

A guide to Chronic Migraine treatment

Your next appointment	Date:	Time:
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#### Indication

BOTOX® is a prescription medicine that is injected to prevent headaches in adults with chronic migraine who have 15 or more days each month with headache lasting 4 or more hours each day in people 18 years or older.

It is not known whether  $BOTOX^{\otimes}$  is safe or effective to prevent headaches in patients with migraine who have 14 or fewer headache days each month (episodic migraine).

#### **IMPORTANT SAFETY INFORMATION**

BOTOX® may cause serious side effects that can be life threatening. Get medical help right away if you have any of these problems any time (hours to weeks) after injection of BOTOX®:

 Problems swallowing, speaking, or breathing, due to weakening of associated muscles, can be severe and result in loss of life. You are at the highest risk if these problems are pre-existing before injection. Swallowing problems may last for several months. Spread of toxin effects. The effect of botulinum toxin may affect areas away
from the injection site and cause serious symptoms including: loss of strength
and all-over muscle weakness, double vision, blurred vision and drooping eyelids,
hoarseness or change or loss of voice, trouble saying words clearly, loss of
bladder control, trouble breathing, trouble swallowing.

There has not been a confirmed serious case of spread of toxin effect away from the injection site when BOTOX® has been used at the recommended dose to treat chronic migraine.

BOTOX® may cause loss of strength or general muscle weakness, vision problems, or dizziness within hours to weeks of taking BOTOX® If this happens, do not drive a car, operate machinery, or do other dangerous activities.

Please see additional Important Safety Information throughout

Please see additional Important Safety Information throughout the brochure.



# Important Information Before You Begin BOTOX® Treatment



# Prevent headaches before they start

Preventive treatments like BOTOX® are often an important part of a Chronic Migraine treatment plan<sup>1-3</sup>



# Your treatment journey starts with 2 treatments, 12 weeks apart

The proven way to see how well BOTOX® is working<sup>1</sup>



# **Approximately 15 minutes**

Injections don't take very long and are usually done in a normal exam room<sup>4</sup>



# Tiny needles

The actual needle size is a half-inch long and very thin<sup>1</sup>



# **Shallow injections**

They feel like tiny pinpricks and are in 7 head and neck muscle areas (31 injections total)<sup>1</sup>

# Side effects

The most common side effects in Chronic Migraine clinical studies were neck pain, headache, migraine, slight or partial facial paralysis, eyelid drooping, bronchitis, musculoskeletal stiffness, muscle weakness, pain in 1 or more muscles, ligaments, tendons, or bones, muscle spasms, injection-site pain, and high blood pressure. These occurred in 2% to 9% of patients (9% = 9 patients out of every 100 patients)<sup>1,5,6</sup>

This does not cover all the possible serious side effects of BOTOX. Please see the Summary of Information about BOTOX and talk to your doctor.

# VISIT **BOTOXChronicMigraine.com** for more information

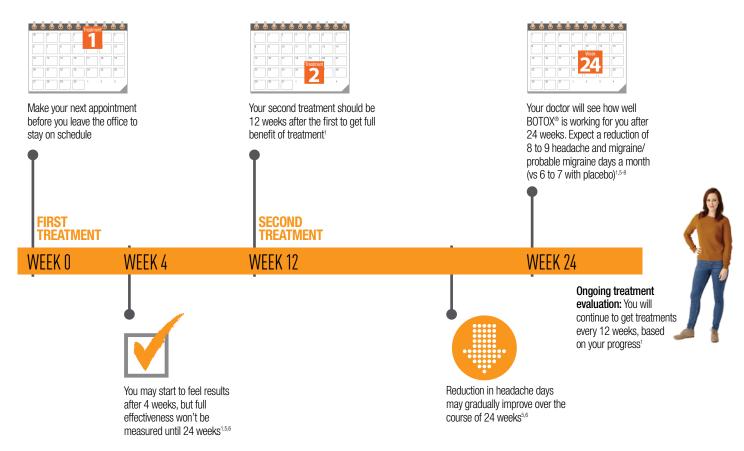
# **IMPORTANT SAFETY INFORMATION (continued)**

**Do not take BOTOX® if you:** are allergic to any of the ingredients in BOTOX® (see Medication Guide for ingredients); had an allergic reaction to any other botulinum toxin product such as *Myobloc*® (rimabotulinumtoxinB), *Dysport*®

(abobotulinumtoxinA), or *Xeomin*® (incobotulinumtoxinA); have a skin infection at the planned injection site.

The dose of  $BOTOX^{\odot}$  is not the same as, or comparable to, another botulinum toxin product.

# Important Information **After** You Begin BOTOX® Treatment





# Save year round on out-of-pocket costs with the BOTOX® Savings Card

Most insurance plans cover the majority of treatment costs, but you may be eligible for additional savings of up to \$1200 total per year, over the course of multiple treatments (see details on back cover)\*.†

# VISIT BOTOXSavingsCard.com TO GET STARTED

\*Covers out-of-pocket costs of BOTOX® and related procedures for up to 5 treatments in a 12-month period.

