



### PREVENT HEADACHES AND MIGRAINES BEFORE THEY EVEN START

BOTOX® prevents on average 8 to 9 headache days and migraine/probable migraine days a month (vs 6 to 7 for placebo)<sup>1-5</sup>

For adults with Chronic Migraine, 15 or more headache days a month, each lasting 4 hours or more. BOTOX<sup>®</sup> is not approved for adults with migraine who have 14 or fewer headache days a month.

#### Indication

BOTOX<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup>:

- 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  $BOTOX^{\otimes}$  has been used at the recommended dose to treat chronic migraine.

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



Think You Have Chronic Migraine? You Are Not Alone



U.S. adults are living with Chronic Migraine<sup>6,7</sup>

> did not receive a Chronic Migraine diagnosis<sup>83,\*</sup>

\*Based on a study of 200 Chronic Migraine patients who had sought evaluation from a Headache Specialist.

#### **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  $^{\scriptscriptstyle \otimes}$  is not the same as, or comparable to, another botulinum toxin product.

### Chronic Migraine Is a Severe Subtype of Migraine<sup>®</sup>

You may start with a different headache condition that gets worse until it becomes Chronic Migraine<sup>11</sup>

### Episodic Migraine<sup>12</sup>

Fewer than 15 headache days per month

Headaches don't last as long

Pain is often less severe

### Chronic Migraine<sup>12</sup>

15 or more headache days per month

Headaches last longer

Pain is often more severe

### Chronic Migraine can be very disabling and difficult for you and the people you know<sup>13,14</sup>



#### **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<sup>®</sup> should be discontinued.



### Finding Out if You're One of the Millions Living With Undiagnosed Chronic Migraine<sup>8,9</sup>

15+ headache days a month<sup>10,15</sup>

of those days are associated with migraine<sup>10,15</sup>

hours of headache per headache day<sup>10,15</sup>





### Make Sure You **Count All Headache Days** to See if You Have Chronic Migraine

Both headaches and migraines count toward your monthly headache day total



Think about days when you had no headache, which may be easier to remember



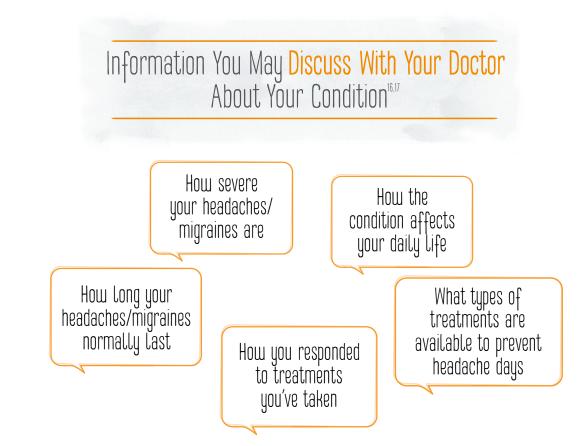
Count any day you took a medicine to treat headache symptoms



Keep track with a headache diary, then bring it to every appointment

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

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  $\mathsf{BOTOX}^\circledast$ 



A Chronic Migraine diagnosis may change the course of your treatment plan



### Talk to your doctor to find out more about Chronic Migraine



#### **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<sup>®</sup> can harm your unborn baby); are breastfeeding or plan to (it is not known if BOTOX<sup>®</sup> passes into breast milk).



### Prevention Is One of 2 Common Ways to Attack Chronic Migraine

### Acute Treatments<sup>16,17</sup>

Taken *after* headache/migraine pain has started to *reduce symptoms* 

### Preventive Treatments<sup>16,17</sup>

Taken on a *schedule* to prevent headaches/migraines *before they start* 

# A Chronic Migraine management plan may include acute and preventive treatment<sup>16,18</sup>



#### Talk to your doctor to find the treatment plan that's right for you

**IMPORTANT SAFETY INFORMATION (continued)** 

Tell your doctor about all the medicines you take, including prescription and nonprescription medicines, vitamins, and herbal products. Using BOTOX<sup>®</sup> 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  $\text{BOTOX}^{\otimes}$  in the past.

