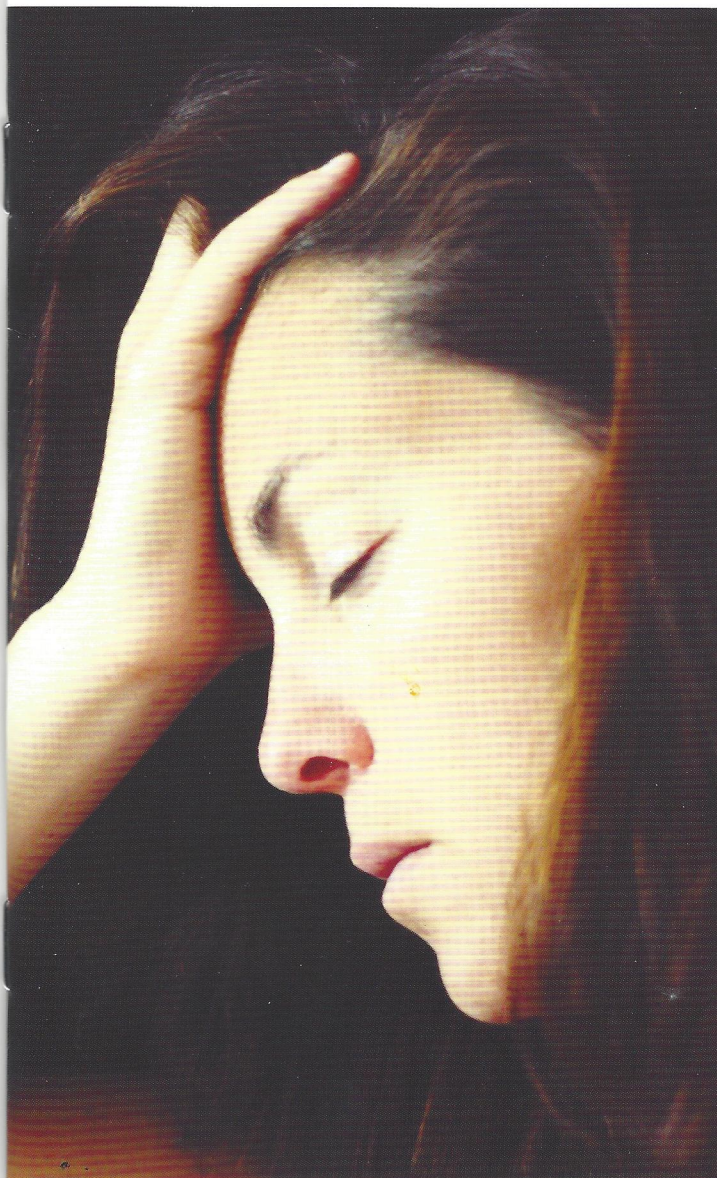


BOTOX[®]

For the Prevention of
Headaches in Adults Suffering
from **Chronic Migraine**

Who Have 15 or More Days Each Month with
Headache Lasting 4 or More Hours Each Day.¹



For more information about BOTOX[®] and
Chronic Migraine visit www.BOTOX.ca
and enter the drug identification
number (DIN) 01981501.

BOTOX[®]
onabotulinumtoxinA

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DIN 01981501

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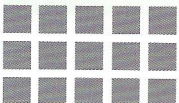
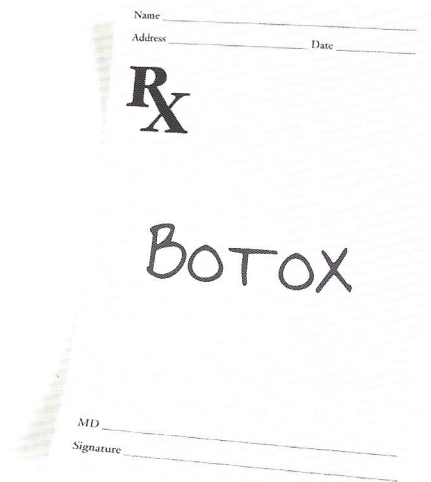
Please be sure to use the
attached **Headache Diary**
to track the frequency and
intensity of your headaches.



Introduction

As a Chronic Migraine sufferer, you likely experience headaches a number of days each month, and these headaches likely last for hours at a time.¹

Your doctor has prescribed BOTOX[®] to help prevent these headaches.²



What is Chronic Migraine?

■ Chronic Migraine is defined as:³

- Migraine with 15 or more headache days per month over the past 3 months, of which at least 8 headache days meet criteria for migraine without aura.

