What to do when BOTULISM poisoning is suspected.

A. Notify prescribing doctor, nurse practitioner, aesthetic injector etc. what has happened, include a written account of your adverse side effects and when they started. *This should be done in BOTH verbal and written form. When you send in your written account you will include specific information, see *C
B. Request that they immediately provide you with written documentation (they must email you that day) the product that was injected, its batch and lot number, the number of units received/where, and any paperwork (consent form) that you signed.
C. Send the prescribing injector a copy of the black box warning label, which clearly states that botulism can occur. Tell them that they must file a report with your country's regulating body on your behalf, and that you WILL be doing the same. For example, in the UK a report will be filed with the MHRA, and in the U.S. it will be filed with the FDA, there is a self-reporting form. *Find your country below.

   In addition, mention to your prescribing doctor that the botulinum toxin A product you received states a protocol for such reaction (when botulism poisoning is suspected and notifying the local health department, and CDC is not negotiable.) Technically, it is their job to connect your adverse symptoms to those of botulism, but as we know this rarely happens.

   *Your injector may state that you were *not* overdosed, THIS DOES NOT MATTER. There are court cases proving botulism with typical cosmetic doses, in addition to support groups everywhere with thousands of people suffering. It is your duty to demand that they report anyway, (and they will need to provide you proof it has been done,) or you will also file a claim against them for not reporting. See your product's information below.

10 OVERDOSAGE Excessive doses of DAXXIFY may be expected to produce neuromuscular weakness with a variety of symptoms. Respiratory support may be required where excessive doses cause paralysis of the respiratory muscles. In the event of overdose, the patient should be medically monitored for symptoms or excessive muscle weakness or muscle paralysis. [see Warnings and Precautions (5.6), (5.7)] Symptomatic treatment may be necessary. Symptoms of overdose are not likely to be present immediately following injection. Should accidental injection or oral ingestion occur, the person should be medically supervised for several weeks for signs and symptoms of excessive muscle weakness or paralysis. In the event of overdose, antitoxin raised against botulinum toxin is available from the Centers for Disease Control and Prevention (CDC) in Atlanta, GA. However, the antitoxin will not reverse any botulinum toxin induced effects already apparent by the time of antitoxin administration. In the event of suspected or actual cases of botulinum toxin poisoning, please contact your local or state Health Department to process a request for antitoxin through the CDC. If you do not receive a response within 30 minutes, please contact the CDC directly at 1-770-488-7100. (Daxxify Label)

10 OVERDOSAGE There is no information regarding overdose from clinical studies of JEUVEAU. Excessive doses of JEUVEAU (prabotulinumtoxinAxvfs) Injection may be expected to produce neuromuscular weakness with a variety of symptoms. Symptoms of overdose are likely not to be present immediately following injection. Should accidental injection or oral ingestion occur, or overdose be suspected, these patients should be considered for further medical evaluation and appropriate medical therapy immediately instituted, which may include hospitalization. The person should be medically supervised for several weeks for signs and symptoms of systemic muscular weakness which could be local, or distant from the site of injection [see Boxed Warning and Warnings and Precautions (5.1)]. If the musculature of the oropharynx and esophagus are affected, aspiration may occur which may lead to development of aspiration pneumonia.

If the respiratory muscles become paralyzed or sufficiently weakened, intubation and assisted respiration may be necessary until recovery takes place. Supportive care could involve the need for a tracheostomy and/or prolonged mechanical ventilation, in addition to other general supportive care. In the event of overdose, antitoxin raised against botulinum toxin is available from the Centers for Disease Control and Prevention (CDC) in Atlanta, GA. However, the antitoxin will not reverse any botulinum toxin-induced effects already apparent by the time of antitoxin administration. In the event of suspected or actual cases of botulinum toxin poisoning, please contact your local or state Health Department to process a request for antitoxin through the CDC. If you do not receive a response within 30 minutes, please contact the CDC directly at 1-770-488-7100. More information can be obtained at http://www.cdc.gov/ncidod/srp/drugs/formulary.html#1a.

