# 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 Botulinum neurotoxin type A temporarily paralysing nearby muscle groups (see box). Patients who receive the recommended doses may experience excessive muscle weakness.Usually, side effects are observed within the first week after treatment and are temporary in nature.

In patients with **blepharospasm,** the following side effects were reported **very common**:

- drooping eyelid, dry eyes

In patients with **spasmodic torticollis,** the following side effects were reported **very common**:

- swallowing difficulties (dysphagia)

In patients with **post-stroke spasticity of the upper limb,** the following side effects were reported **common****:

- headache, decreased or abnormal skin sensation including partial loss of sensation or sensation of heat, muscular weakness, feeling hot, injection site pain, pain in extremity, swallowing difficulties (dysphagia)

**Very common = may affect more than 1 in 10 people. Common and less*

*common side effects are listed in the package leaflet.*

***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?**

Contact your doctor and seek medical attention immediately if you experience any of the following:

- difficulty in breathing, swallowing or speaking
- hives, swelling including swelling of the face or throat, wheezing, feeling faint and shortness of breath (possible symptoms of severe allergic reactions)

Side effects such as excessive muscle weakness or swallowing difficulties are caused by the relaxation of muscles far from the injection site of XEOMIN. Swallowing difficulties can cause inhalation of foreign bodies resulting in lung inflammation and in some cases, death.

An allergic reaction may occur with XEOMIN. Serious immediate allergic reactions or allergic reactions to the serum in the product (serum sickness), causing of example difficulty in breathing, hives (a raised, red rash) or swelling of the soft tissue , have been rarely reported.

**If you notice any of these side effects, please contact your doctor immediately or go to the accident and emergency department of your nearest hospital ** or ask your relatives to do so.**

**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