†Coverage and out-of-pocket costs may vary. Must be commercially insured and meet eligibility criteria to qualify.

# **IMPORTANT SAFETY INFORMATION (continued)**

**Serious and/or immediate allergic reactions have been reported.** They include itching, rash, red itchy welts, wheezing, asthma symptoms, or dizziness or feeling faint. Get medical help right away if you experience symptoms; further injection of BOTOX® should be discontinued.

**Tell your doctor about all your muscle or nerve conditions** such as ALS or Lou Gehrig's disease, myasthenia gravis, or Lambert-Eaton syndrome, as you may be at increased risk of serious side effects including difficulty swallowing and difficulty breathing from typical doses of BOTOX®.

Please see additional Important Safety Information throughout the brochure.



# WAYS TO STAY ON TRACK



Sign up for the *Pathways to Prevention* support program at **BOTOXChronicMigraine.com/Register** 



Use a headache diary to track your progress



Schedule and set a reminder for your next BOTOX® appointment



Call your doctor with any questions between treatments

# **IMPORTANT SAFETY INFORMATION (continued)**

**Tell your doctor about all your medical conditions, including if you:** have or have had bleeding problems; have plans to have surgery; had surgery on your face; weakness of forehead muscles; trouble raising your eyebrows; drooping eyelids; any other abnormal facial change; are pregnant or plan to become pregnant (it is not known if BOTOX® can harm your unborn baby); are breastfeeding or plan to (it is not known if BOTOX® passes into breast milk).

Tell your doctor about all the medicines you take, including prescription and nonprescription medicines, vitamins, and herbal products. Using BOTOX® with certain other medicines may cause serious side effects. Do not start any new medicines until you have told your doctor that you have received BOTOX® in the past.

Tell your doctor if you have received any other botulinum toxin product in the last 4 months; have received injections of botulinum toxin such as *Myobloc*, *Dysport*, or *Xeomin* in the past (tell your doctor exactly which product you received); have recently received an antibiotic by injection; take muscle relaxants; take an allergy or cold medicine; take a sleep medicine; take aspirin-like products or blood thinners.

**Other side effects of BOTOX® include:** dry mouth, discomfort or pain at the injection site, tiredness, headache, neck pain, and eye problems: double vision, blurred vision, decreased eyesight, drooping eyelids, swelling of your eyelids, and dry eyes.

For more information refer to the Medication Guide or talk with your doctor.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Please see accompanying Summary of Information about BOTOX®.

Your BOTOX® Savings Card may only be used at hospitals, physician offices, and pharmacies, and will not be accepted at any other location that normally accepts Visa® Debit cards. The BOTOX® Savings Card cannot be used at merchants outside the United States (including Internet and mail/telephone merchants).

The BOTOX® Savings Card is issued by Metropolitan Commercial Bank, member FDIC, pursuant to license by Visa U.S.A., Inc. "Metropolitan Commercial Bank" and "Metropolitan" are registered trademarks of Metropolitan Commercial Bank ©2014. See the Cardholder Agreement for Terms and Conditions. By accepting, signing, or using this savings card, you agree to the Terms and Conditions of the Cardholder Agreement. This savings card will remain the property of the issuing institution and the privilege of its use may be withdrawn at any time.

# **Terms and Conditions**

By participating, you understand and agree to comply with the Program rules as set forth below.

Your BOTOX® Savings Card provides savings on out-of-pocket costs for BOTOX® (onabotulinumtoxinA) and related procedures. The offer is valid for up to \$400 off 1 treatment received January-March 2016 and up to \$200 off per treatment for up to 4 treatments received April-December 2016. All treatments must be received within a 12-month period.

Offer is not valid for any other products or other out-of-pocket costs, even if those costs are associated with the administration of BOTOX® treatment. The BOTOX® Savings Card will be funded upon approval of a claim. The claim must be submitted with an Explanation of Benefits (EOB) or a Specialty Pharmacy Provider (SPP) receipt. (If the BOTOX® prescription was filled by a Specialty Pharmacy Provider, both an EOB and SPP receipt must be sent.)

All claims must be submitted within 90 days of the date of service listed on the EOB. BOTOX® Savings Card may not be combined with any other offer or discount. This BOTOX® Savings Card is not health insurance.

Offer not valid for patients participating in Medicare, Medicare, Medicare, Medicare, or any similar federal or state healthcare program, including any state medical or pharmaceutical assistance programs. If patients are eligible for drug benefits under any such program, they cannot use this BOTOX® Savings Card.

Offer void where prohibited by law, taxed, or restricted. Offer good only in the United States. Allergan reserves the right to rescind, revoke, and amend this offer without notice.