Because Chronic Migraine Is So Severe, GuideLines\* **Recommend Use of Preventive Treatments**<sup>116</sup>



### BOTOX<sup>®</sup> Prevents Headaches and Migraines Before They Even Start

BOTOX<sup>®</sup> prevents on average 8 to 9 headache days and migraine/probable migraine days a month (vs 6 to 7 for placebo)<sup>1-5</sup>



\*American Academy of Neurology guidelines.

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

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*<sup>®</sup>, *Dysport*<sup>®</sup>, or *Xeomin*<sup>®</sup> 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.



# BOTOX<sup>®</sup> Is the Only **FDA-Approved** Preventive Treatment for Chronic Migraine'



### The Path to FDA Approval'

Studied in large clinical trials of people with Chronic Migraine



Met FDA requirements for safety and effectiveness in these Chronic Migraine trials



FDA approved in 2010

IMPORTANT SAFETY INFORMATION (continued) 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.

### An **Established Option** for People With Chronic Migraine



People with Chronic Migraine have been treated with BOTOX<sup>®</sup> since its FDA approval in 2010<sup>1,19,\*</sup>



\*Results may vary. Based on IMS Health Pharmetrics Plus data.

**IMPORTANT SAFETY INFORMATION (continued)** 

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®



### BOTOX<sup>®</sup> Prevents Headaches and Migraines Before They Even Start



#### headache days and migraine/ probable migraine days a month

(vs 6 to 7 with placebo) after 2 treatments (at 24 weeks).<sup>1-5</sup>

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

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.



Talk to your doctor about what to expect with BOTOX° treatment and when to expect results



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

 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<sup>®</sup> has been used at the recommended dose to treat chronic migraine.



### Most Insurance Plans Cover the Majority of the Cost of BOTOX® Treatment<sup>20,21</sup>

Plus, the BOTOX<sup>®</sup> Savings Card can help with possible out-of-pocket costs<sup>\*</sup>

More savings when you need it most

Up to \$

savings on out-of-pocket costs for 1 treatment<sup>+,‡</sup> **JANUARY-MARCH** 

#### Your total savings per calendar year can add up to \$1200.

Treatment must be at least 12 weeks apart.

After you may have met your deductible

Up to S savings on out-of-pocket costs per treatment (up to 4 treatments)<sup>†,‡</sup>

APRIL-DECEMBER

82% of commercially insured patients pay nothing with the **BOTOX® Savings Card**<sup>21.§</sup>

\*Some insurance plans require you to have tried 2 or more other preventive treatments before covering BOTOX®

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.

<sup>§</sup>Based on data pulled from January to December 2014 (n = 29,388).





### Talk to your doctor about the BOTOX° Savings Card or visit **BOTOXSavingsCard.com** to get started

#### IMPORTANT SAFETY INFORMATION (continued)

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.

Do not take BOTOX<sup>®</sup> if you: are allergic to any of the ingredients in BOTOX<sup>®</sup> (see

Medication Guide for ingredients); had an allergic reaction to any other botulinum toxin product such as *Myobloc*<sup>®</sup> (rimabotulinumtoxinB), *Dysport*<sup>®</sup> (abobotulinumtoxinA), or Xeomin<sup>®</sup> (incobotulinumtoxinA); have a skin infection at the planned injection site.

The dose of BOTOX<sup>®</sup> is not the same as, or comparable to, another botulinum toxin product.

#### Indication

BOTOX<sup>®</sup> (onabotulinumtoxinA) 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup>:

- **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 $^{\odot}$  has been used at the recommended dose to treat chronic migraine.

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

Please see additional Important Safety Information about BOTOX® inside.



Fill out and mail the attached form to get emailed treatment reminders, patient stories, and more! POSTAGE WILL BE PAID BY ADDRESSEE





GET SUPPORT FROM <i>PATHWAYS TO PREVENTION</i> AS YOU CONTINUE YOUR JOURNEY Updates, treatment reminders, real Chronic Migraine patient stories, and more are available to keep you inspired and help you and your doctor stay on top of your condition. Sign up today!
DATE OF BIRTH (You must be at least 18 years of age.)
EMAIL
PHYSICIAN What type of physician are you seeing to manage your Chronic Migraine? Primary Care Physician Neurologist Headache Specialist Other None
bes your BOTOX $^{\scriptscriptstyle (\! 8\!)}$ (onabotulinumtoxinA) experience?
I am not currently using BOTOX <sup>®</sup> , but am interested in learning more I am planning to receive my first BOTOX <sup>®</sup> treatment I have received only 1 BOTOX <sup>®</sup> treatment I have received 2 or more BOTOX <sup>®</sup> treatments
If you are currently taking BOTOX* tell us about your BOTOX* treatments:
I first began BOTOX <sup>®</sup> My next BOTOX <sup>®</sup> My next BOTOX <sup>®</sup> treatment on: M M Construction My next BOTOX <sup>®</sup> My next BOTOX <sup>®</sup> My next BOTOX <sup>®</sup> Treatment on: M M M MM MM MAXENT Construction and provide the structure of the structure
By filling out and mailing this card, I agree to receive information from Allergan related to education on headache disorders like Chronic Migraine, as well as other Allergan products and services. I understand I can opt out at any time. APC45IB16 [B16AD4] Please see Important Safety Information including Boxed Warning throughout this card.

#### IMPORTANT SAFETY INFORMATION (continued)

Do not take BOTOX<sup>®</sup> (onabotulinumtoxinA) if you: are allergic to any of the ingredients in BOTOX<sup>®</sup> (see Medication Guide for ingredients); had an allergic reaction to any other botulinum toxin product such as *Myobloc*<sup>®</sup> (rimabotulinumtoxinB), *Dysport*<sup>®</sup> (abobotulinumtoxinA), or Xeomin® (incobotulinumtoxinA); have a skin infection at the planned injection site.

The dose of BOTOX<sup>®</sup> is not the same as, or comparable to, another botulinum toxin product.

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®.

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 evebrows; drooping evelids; 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<sup>®</sup> passes into breast milk).

Please see additional Important Safety Information on the following pages.

#### IMPORTANT SAFETY INFORMATION (continued)

Tell your doctor about all the medicines you take, including prescription and nonprescription medicines, vitamins, and herbal products. Using BOTOX® (onabotulinumtoxinA) 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<sup>®</sup> 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.

#### Please see accompanying Summary of Information about BOTOX®



Other side effects of BOTOX® include: dry mouth, discomfort or pain at the injection site, tiredness, headache, neck pain, and eve 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.

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<sup>®</sup> 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<sup>®</sup> Savings Card may not be combined with any other offer or discount. This BOTOX<sup>®</sup> Savings Card is not health insurance.

Offer not valid for patients participating in Medicare, Medicaid, 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.



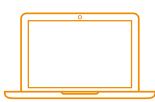
#### **IMPORTANT SAFETY INFORMATION (continued)**

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<sup>®</sup> 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<sup>®</sup>.



## **Resources** Available for You



Visit **BOTOXChronicMigraine.com** to further your education about Chronic Migraine and BOTOX<sup>®</sup> treatment



Sign up for appointment reminders, information about managing Chronic Migraine, and healthy living tips at BOTOXChronicMigraine.com/Register



Start a headache diary to measure the frequency, severity, and impact of your headaches. Then bring the diary to every appointment to track your progress. Be sure to ask your doctor for a headache diary today

#### **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 $^{\circ}$  can harm your unborn baby); are breastfeeding or plan to (it is not known if BOTOX $^{\circ}$  passes into breast milk).

