A guide to Chronic Migraine treatment

Your next appointment

Date:________________________ Time:________________________

#1 PRESCRIBED BRANDED TREATMENT FOR CHRONIC MIGRAINE*

WHAT TO EXPECT WITH BOTOX®

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® 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 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 the brochure.

*Truven Health MarketScan Data, October 2010-April 2017.
BOTOX® BREAKDOWN
Key info about Chronic Migraine treatment

Prevent headaches before they start
Preventive treatments like BOTOX® are an important part of a Chronic Migraine treatment plan.

Established treatment option
2 million BOTOX® treatments given to 500,000 Chronic Migraine patients since FDA approval in 2010.

Significant headache-day reduction
8 to 9 fewer headache and migraine/probable migraine days a month (vs 6 to 7 with placebo).

Side effects
- 9%: Neck pain
- 5%: Headache
- 4% each: Migraine, eyelid drooping, musculoskeletal stiffness, muscle weakness
- 3% each: Bronchitis, pain in 1 or more muscles, ligaments, tendons, or bones, injection-site pain
- 2% each: Slight or partial facial paralysis, muscle spasms, high blood pressure

This does not cover all the possible serious side effects of BOTOX®. Please see the Important Safety Information including Boxed Warning and the Summary of Information about BOTOX®.

Approximately 15 minutes
Injections don’t take very long and are usually done in a normal exam room.

Tiny needles
The actual needle size is a half-inch long and very thin.

Shallow injections
They feel like tiny pinpricks and are in 7 head and neck muscle areas (31 injections total).

2 treatments, 12 weeks apart
The proven way to see how well BOTOX® is working.

BOTOX® Treatment Journey

FIRST TREATMENT
Make your next appointment before you leave the office to stay on schedule.

INITIAL RESULTS
You may start to feel results after 4 weeks, but full effectiveness won’t be measured until 24 weeks.

SECOND TREATMENT
Your second treatment should be 12 weeks after the first to get full benefit of treatment.

EVALUATING EFFECTIVENESS
Your doctor will see how well BOTOX® is working for you after 24 weeks.

Tell your doctor about all your muscle or nerve conditions such as ALS or Lou Gehring’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 on the back cover.

IMPORTANT SAFETY INFORMATION (continued)
Do not take BOTOX® if you: are allergic to any of its ingredients (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® is not the same as, or comparable to, another botulinum toxin product.

IMPORTANT SAFETY INFORMATION (continued)
Serious and/or immediate allergic reactions have been reported, including 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 Gehring’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 on the back cover.

This does not cover all the possible serious side effects of BOTOX®. Please see the Important Safety Information including Boxed Warning and the Summary of Information about BOTOX®.
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

The BOTOX SAVINGS PROGRAM

Most insurance plans cover the cost of BOTOX® treatment. For help with any remaining out-of-pocket costs there is the BOTOXSavingsProgram.com (eligibility rules apply).

Restrictions and maximum savings limits apply. Patient out-of-pocket expense may vary. Offer not valid for patients enrolled in Medicare, Medicaid, or other federal or state healthcare programs. Please see full terms and conditions at BOTOXSavingsProgram.com.

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 medicines may cause serious side effects. Do not start any new medicines until you have told your doctor that you received BOTOX® in the past.

Tell your doctor if you 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 injection; take muscle relaxants; take allergy or cold medicines; take sleep medicine; take aspirin-like products or blood thinners.

Other side effects of BOTOX® include: dry mouth, discomfort or pain at injection site, tiredness, headache, neck pain, and eye problems: double vision, blurred vision, decreased eyesight, drooping eyelids, swelling of 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®.
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 over-the-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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Xeomin® is a registered trademark of Merz Pharma GmbH & Co KGaA