10 OVERDOSAGE Excessive doses of DYSPORT may be expected to produce neuromuscular weakness with a variety of symptoms. Respiratory support may be required where excessive doses cause paralysis of respiratory muscles. In the event of overdose, the patient should be medically monitored for symptoms of excessive muscle weakness or muscle paralysis [see Boxed Warning and Warnings and Precautions (5.2)]. Symptomatic treatment may be necessary. Symptoms of overdose are likely not to be present immediately following injection. Should accidental injection or oral ingestion occur, the person should be medically supervised for several weeks for signs and symptoms of excessive muscle weakness or paralysis. There is no significant information regarding overdose from clinical studies. In the event of overdose, antitoxin raised against botulinum toxin is available from the Centers for Disease Control and Prevention (CDC) in Atlanta, GA. However, the antitoxin will not reverse any botulinum toxin-induced effects already apparent by the time of antitoxin administration. In the event of suspected or actual cases of botulinum toxin poisoning, please contact your local or state Health Department to process a request for antitoxin through the CDC.

If you do not receive a response within 30 minutes, please contact the CDC directly at 770-488-7100. More information can be obtained at https://www.cdc.gov/laboratory/drugservice/index.html.

10 OVERDOSAGE Excessive doses of BOTOX Cosmetic (onabotulinumtoxinA) for injection may be expected to produce neuromuscular weakness with a variety of symptoms. Symptoms of overdose are likely not to be present immediately following injection. Should accidental injection or oral ingestion occur or overdose be suspected, these patients should be considered for further medical evaluation and appropriate medical therapy immediately instituted, which may include hospitalization. The person should be medically supervised for several weeks for signs and symptoms of systemic muscular weakness which could be local, or distant from the site of injection [see Boxed Warning and Warnings and Precautions (5.2, 5.7)]. If the musculature of the oropharynx and esophagus are affected, aspiration may occur which may lead to development of aspiration pneumonia. If the respiratory muscles become paralyzed or sufficiently weakened, intubation and assisted respiration may be necessary until recovery takes place. Supportive care could involve the need for a tracheostomy and/or prolonged mechanical ventilation, in addition to other general supportive care. In the event of overdose, antitoxin raised against botulinum toxin is available from the Centers for Disease Control and Prevention (CDC) in Atlanta, GA. However, the antitoxin will not reverse any botulinum toxin-induced effects already apparent by the time of antitoxin administration. In the event of suspected or actual cases of botulinum toxin poisoning, please contact your local or state Health Department to process a request for antitoxin through the CDC. If you do not receive a response within 30 minutes, please contact the CDC directly at 1-770-488-7100. More information can be obtained at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5232a8.htm.

10 OVERDOSAGE Excessive doses of XEOMIN may be expected to produce neuromuscular weakness with a variety of symptoms, particularly when treated intramuscularly. Respiratory support may be required where excessive doses cause paralysis of the respiratory muscles. In the event of overdose, the patient should be medically monitored for symptoms of excessive muscle weakness or muscle paralysis [see Warnings and Precautions (5.1, 5.4)]. Symptomatic treatment may be necessary. Symptoms of overdose are not likely to be present immediately following injection. Should accidental injection or oral ingestion occur, the person should be medically supervised for several weeks for signs and symptoms of excessive muscle weakness or paralysis. There is no significant information regarding overdose from clinical studies of XEOMIN. In the event of overdose, antitoxin raised against botulinum toxin is available from the Centers for Disease Control and Prevention (CDC) in Atlanta, GA. However, the antitoxin will not reverse any botulinum toxin-induced effects already apparent by the time of antitoxin administration. In the event of suspected or actual cases of botulinum toxin poisoning, please contact your local or state Health Department to process a request for antitoxin through the CDC. If you do not receive a response within 30 minutes, please contact the CDC directly at 770-488-7100. More information can be obtained at http://www.cdc.gov/ncidod/srp/drugs/formulary.html#1a.