To meet the criteria for migraine without aura, the migraine sufferer will be experiencing two of the following symptoms:³

- The headache is on one side of the head only.
- The headache has a throbbing or pulsing quality to it.
- The headache is moderate to severe in pain intensity.
- The headache is aggravated by or causes avoidance of physical activity and is accompanied by one of the following: nausea and/or vomiting or sensitivity to light or sound.

And/or

- The migraine sufferer will have treated or relieved their headache with migraine medication prior to the expected development of the symptoms listed above.³



What is BOTOX®?

BOTOX® (onabotulinumtoxinA) is a purified neurotoxin complex protein produced from the bacterium *Clostridium botulinum*.²

BOTOX® can be used to prevent headaches in adults with Chronic Migraine who have 15 or more days each month with the headache lasting 4 or more hours each day.²

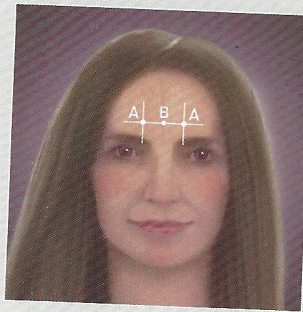
How is BOTOX® administered?

BOTOX® is injected by needle into 31 to 39 sites in 7 specific head and neck muscle areas. These areas may be contributing to your headaches. Your doctor will determine the number of injections and injection sites required to treat your specific condition.²

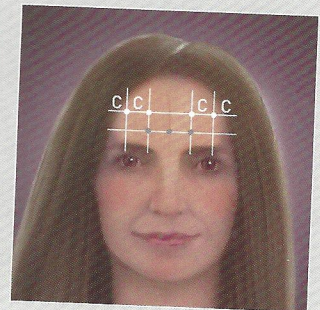
The recommended dose of BOTOX® is 155 units in 31 sites. If your doctor thinks it is necessary, he or she may decide to inject up to 40 additional units of BOTOX® into three specific muscle groups for a total maximum dose of 195 units.²



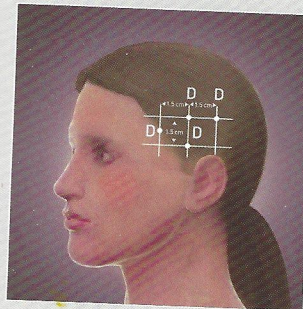
Injection Sites



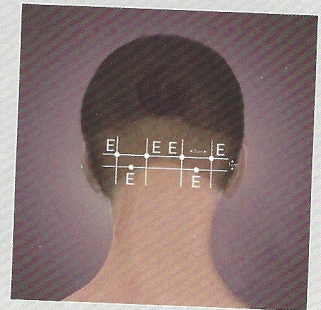
A. Corrugator
(10 Units/2 sites; 5 Units/site)¹
B. Procerus
(5 Units/1 site)¹



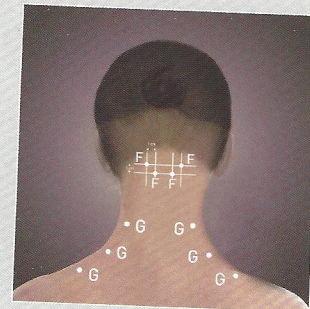
C. Frontalis
(20 Units/4 sites; 5 Units/site)¹



D. Temporalis
(40 Units/8 sites; 5 Units/site)¹



E. Occipitalis
(30 Units/6 sites; 5 Units/site)¹



F. Cervical paraspinals
(20 Units/4 sites; 5 Units/site)¹
G. Trapezius
(30 Units/6 sites; 5 Units/site)¹

Are there any side effects?

In general, the following have been reported in association with BOTOX® treatment: pain, tenderness and/or bruising at the site of injection. Malaise (generally feeling unwell) lasting up to six weeks after injection with BOTOX® has also been reported. In addition, weakness, changes in the way the heart beats (reported rarely), chest pain, skin rash or allergic reaction (symptoms: shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue, or other parts of the body, rash, itching, or hives on the skin), anaphylaxis, cardiovascular events, seizures, dysphagia, and respiratory compromise may occur in association with BOTOX®.²

The following events have been reported rarely (<0.1%) since BOTOX® has been marketed: skin rash, itching, allergic reaction, and facial paralysis. There have also been rare reports of adverse events involving the cardiovascular system, including arrhythmia and myocardial infarction, some with fatal outcomes. Some of these patients had risk factors, including cardiovascular disease.²

In patients being treated for Chronic Migraine in clinical trials, the following side effects were commonly reported: headache, facial muscle weakness, drooping of the eyelids, muscle spasm, muscle tightness, injection pain, and rash.²

What might I experience after treatment?