Tell your doctor about all the medicines you take, including prescription and nonprescription medicines, vitamins, and herbal products. Using BOTOX<sup>®</sup> with certain other medicines may cause serious side effects. Do not start any new medicines

Now That You've Learned More About BOTOX<sup>®</sup> What's Your **Next Step?** 

Get prepared to discuss Chronic Migraine and BOTOX® with your doctor. Here are some important topics to think about





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

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*, *Dysport* 

or *Xeomin*<sup>®</sup> 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.



### 100,000 People Have Used BOTOX° for Chronic Migraine. Talk to Your Doctor to See if You're Next



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

**Other side effects of BOTOX**<sup>®</sup> **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.

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<sup>®</sup>.

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

References: 1. BOTOX® Prescribing Information, January 2016. 2. Data on file, Allergan; PREEMPT 1 Final Report. 3. Data on file, Allergan; PREEMPT 2 Final Report. 4. Data on file, Allergan; PREEMPT 1 Efficacy Data. 5. Data on file, Allergan; PREEMPT 2 Final Report. 4. Data on file, Allergan; PREEMPT 1 Efficacy Data. 5. Data on file, Allergan; PREEMPT 2 Final Report. 4. Data on file, Allergan; PREEMPT 1 Efficacy Data. 5. Data on file, Allergan; PREEMPT 2 Final Report. 4. Data on file, Allergan; PREEMPT 1 Efficacy Data. 5. Data on file, Allergan; PREEMPT 2 Efficacy Data. 5. Centers for Disease Control and Prevention. Census projections request. CDC WONDER website. http://wonder.cdc.gov/population-projections.html. Accessed March 30, 2016. 7. Natoli JL, Manack A, Dean B, et al. Global prevention: migraine: a systematic review. *Cephalalgia*. 2010;30(5):599-609. 8. Lipton RB, Serrano D, Buse DC, et al. Improving the detection of chronic migraine: development and validation of Headache Disorders, 3rd edition (beta version). *Cephalalgia*. 2013;33(9):629-808. 11. Bigal ME, Lipton RB. Cncepts and mechanisms of migraine chronification. *Headache*. 2008;44(1):7-15. T2. Blummefield AM, Yaron SF, Wilkox TK, et al. Disability. HNOOL and resource use among chronic and episodic migraineus: results from the International Burden of Migraine Study (BMS). *Cephalalgia*. 2011;31(3):310-315. 13. Adams AM, Serrano D, Buse DC, et al. The impact of chronic migraine: The Chronic Migraine Ejdemiology and Outcomes (CaMEO) Study methods and baseline results. *Cephalalgia*. 2015;35(7):563-578. 14. Bigal ME, Rapoport AM, Lipton RB, Fepper SJ, Sheffell FD. Assessment of migraine disability assessment (MIDAS) questionnaire: a comparison of chronic migraine with episodic migraine. *Headache*. 2003;43(4):336-342. 15. Lipton RB, Fepper SJ, Sheffell FD. Assessment of migraine backache. 2003;42(4):326-342. 15. Upton RB, Teoport AM, Lipton RB, Coadsby PJ. Migraine: diagnosis and treatments and environe-based quidelines for migraine backache and e

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Summary of Information about BOTOX<sup>®</sup> (onabotulinumtoxinA)

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

BOTOX<sup>®</sup> 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<sup>®</sup>:

- 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<sup>®</sup> may cause loss of strength or general muscle weakness, vision problems, or dizziness within hours to weeks of taking BOTOX<sup>®</sup>. 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> if you are: allergic to any of the ingredients in BOTOX<sup>®</sup> such as botulinum toxin type A and human serum albumin; had an allergic reaction to another botulinum toxin product such as Myobloc<sup>®</sup> (rimabotulinumtoxinB), Dysport<sup>®</sup> (abobotulinumtoxinA), or Xeomin<sup>®</sup> (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<sup>®</sup> (onabotulinumtoxinA) can harm your unborn baby or if BOTOX<sup>®</sup> 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<sup>®</sup>.

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

Using BOTOX<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup>, Dysport<sup>®</sup>, or Xeomin<sup>®</sup>. 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.

Based on 72511US15 Rev. 01/2016

#### APC05FR16

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