• 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,) trouble saying words clearly (dysarthria,) loss of bladder control, trouble breathing, trouble swallowing. These symptoms can happen hours, days, to weeks after you receive an injection of BOTOX or BOTOX Cosmetic, Dysport (Azzalure), Xeomin (Bocouture,) Jeuveau, or Daxxify. These problems could make it unsafe for you to drive a car or do other dangerous activities.

Other helpful links to give your prescribing physician. (To help them connect the dots that your symptoms are the clinical signs of botulism.

https://www.cdc.gov/botulism/health-professional.html

https://www.cdc.gov/botulism/index.html

https://www.cdc.gov/botulism/definition.html (HERE IT STATES BOTULISM FROM COSMETIC BOTOX.)

Black Box Warning Label Links

Botox
https://www.rxabbvie.com/pdf/botox-cosmetic_pi.pdf

Dysport (Azzalure)
https://www.ipsen.com/websites/Ipsen_Online/wp-content/uploads/2020/07/10002305/DYS-US-004998_Dysport-PI-July-2020.pdf

Xeomin
https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=3f35d6e0-3450-4abc-a0da-cc7b277e7c6e

Jeuveau
https://info.evolus.com/hubfs/Jeuveau_USPI.pdf?_ga=2.241945860.766501323.1667834282-84843889.1667834282

Daxxify
https://revance.com/wp-content/themes/allen-larson-theme/files/daxi-pi-and-med-guide.pdf

D. File a Report with your regulating body.

USA: Medwatch

The FDA number is:

1 800 332 1088

ONLINE REPORTING LINK:

https://www.accessdata.fda.gov/scripts/medwatch/index.cfm

United Kingdom:

UK Yellow Card Scheme number is: 0800 731 6789 or Email aic@mhra.gov.uk

ONLINE REPORTING LINK:

https://yellowcard.mhra.gov.uk

AUSTRALIA:

Adverse Medicine Events number is: 1 300 134 237

TGA 1 800 020 653 or Email info@tga.gov.au

ONLINE REPORTING LINK:

https://www.tga.gov.au/adverse-event-reporting

CANADA: Health Canada number is: 613 957 2991 or Email hcinfo.infosc@canada.ca

ONLINE REPORTING LINK:

https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html

NEW ZEALAND: Pharmacovigilance Centre number is: +64 3 479 7185 or Email nzphvc@otago.ac.nz

ONLINE REPORTING LINK:

https://nzphvc.otago.ac.nz/consumer-reporting/

SOUTH AFRICA: SAHPRA

South African Health Products Regulatory Authority

number is: 012 501 0300 or Email enquiries@sahpra.org.za

ONLINE REPORTING LINK:

https://primaryreporting.who-umc.org/ZA

RUSSIA: Federal Service for Surveillance in Health Care

number is: 495 698 4538 & 495 578 02 30 or Email info@roszdravnadzor.ru

Visit their website at: https://roszdravnadzor.gov.ru/

BULGARIA:

number is: 359 2 890 3417

or Email bda@bda.bg

Visit their website at:

https://www.bda.bg/bg/

Online form is located on the right side of the home page.

GERMANY:

The Paul-Ehrlich-Institut, Email pharmakovigilanz1@pei.de

ONLINE REPORTING LINK:

https://nebenwirkungen.bund.de/nw/EN/home/home_node.html

ARGENTINA: ANMAT

Ministry of Health

Number is: 011 4340 0800 ext. 5166 or Email

depto.snfvg.@anmat.gob.ar

ONLINE REPORTING LINK:

https://www.argentina.gob.ar/anmat/farmacovigilancia/notificanos/pacientes

BRASIL: Anvisa Agency

National Health Surveillance Number is:

0 800 642 9782

Visit Anvisa website:

https://www.gov.br/anvisa/pt-br

HUNGARY: Ogyéi

National Institute of

Pharmacy and Nutrition

Number is: 1 8869 300

Email ogyei@ogyei.gov.hu

Visit Ogyéi website:

https://ogyei.gov.hu/main_page

SWEDEN: Läkemedelsverket

Swedish Medical Products

Agency Number is:

+46 018 17 46 00

Email registrator@

lakemedelsverket.se

Visit website:

https://www.lakemedelsverket.se/en/about-the-swedish-mpa/contact-us

FRANCE: ANSM

The National Agency

for the Safety of Medicines

and Health Products

Number is: 01 55 87 30 00

Send contact form:

https://ansm.sante.fr/contact

ONLINE REPORTING LINK:

https://ansm.sante.fr/vos-demarches/patient#collapse-3

**If you live in a country not listed, please contact us via our public page.

https://www.facebook.com/botulismsupport/

*IN ADDITION.
You will have your regular general physician contact both the CDC and your local State or Health Department, to report that they have a patient with suspected botulism and for them to discuss the possible need for antitoxin.

To contact the CDC USA directly concerning antitoxin 770 488 7100

And your local health department. Follow the link below.

USA State and Territorial Health Department Directory
https://www.cdc.gov/publichealthgateway/healthdirectories/healthdepartments.html

UK Health Security Agency - (Public Health England)
https://www.gov.uk/guidance/notifiable-diseases-and-causative-organisms-how-to-report

CDC - UK
https://wwwnc.cdc.gov/travel/destinations/traveler/none/united-kingdom

E. Get into an appointment immediately with your regular doctor, do not wait. It is unlikely that your injector will be of any help at all. So, we can't stress enough how important this is. Armed with the information above you must meet with your doctor, and tell them exactly what "clinical signs of botulism" you have. Tell them what has happened, when it began and that you have read the label. Have a copy of the label with you, (printable from the links above) and highlight where it outlines the protocol of contacting these agencies (section 10, also above.) Tell them you feel you may need antitoxin and that you are demanding that they contact the health department, and CDC on your behalf to discuss its use.

   Note:
   *This is when your doctor may also try to say that "this can't happen." It is up to YOU to tell them you know your patient rights, and you will act as an advocate for YOURSELF. You may want to have a close friend or family member with you for your support. You are welcome to state that you know there are court cases proving this has happened to people. Also, that you have found a support group with thousands of others, and most importantly that the warning label states this can happen and the protocol of requesting antitoxin.

   It is important to understand that the amount of botulinum toxin A you received is *rarely* fatal, however, this does not mean that it was "not enough" to give you botulism.

   The product you received is dosed in MU (mouse units) so if you received 50 units this is enough toxin to be fatal to 25 mice. If you received 34 units this is enough to be fatal to 17 mice, and so on.. Reiterate with your physician that you are experiencing the clinical symptoms of botulism, go into great detail about its onset, and how you have never had this happen before.

If you have never had anxiety or heart racing, state that. If you have never had dizziness like what you are experiencing make this statement.

Do NOT let them dismiss your claims or medically gaslight you. Do NOT let them tell you this is “anxiety” and send you home with a benzodiazepine. This is not proactive, this is not following the protocol for botulism, this is not following their oath to do no harm and to help.
To note, there is no blood test your doctor can give you to prove you have botulism. You might be able to take a stool test. Ask about it, the CDC has information on this. Typically, botulism is determined based *only on your clinical symptoms.

*It is rare to get antitoxin, (typically) only your doctor can request it through your local health department and CDC. That is why you must advocate for yourself and get your general physician on board with you. This will require both you and them to do some leg work! Also, we must state that antitoxin may come with risks and side effects too. That is why it is up to you and your doctor to determine if your symptoms are severe enough to warrant its use. If you determine that they are not, then our advice is to follow the protocol outlined in the group.

F. Acknowledgment of botulism from Botox, Dysport, Xeomin, Jeuveau, or Daxxify - If your doctor refuses to acknowledge that you may have botulism, you can seek advice from another provider. You can also call your local health department *yourself* and tell them that your doctor has refused to acknowledge the warning label for the product you received and you would like to be seen by one of *their* physicians. Tell them that the warning label states to call them. You can also call the manufacturer for the product and ask them for step-by-step instructions of what you should do.

   We *do* recommend calling as many agencies as possible, health dept., CDC, manufacturer, or even local medical advocacy agencies in your area. *Advocating for yourself in this situation is a must.*