You may experience pain or inflammation in a muscle or muscles that have been injected with BOTOX®. You may also experience bleeding, swelling, or bruising in the area injected.²

When should BOTOX® not be used?

- BOTOX® should not be used in patients who are hypersensitive to botulinum toxin type A or to any ingredient of BOTOX®.
- BOTOX® should not be used when there is an infection in the muscles that would normally be injected.²
- BOTOX® should not be used in patients with any muscle disorders in other parts of their body, including myasthenia gravis, Eaton Lambert syndrome, or amyotrophic lateral sclerosis.²

If you have any questions regarding the use of BOTOX®, please consult your doctor. Only your doctor can determine the best course of therapy for you and your condition.

What should I talk to my doctor or pharmacist about before receiving BOTOX® injections?

Before receiving BOTOX® talk to your doctor or pharmacist if:²

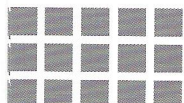
- You have myasthenia gravis, Eaton Lambert syndrome, amyotrophic lateral sclerosis or another muscle disorder.
- You are allergic or sensitive to BOTOX®.
- You have an infection at a proposed injection site.
- You are scheduled to have surgery using a general anaesthetic.
- You are taking or are likely to take antibiotics, especially aminoglycoside antibiotics.
- You are pregnant or may become pregnant while being treated. Repeated doses of BOTOX® given to rabbits during pregnancy have caused abortion or fetal malformations.
- You are nursing. It is not known whether this drug is excreted in human milk, but many drugs are excreted in human milk.

Will I receive the same number of injections and same quantity of BOTOX® each time I am treated?

Your doctor will determine the number of injections and the dose of BOTOX® you require.

Based on your condition and how you respond to treatment, your doctor may decide that changes to your treatment are required.

Use the pages that follow to track your headaches and medication use. Be sure to bring this information with you on your next appointment. This information is very useful and will help your doctor determine whether or not changes to your treatment are required.



Frequently asked questions

■ How often do I have to get BOTOX® injections?

It is recommended that you get your BOTOX® injections every 12 weeks.²



■ When can I stop getting BOTOX® injections?

Your doctor will help determine how long you will have to receive BOTOX® injections.

■ Is there anything I should tell my doctor while I'm on BOTOX®?

Tell your doctor if you experience any difficulties in swallowing food while on BOTOX®, as it could be related to the dosage. Difficulty in swallowing food, ranging from very mild to severe, can persist for 2 to 3 weeks after injection, or longer.²

For more information about BOTOX® and Chronic Migraine visit www.BOTOX.ca and enter the DIN 01981501.

■ How will I know that BOTOX® is working?

It is a good idea to keep track of your progress. To assist you in doing so, a simple to use Headache Diary can be conveniently found at the back of this booklet. Make sure to fill it out as accurately and completely as possible, every day. Be sure to bring it with you to discuss with your doctor at your next visit.

■ Can I be treated with BOTOX® for Chronic Migraine if I am receiving BOTOX® treatment already for another condition?

It is important that you let your doctor know that you are receiving BOTOX® for another condition. Your doctor will determine the appropriateness.

■ Can I receive BOTOX® injections if I am taking other medications?

Yes, you can, but it is important that you tell your doctor about the medicines you are taking, including any you have bought at your pharmacy, supermarket, or health food shop.²

■ Are there interactions with BOTOX®?

The effect of BOTOX® may be increased by certain types of antibiotics known as aminoglycoside antibiotics (e.g. streptomycin, tobramycin, neomycin, gentamicin, netilmicin, kanamycin, amikacin), spectinomycin, polymyxins, tetracyclines, lincomycin or any other drugs that interfere with neuromuscular transmission.²

Name: _____

Headache Diary

Part 1: Headache severity

Record the strength of your headache pain using an 11-point scale, where 0 = no pain and 10 = the worst pain you have experienced. Provide scores for different times of the day – morning, afternoon, and evening – to see how your headache pain changes.

Part 2: Headache duration

Record how long your headaches last: less than 4 hours, 4 to 12 hours, or 13 to 24 hours.

Part 3: Headache symptoms

Record all symptoms that accompany each headache. Choose from the list provided, or list any other symptoms in the space(s) noted "Other."

Part 4: Medication use

Record the name and dose of medication used, if any. This includes all acute and preventive medications, both over-the-counter and prescription.

Instructions:

Use this diary to track details of your headaches. You can share this information with your doctor when talking about your condition and treatment plan.



