam botol gelas tertutup dengan tutup karet dan disegel dengan tutup aluminium.

XEOMIN tersedia dalam bentuk vial 50 dan 100 unit.

Komposisi

XEOMIN mengandung Clostridium Botulinum neurotoxin tipe A (150kD), bebas dari protein pengompleks sebagai zat aktif.

XEOMIN juga mengandung zat tambahan berikut :

- sukrosa
- albumin (manusia)

XEOMIN tidak mengandung laktosa, zat perekat, tartrazin, atau pewarna azo lainnya.

Kondisi Penyimpanan

Jangan disimpan diatas suhu 30ºC.

Batas Kadaluarsa

Sebelum dibuka: 3 tahun

Setelah larutan direkonstitusi: Stabilitas penggunaan secara fisik dan kimia telah ditunjukkan selama 24 jam pada suhu 2-8ºC.

Produsen Obat dan Pendaftar

XEOMIN diproduksi oleh :
Merz Pharma GmbH & Co. KGaA, Germany

XEOMIN didaftarkan oleh :
PT. Pyridam Farma
Jakarta – Indonesia

Nomor Registrasi

DKI1691300444A1

HARUS DENGAN RESEP DOKTER

Pada proses pembuatannya, bersinggungan dengan bahan bersumber babi

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