

XEOMIN

Clostridium Botulinum neurotoxin type A, free from complexing proteins

Welcome to the Patient Information Sheet

This Patient Information Sheet is a key element of the Risk Management Plan for XEOMIN to ensure an early recognition of symptoms that could indicate adverse spread reaction after injection and that require speedy medical attention.

XEOMIN is a medicine that is used to relax over-active muscles. It is prescribed by doctors for the treatment of eyelid spasm (blepharospasm), twisted neck (spasmodic torticollis), and increased muscle tension/uncontrollable muscle stiffness in arms or hands after a stroke (post-stroke spasticity of the upper limb, going along with clinical pattern of flexed wrist and clenched fist).

Like all medicines, this medicine can cause side effects, although not everybody gets them. Your doctor will talk you through the possible risks.

What side effects may occur?

Side effects may occur from misplaced injections of XEOMIN temporarily paralysing nearby muscle groups (see box). Large doses may cause paralysis in muscles distant to the injection site. Usually, side effects are observed within the first week after treatment and are temporary in nature.

In patients with **blepharospasm** the most common* possible side effects are:

- drooping eyelid, dry eyes.

In patients with **spasmodic torticollis** the most common* possible side effects are:

- swallowing difficulties, muscle weakness, back pain.

In patients with **post-stroke spasticity** of the upper limb the most common* possible side effects are:

- muscle weakness, reactions at the injection site including pain and haematoma (a localised collection of blood).

**Common = may affect up to 1 in 10 people. Less common side effects are listed in the package leaflet.*

What to do in an emergency?

If you develop swallowing difficulties, speech or breathing disorders, please contact medical emergency services immediately, or ask your relatives to do so.

A very small number of people may develop a severe reaction or allergic response to Botulinum neurotoxin.

As with any other medicine these reactions occur only rarely but it is important to know what to do in case of emergency.

If you develop hives (a raised, red rash), swelling (of the hands, feet, ankles, face, lips, mouth or throat), wheezing, difficulty in or shortness of breath, or feel faint, then this may indicate a severe allergic reaction.

Tell your doctor immediately or go to the casualty department at your nearest hospital** if you suffer from any of these symptoms.

** Services accessible by 112 from a landline or mobile telephone.

Side-effects or medication errors can be reported to

The Medicines Authority
Post-Licensing Directorate
203 Level 3, Rue D'Argens
GŻR-1368 Gżira
Website: www.medicinesauthority.gov.mt
e-mail: postlicensing.medicinesauthority@gov.mt

Alternatively they may be reported to

Merz Pharmaceuticals GmbH
Therapeutic Area Neurology (TAN)
Eckenheimer Landstraße 100
D-60318 Frankfurt am Main

If you have any questions, please contact your doctor for advice.

DOCTOR'S STAMP