

# Use this tracker to help your doctor better understand your headaches and migraines.

The more doctors know about your headaches and migraines, the better they can decide if you have Chronic Migraine (15 or more headache days a month, each lasting 4 or more hours).

## If your doctor decides that you have Chronic Migraine:

Ask if BOTOX® treatment is right for you. BOTOX® prevents headaches and migraines before they even start:

- For adults with Chronic Migraine, <u>15 or more</u> headache days a month, each lasting
   4 or more hours. (It is not approved for 14 or fewer headache days a month.)
- Proven for Chronic Migraine for 10 years\*
- Prevents, on average, 8 to 9 headache days and migraine/probable migraine days a month (vs 6 to 7 for placebo)

\*FDA-approved, 2010.

## INDICATION

BOTOX® (onabotulinumtoxinA) is a prescription medicine that is injected into muscles and used 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 and 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 preexisting 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;
  drooping eyelids; hoarseness or change or loss of voice; trouble saying
  words clearly; loss of bladder control; trouble breathing; and trouble
  swallowing.

Please see additional Important Safety Information throughout.

Please see accompanying or click here for Consumer Brief Summary, including Boxed Warning, or visit <a href="https://www.rxabbvie.com/pdf/botox\_pi.pdf">https://www.rxabbvie.com/pdf/botox\_pi.pdf</a> pdf for full Prescribing Information.

# TIPS FOR TRACKING YOUR HEADACHES AND MIGRAINES



## Do it for one month

Give your doctor a full 30-day picture of your headaches, and how they affect you.



## Record every day that you're headache and migraine free

Your doctor needs to know how many days a month you're free from headache.



## Track them as they happen

It's easiest to remember how a headache felt and how it affected you if you record it right away.



## Note their impact on your life

Specify if your headaches affect you at work, doing everyday things, and your relationships with family and friends.



## List on the tracker any medicines you took

Whether it is prescription, over-the-counter, or an herbal treatment, your doctor needs to know what you are taking.

## **IMPORTANT SAFETY INFORMATION (continued)**

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 receiving BOTOX. If this happens, do not drive a car, operate machinery, or do other dangerous activities.



# MY MONTHLY HEADACHE AND MIGRAINE TRACKER:

(Month)

Please put a check mark ( 🗸 ) in the boxes below to show the days when you had a headache and how it affected you. List any medicines you took for it.

	Did I have	Did my headache impact:				
Day	a headache today?	Daily activities?	Work?	Friends/ family?	Other?	Medicine(s) taken:
1	☐ Yes ☐ No					
2	□ Yes □ No	•				
3	☐ Yes ☐ No	1				
4	☐ Yes ☐ No	1				
5	☐ Yes ☐ No	1				
6	☐ Yes ☐ No	1				
7	☐ Yes ☐ No					
8	☐ Yes ☐ No	1				
9	☐ Yes ☐ No					
10	□ Yes □ No					
11	☐ Yes ☐ No	1				
12	□ Yes □ No					
13	☐ Yes ☐ No					
14	☐ Yes ☐ No					
15	☐ Yes ☐ No	1				
16	☐ Yes ☐ No					
17	☐ Yes ☐ No	1				
18	☐ Yes ☐ No					
19	☐ Yes ☐ No					
20	☐ Yes ☐ No	1				
21	☐ Yes ☐ No	1				
22	☐ Yes ☐ No	1				
23	☐ Yes ☐ No					
24	☐ Yes ☐ No					
25	☐ Yes ☐ No					
26	☐ Yes ☐ No					
27	☐ Yes ☐ No					
28	☐ Yes ☐ No					
29	☐ Yes ☐ No					
30	☐ Yes ☐ No					
31	☐ Yes ☐ No					

Are you satisfied with the current medicines you're taking? ☐ Yes ☐ No When you've completed this tracker page, share it with your doctor.



# BOTOX® (onabotulinumtoxinA) IMPORTANT INFORMATION INDICATION

BOTOX® (onabotulinumtoxinA) is a prescription medicine that is injected into muscles and used 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 and 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 preexisting 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;
  drooping eyelids; hoarseness or change or loss of voice; trouble saying
  words clearly; loss of bladder control; trouble breathing; and 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 receiving BOTOX. If this happens, do not drive a car, operate machinery, or do other dangerous activities.

**Do not receive 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 is not the same as, or comparable to, another botulinum toxin product.

**Serious and/or immediate allergic reactions have been reported,** including itching; rash; red, itchy welts; wheezing; asthma symptoms; 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.