References: 1. BOTOX® Prescribing Information, January 2016. 2. Silberstein SD. Practice parameter: evidence-based guidelines for migraine headache (an evidence-based review): report of the Quality Standards Subcommittee of the American Academy of Neurology. Neurology. 2000;55(6):754-762. 3. Dodick DW. Chronic daily headache. N Engl J Med. 2006;354(2):158-165. 4. Rothrock JF. Botox-A for suppression of chronic migraine: commonly asked questions. Headache. 2012;52(4):716-717. 5. Data on file, Allergan; PREEMPT 1 Final Report. 6. Data on file, Allergan; PREEMPT 2 Final Report. 7. Data on file, Allergan; PREEMPT 1 Efficacy Data. 8. Data on file, Allergan; PREEMPT 2 Efficacy Data.



Summary of Information about BOTOX® (onabotulinumtoxinA)

What is the most important information I should know about BOTOX\*?

BOTOX® may cause serious side effects that can be life threatening. Call your doctor or get medical help right away if you have any of these problems any time (hours to weeks) after injection of BOTOX®:

- Problems swallowing, speaking, or breathing, due to weakening of associated muscles, can be severe and result in loss of life. You are at the highest risk if these problems are pre-existing before injection.
   Swallowing problems may last for several months.
- Spread of toxin effects. The effect of botulinum toxin may affect areas away from the injection site and cause serious symptoms including: loss of strength and all-over muscle weakness, double vision, blurred vision and drooping eyelids, hoarseness or change or loss of voice, trouble saying words clearly, loss of bladder control, trouble breathing, trouble swallowing.

There has not been a confirmed serious case of spread of toxin effect away from the injection site when BOTOX® has been used at the recommended dose to treat Chronic Migraine.

BOTOX® may cause loss of strength or general muscle weakness, vision problems, or dizziness within hours to weeks of taking BOTOX®. If this happens, do not drive a car, operate machinery, or do other dangerous activities.

BOTOX® dosing units are not the same as, or comparable to, any other botulinum toxin product.

## What is BOTOX®?

BOTOX® is prescription medicine a medical professional injects into muscles to prevent headaches in adults with Chronic Migraine who have 15 or more days each month with headache lasting 4 or more hours each day in people 18 years and older.

It is not known whether BOTOX® is safe or effective to prevent headaches in people with migraine who have 14 or fewer headache days each month (episodic migraine).

## Who should not take BOTOX®?

Do not use BOTOX® if you are: allergic to any of the ingredients in BOTOX® such as botulinum toxin type A and human serum albumin; had an allergic reaction to another botulinum toxin product such as Myobloc® (rimabotulinumtoxinB), Dysport® (abobotulinumtoxinA), or Xeomin® (incobotulinumtoxinA); or have a skin infection at the planned injection site.

### What should I tell my doctor before treatment?

Tell your doctor about all your muscle or nerve conditions, such as amyotrophic lateral sclerosis (Lou Gehrig's disease), myasthenia gravis, or Lambert-Eaton syndrome, as you may be at increased risk of serious side effects.

Tell your doctor if you have or have had breathing problems such as asthma or emphysema; swallowing problems; bleeding issues; plan to or have had surgery; have forehead muscle weakness such as trouble raising your eyebrows; drooping eyelids; or any changes to your face.

Tell your doctor if you are pregnant, plan to become pregnant, are breastfeeding or plan to breast feed. It is not known if BOTOX® (onabotulinumtoxinA) can harm your unborn baby or if BOTOX® passes into breast milk.

### What Are Common Side Effects?

The most common side effects include neck pain; headache; migraine; slight or partial facial paralysis; eyelid drooping; bronchitis; musculoskeletal stiffness; muscular weakness; pain in 1 or more muscles, ligaments, tendons, or bones; muscle spasms; injection site pain; and high blood pressure. Other side effects have been reported including allergic reactions e.g. itching, rash, red itchy welts, wheezing, asthma symptoms, or dizziness or feeling faint.

These are not all of the possible side effects. Call your doctor for medical advice if you experience any side effects after treatment with BOTOX®.

# What Should I Tell My Doctor About Medicines and Vitamins I Take?

Using BOTOX® with certain medicines may cause serious side effects. Do not start any new medicines until you have told your doctor that you have received BOTOX® in the past. Tell your doctor if you have received an injection with another botulinum toxin product in the last 4 months, such as Myobloc®, Dysport®, or Xeomin®. Be sure your doctor knows which product you received.

Tell your doctor about all prescription and overthe-counter medicines and supplements you take including: vitamins and herbal products; recent antibiotic injections; anticholinergics; muscle relaxants; allergy or cold medicine; sleep medicine; aspirin-like products; and blood thinners. Ask your doctor if you are not sure whether your medicine is listed above.

#### To Learn More

If you would like more information, talk to your doctor and/or go to BotoxChronicMigraine.com for full Product Information.

You may report side effects to the FDA at www.fda.gov/medwatch or call 1-800-FDA-1088.

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Dysport\* is a registered trademark of Ipsen Biopharm Limited Company.

Xeomin\* is a registered trademark of Merz Pharma GmbH & Co KGaA

