PATIENT INFORMATION: Botulism

Botulism is a rare, but serious, cause of paralysis. Botulism is caused by a toxin produced by Clostridium botulinum, a bacteria found in soil. All types of botulism may be fatal and are considered to be medical emergencies. Approximately 145 cases of botulism are reported each year in the United States. Many cases are associated with home-canned food.

Types of botulism

Foodborne botulism results from eating food that contains the botulinum toxin. About 15% of botulism cases are caused by food. Home-canned vegetables, smoked or raw fish, and cured pork are foods most commonly contaminated with botulinum toxin.

Wound botulism occurs when a wound becomes infected with Clostridium botulinum bacteria. Wound botulism accounts for around 20% of reported cases. Injection of black-tar heroin is the most common cause of wound botulism.

Infant botulism is caused by eating the bacterial spores which produce the toxin. Honey and corn syrup are the largest contributors to infant botulism and should be avoided in infants under 12 months of age. Infant botulism is the most common form of botulism in the United States.

Adult intestinal toxemia, also known as “adult intestinal colonization”, is caused by the bacterial spores growing in the intestines and releasing toxin.

Iatrogenic botulism is the rarest type and is caused by overdose of medicinal botulinum toxin.

How can botulism be prevented?

⇒ NEVER give honey or corn syrup to infants younger than 1 year of age
⇒ Throw away bulging cans and foul-smelling foods
⇒ Use proper home-canning techniques, including pressure cooking
⇒ Refrigerate oils infused with garlic or herbs
⇒ Keep baked potatoes hot or refrigerated, not at room temperature
⇒ Prevent wound botulism by seeking medical treatment immediately for wounds and avoid injecting street drugs

What are the symptoms of botulism?

In adults:
⇒ Double or blurred vision
⇒ Slurred speech
⇒ Difficulty swallowing
⇒ Dry mouth
⇒ Abdominal cramps
⇒ Difficulty breathing
⇒ Muscle weakness with paralysis both sides of the body

In infants:
⇒ Constipation
⇒ Weak cry
⇒ Poor feeding
⇒ Lethargy
⇒ Drooling
⇒ Weakness
⇒ Poor muscle tone

Symptoms usually occur within 8-36 hours of eating contaminated food. Note that NO fever occurs with this infection.

How is botulism treated?

The patient may need to have their stomach pumped, have vomiting induced, or have an enema to remove contaminated food from the stomach and intestines. Paralysis may be reversed using an antitoxin to the botulinum toxin. Severe difficulty breathing due to botulism may require hospitalization and the use of a ventilator (mechanical breathing device). Wound botulism is treated with antibiotics and surgery to remove infected tissue.

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Invega Trinza™ (3-month paliperidone palmitate injection)

Adherence is a major concern in patients with schizophrenia. Invega Trinza™ is a new extended release formulation of paliperidone palmitate requiring administration every 3 months and was approved by the FDA on May 18, 2015. This extended dosing interval formulation will assist with medication compliance and reduce relapses. Invega Trinza™ is intended for the treatment of schizophrenia in patients who have been adequately controlled on Invega Sustenna® (1-month paliperidone palmitate injection) for at least four months to ensure adequate tolerance of the medication.

Invega Trinza™ was superior to placebo in preventing relapse of schizophrenia symptoms. The trial had 4 phases to ensure that all patients were on the same baseline of treatment before initiating the double-blind, placebo controlled phase of the study. The first 2 phases were a 3-week screening phase and a 17-week transition phase where all participants received monthly injections of the 1-month paliperidone formulation. The third phase was a 12-week maintenance phase where all participants received a single dose of Invega Trinza™. In the final double-blind phase, half the participants continued to receive 3-month paliperidone palmitate (n=160), and the other half received placebo (n=145).

After 42 total relapses had occurred, the trial was stopped since Invega Trinza™ significantly decreased the relapse rate compared to placebo (HR 3.45; 95% CI 1.73-6.88; p=0.001). Data from this study may not be generalizable because only patients without prior substance abuse and those with a stable home environment were enrolled. In addition, metabolic differences in treatment, such as weight gain, are difficult to interpret due to the variable duration of Invega Trinza™ treatment.

Invega Trinza™ has a safety profile similar to the 1-month paliperidone formulation. The incidence of cerebrovascular accidents and mortality may be increased when Invega Trinza™ is used in elderly patients for dementia-related psychosis. Other potential adverse reactions include, neuroleptic malignancy syndrome, QT prolongation, tardive dyskinesia, metabolic changes (weight gain), hyperprolactinemia, leukopenia, neutropenia, and agranulocytosis.

Invega Trinza™ is an intra-muscular injection intended for administration by a healthcare professional. Dosing of Invega Trinza™ depends upon the previous dose of 1-month paliperidone palmitate prior to changing formulation. Dose conversion between the two paliperidone formulations is given in Table 1 below.

Doses of Invega Trinza™ should be given every 3 months with an administration window 2 weeks before or after day 90. If Invega Trinza™ doses are separated by more than 4 months, a re-initiation regimen must be utilized (see Table 2 below).

Invega Trinza™ offers an alternative dosage regimen for patients requiring treatment with an antipsychotic. Administration every 3 months of Invega Trinza™ is safe and effective and helps to alleviate some of the concern with adherence with its long duration of action. While the process for initiating Invega Trinza™ therapy can be complicated, infrequent dosing and limited opportunity for missed doses is an advantage for some patients.