**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; have weakness of forehead muscles, trouble raising your eyebrows, drooping eyelids, and 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 over-the-counter medicines, vitamins, and herbal supplements. 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 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; eye problems such as double vision, blurred vision, decreased eyesight, drooping eyelids, swelling of your eyelids, and dry eyes; drooping eyebrows; and upper respiratory tract infection.

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 <a href="https://www.fda.gov/medwatch">www.fda.gov/medwatch</a> or call 1-800-FDA-1088.

Please see accompanying or click here for BOTOX® <u>Consumer Brief</u>
<u>Summary</u>, including Boxed Warning, or visit <a href="https://www.rxabbvie.com/pdf/botox\_pi.pdf">https://www.rxabbvie.com/pdf/botox\_pi.pdf</a> for full Prescribing Information.

If you are having difficulty paying for your medicine, AbbVie may be able to help. Visit AbbVie.com/myAbbVieAssist to learn more.

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# BOTOX® (onabotulinumtoxinA) for injection, for intramuscular, intradetrusor, or intradermal use

#### **CONSUMER BRIEF SUMMARY**

Consult Package Insert for full Prescribing Information

## **Patient Information**

This summary contains important risk information about **BOTOX**. This brief summary is not comprehensive and does not take the place of talking with your healthcare provider about your medical condition or treatment. To learn more, talk to your healthcare provider or pharmacist. For a copy of the full Prescribing Information, visit www.BOTOX.com or call 1-800-678-1605.

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

BOTOX may cause serious side effects that can be life threatening, including:

- . Problems breathing or swallowing
- . Spread of toxin effects

These problems can happen hours, days, to weeks after an injection of BOTOX. Call your doctor or get medical help right away if you have any of these problems after treatment with BOTOX:

- Problems swallowing, speaking, or breathing. These problems can happen hours, days, to weeks after an injection of BOTOX usually because the muscles that you use to breathe and swallow can become weak after the injection. Death can happen as a complication if you have severe problems with swallowing or breathing after treatment with BOTOX.
  - People with certain breathing problems may need to use muscles in their neck to help them breathe. These people may be at greater risk for serious breathing problems with BOTOX.
  - Swallowing problems may last for several months. People who cannot swallow well may need a feeding tube to receive food and water. If swallowing problems are severe, food or liquids may go into your lungs. People who already have swallowing or breathing problems before receiving BOTOX have the highest risk of getting these problems.
- Spread of toxin effects. In some cases, the effect of botulinum toxin may affect areas of the body away from the injection site and cause symptoms of a serious condition called botulism. The symptoms of botulism include:
  - loss of strength and muscle weakness all over the body
  - double vision, blurred vision and drooping eyelids
  - hoarseness or change or loss of voice (dysphonia)
  - o trouble saying words clearly (dysarthria)
  - o loss of bladder control
  - o trouble breathing
  - o trouble swallowing

These symptoms can happen hours, days, to weeks after you receive an injection of **BOTOX**.

These problems could make it unsafe for you to drive a car or do other dangerous activities. See "What should I avoid while receiving BOTOX?"

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, severe underarm sweating, blepharospasm, or strabismus.

#### What is BOTOX?

**BOTOX** is a prescription medicine that is injected into muscles and used:

- to treat overactive bladder symptoms such as a strong need to urinate with leaking or wetting accidents (urge urinary incontinence), a strong need to urinate right away (urgency), and urinating often (frequency) in adults when another type of medicine (anticholinergic) does not work well enough or cannot be taken.
- to treat leakage of urine (incontinence) in adults with overactive bladder due to neurologic disease when another type of medicine (anticholinergic) does not work well enough or cannot be taken.
- to treat overactive bladder due to a neurologic disease in children 5 years of age and older when another type of medicine (anticholinergic) does not work well enough or cannot be taken.
- 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.
- to treat increased muscle stiffness in people 2 years of age and older with spasticity.
- to treat the abnormal head position and neck pain that happens with cervical dystonia (CD) in adults.
- to treat certain types of eye muscle problems (strabismus) or abnormal spasm of the eyelids (blepharospasm) in people 12 years of age and older.

**BOTOX** is also injected into the skin to treat the symptoms of severe underarm sweating (severe primary axillary hyperhidrosis) when medicines used on the skin (topical) do not work well enough.

It is not known whether **BOTOX** is safe and effective in people younger than:

- 18 years of age for treatment of urinary incontinence
- 18 years of age for treatment of chronic migraine
- 16 years of age for treatment of cervical dystonia
- 18 years of age for treatment of hyperhidrosis
- 12 years of age for treatment of strabismus or blepharospasm
- · 2 years of age for treatment of spasticity

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

It is not known whether **BOTOX** is safe and effective for severe sweating anywhere other than your armpits.

#### Who should not receive BOTOX?

Do not receive **BOTOX** if you:

- are allergic to any of the ingredients in BOTOX. See the end of this Consumer Brief Summary for a complete list of ingredients in BOTOX.
- had an allergic reaction to any other botulinum toxin product such as Myobloc®, Dysport®, or Xeomin®.
- have a skin infection at the planned injection site.
- are being treated for urinary incontinence and have a urinary tract infection (UTI).
- are being treated for urinary incontinence and find that you cannot empty your bladder on your own (only applies to people who are not routinely catheterizing).

# What should I tell my doctor before receiving BOTOX?

# Tell your doctor about all your medical conditions, including if you:

- have a disease that affects your muscles and nerves (such as amyotrophic lateral sclerosis [ALS or Lou Gehrig's disease], myasthenia gravis, or Lambert-Eaton syndrome). See "What is the most important information I should know about BOTOX?"
- · have allergies to any botulinum toxin product.
- had any side effect from any botulinum toxin product in the past.
- have or have had a breathing problem, such as asthma or emphysema.
- have or have had swallowing problems.
- · have or have had bleeding problems.
- · have plans to have surgery.
- · had surgery on your face.
- have weakness of your forehead muscles, such as trouble raising your eyebrows.
- have drooping eyelids.
- have any other change in the way your face normally looks.
- have symptoms of a urinary tract infection (UTI) and are being treated for urinary incontinence.
   Symptoms of a urinary tract infection may include pain or burning with urination, frequent urination, or fever.
- have problems emptying your bladder on your own and are being treated for urinary incontinence.
- are pregnant or plan to become pregnant.
   It is not known if BOTOX can harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if BOTOX passes into breast milk.

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins and herbal supplements. 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.

#### Especially tell your doctor if you:

- have received any other botulinum toxin product in the last four months.
- have received injections of botulinum toxin, such as Myobloc® (rimabotulinumtoxinB), Dysport® (abobotulinumtoxinA), or Xeomin® (incobotulinumtoxinA) in the past. Be sure your doctor knows 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 anti-platelets (aspirin-like products) or anti-coagulants (blood thinners).

## Ask your doctor if you are not sure if your medicine is one that is listed above.

Know the medicines you take. Keep a list of your medicines with you to show your doctor and pharmacist each time you get a new medicine.

#### **How will I receive BOTOX?**

- BOTOX is an injection that your doctor will give you.
- BOTOX is injected into your affected muscles, skin, or bladder.
- Your doctor may change your dose of BOTOX, until you and your doctor find the best dose for you.
- Your doctor will tell you how often you will receive your dose of BOTOX injections.

### What should I avoid while receiving BOTOX?

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. See "What is the most important information I should know about BOTOX?"

#### What are the possible side effects of BOTOX?

BOTOX can cause serious side effects. See "What is the most important information I should know about BOTOX?"

### Other side effects of BOTOX include:

- · dry mouth.
- discomfort or pain at the injection site.
- tiredness.
- · headache.
- neck pain.
- eye problems: double vision, blurred vision, decreased eyesight, drooping eyelids, swelling of your eyelids, and dry eyes.
- drooping eyebrows.
- urinary tract infection in both children and adults being treated for urinary incontinence.

- painful urination in adults being treated for urinary incontinence.
- bacteria in the urine of children being treated for urinary incontinence.
- inability to empty your bladder on your own and are being treated for urinary incontinence. If you have difficulty fully emptying your bladder after getting BOTOX, you may need to use disposable self-catheters to empty your bladder up to a few times each day until your bladder is able to start emptying again.
- allergic reactions. Symptoms of an allergic reaction to BOTOX may include: itching, rash, red itchy welts, wheezing, asthma symptoms, or dizziness or feeling faint. Tell your doctor or get medical help right away if you are wheezing or have asthma symptoms, or if you become dizzy or faint.
- upper respiratory tract infection.

Tell your doctor if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of **BOTOX**. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

## General information about the safe and effective use of BOTOX:

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. This Consumer Brief Summary summarizes the most important information about **BOTOX**. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about **BOTOX** that is written for health professionals.

## What are the ingredients in BOTOX?

Active ingredient: onabotulinumtoxinA Inactive ingredients: human albumin and sodium chloride

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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.

If you are having difficulty paying for your medicine, AbbVie may be able to help. Visit AbbVie.com/myAbbVieAssist to learn more.

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LAB-7920