By Matthew Crum, PharmD Candidate

REFERENCES:

Table 1: Dose conversion between Invega Trinza™ and Invega Sustenna®

<table>
<thead>
<tr>
<th>Invega Sustenna® dose</th>
<th>Invega Trinza™ equivalent dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>78 mg</td>
<td>273 mg</td>
</tr>
<tr>
<td>117 mg</td>
<td>410 mg</td>
</tr>
<tr>
<td>156 mg</td>
<td>546 mg</td>
</tr>
<tr>
<td>234 mg</td>
<td>819 mg</td>
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</tbody>
</table>

Table 2: Re-initiation regimen for Invega Trinza™

<table>
<thead>
<tr>
<th>Last Dose of Invega Trinza™</th>
<th>First Invega Sustenna®, two doses one week apart (into deltoid muscle)</th>
<th>Then Invega Trinza™ (into deltoid or gluteal muscle)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Day 1</td>
<td>Day 8</td>
</tr>
<tr>
<td>273 mg</td>
<td>78 mg</td>
<td>78 mg</td>
</tr>
<tr>
<td>410 mg</td>
<td>117 mg</td>
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Plaque psoriasis is an autoimmune disorder of the skin. This means that the body attacks its own skin cells by mistake. This causes many more skin cells to grow than usual.

Plaque psoriasis is identified by flat patches of skin which may be red and covered with silver, flaking scales and may be itchy. These flat patches of skin are also called plaques. Plaques are often found on the knees, elbows, head, or face, but they can be found anywhere on the body.

People with plaque psoriasis may also have what is called psoriatic arthritis. Psoriatic arthritis is a complication of psoriasis where the joints become swollen and painful.

Psoriasis can be confused with other skin conditions, such as eczema. Plaque psoriasis can get better for a while and then get worse again, this is known as a flare-up. Plaque psoriasis is not contagious and cannot be spread to other people.

Plaque psoriasis is diagnosed from the symptoms and the presence of plaques. Psoriasis is classified as mild, moderate, or severe based on how much of the body is covered with plaques. A dermatologist is best trained to diagnose plaque psoriasis and other skin conditions.

**Treatment of Plaque Psoriasis:**

Plaque psoriasis cannot be completely cured. The goal is to stop skin cells from growing too fast and to make skin healthier by:

- Reducing plaques and/or scales
- Reducing itching
- Reducing flare-ups

**Prevent Flare-ups**

- Use sunscreen with SPF 30 or higher regularly because too much sun exposure can make symptoms worse
- Use fragrance-free soaps and detergents
- Bathe with warm water, because hot water worsens symptoms
- Stress reduction can lessen psoriasis symptoms

**Prescription drug treatments** include topical skin creams as well as oral and injectable medications.

**Talk With Your Doctor About Which Treatment Is Best for You**

**More Information**

- www.nlm.nih.gov/medlineplus
- www.healthline.com
- www.webmd.com
- www.medicinenet.com
- www.cdc.gov
- www.mayoclinic.org
- www.niams.nih.gov

- www.psoriasis.org

**REFERENCES:**


**PATIENT INFORMATION:**

**Plaque Psoriasis**

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What are the complications of botulism?

⇒ Inability to breathe (respiratory failure) which may cause death
⇒ Long-lasting weakness and shortness of breath
⇒ Nervous system problems after infection
⇒ Aspiration pneumonia and respiratory infection

REFERENCES:
Viberzi™ (eluxadoline) for IBS

Eluxadoline is the first in a new drug class which targets symptoms of diarrhea and abdominal pain associated with irritable bowel syndrome with diarrhea (IBS-D). It was approved by the FDA in May 2015 and is available as an oral tablet in either 75 mg or 100 mg strengths taken twice daily.

Eluxadoline is a μ (mu) opioid receptor agonist and δ (delta) opioid receptor antagonist, acting locally in the gastrointestinal (GI) lumen. The agonist activity at the μ opioid receptor induces analgesia and slows gastric propulsion, whereas the δ opioid receptor antagonism stabilizes GI motility and inhibits μ agonist desensitization. Systemic opioid effects should not occur with eluxadoline because the bioavailability of eluxadoline is estimated at 1.02%. Eluxadoline improved quality of life in patients with IBS-D in 3 randomized, multi-center, double-blind, placebo-controlled trials. Eluxadoline 100 mg was more effective at treating both abdominal pain and diarrhea by the end of 12 weeks compared to placebo in the phase II trial.

Eluxadoline-treated patients in the phase III trials had significantly less diarrhea than control patients. Abdominal pain was slightly decreased by eluxadoline treatment compared to placebo (3-6%), but this was not statistically significant. Data from the 2 phase III studies are summarized in the eluxadoline package insert. Small population sizes and the inability to fully evaluate the studies limit the application the study results.

Common adverse events reported with eluxadoline include constipation, nausea, and abdominal pain. Severe constipation or sequelae from constipation are contraindications. Other contraindications include biliary duct obstruction, sphincter of Oddi disease or dysfunction, alcoholism, history of pancreatitis, or severe hepatic impairment. Hepatobiliary sphincter of Oddi spasms have occurred in patients with a cholecystectomy during trials, so eluxadoline should be used with caution in those patients.

Although eluxadoline can lessen diarrheal symptoms of patients with IBS-D, the data is not as strong for abdominal pain reduction with eluxadoline. Eluxadoline’s action at μ opioid receptors has potential for abuse, but this is unlikely due to the poor bioavailability of the oral drug. Eluxadoline may help improve quality of life in patients with IBS-D.

By Russel Arnold, PharmD Candidate

REFERENCES: