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RPCC Pharmacy Forum

Special Interest Articles:

- Xeomin
- Vitamin D
- Andexxa

Did you know?

Approximately one in seven United States youths aged 12-19 years had elevated BP or hypertension during 2013-2016, according to the criteria of the 2017 AAP Clinical Practice Guideline.

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FDA Approves Treatment for Excessive Drooling

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Xeomin® (incobotulinumtoxinA) has been approved by the Food and Drug Administration for the treatment of chronic sialorrhea, or excessive drooling. Excessive drooling is a common symptom among patients with neurological disorders including, amyotrophic lateral sclerosis (ALS), stroke patients, Parkinson's disease and cerebral palsy. Xeomin is the first and only neurotoxin approved for this indication in the United States. Prior to the drug's approval for sialorrhea, it had been used to treat cervical dystonia, blepharospasm, and upper limb spasticity.

Botulinum toxins like Xeomin are purified neurotoxins that act in the neuromuscular junction to produce flaccid paralysis. The toxins are produced from fermentation of the bacterium Clostridium Botulinum based on the individual strains (ie, Type A or B). The usual dosage of Xeromin for excessive salivation is 100 units via intra-salivary gland injection, divided in the parotid glands (30 units per side, 60 units total) the submandibular glands (20 units per side, 40 units total).

Botulinum neurotoxin is the most poisonous substance known, however, overdose is unlikely with pharmaceutical grade products. A single vial is approximately 0.005% of the estimated lethal oral dose. One adult did develop severe toxicity after illicit use of research grade botulinum toxin for cosmetic purposes. It was estimated that the patient was administered a dose in excess of 100,000 units. Common side effects with therapeutic use include dry mouth, dysphagia, dyspepsia and injection site pain.

Xeomin is similar to other botulinum toxins, such as Botox® and Dysport®. Xeomin is used cosmetically for labeled and off-label indications, including treatment of frown lines, crow's feet and forehead wrinkles.

References

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Does Sunscreen Prevent Vitamin D Absorption?

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Most individuals get at least some of their vitamin D through exposure to sunlight. Vitamin D3 is produced from the conversion of cutaneous 7-dehydrocholesterol to pre-vitamin D3 by ultraviolet (UV) B radiation with a wavelength of 290-320 nanometers penetrating uncovered skin.

"Vitamin D-producing UV rays appear to be blocked by sunscreens with a sun protection factor (SPF) or 8 or more."

Vitamin D-producing UV rays appear to be blocked by sunscreens with a sun protection factor (SPF) of 8 or more. Generally, people do not apply sufficient amounts to cover all exposed skin. The face and backs of hands have a total body surface area greater than 5%. It has been determined that most people already receive at least 15 minutes of incidental unprotected sun exposure daily to these areas without additional unprotected sun exposure.

The American Academy of Dermatology advises that photo-protective measures be taken, including the use of sunscreen, whenever one is exposed to the sun. Many people can get the vitamin D they need from foods and/or vitamin supplements. The American Academy of Dermatology recommends that an adequate amount of vitamin D should be obtained from a healthy diet that includes foods naturally rich in vitamin D, foods/beverages fortified with vitamin D, and/or vitamin D supplements. Vitamin D should not be obtained from unprotected exposure to ultraviolet (UV) radiation.

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Selected Food Sources of Vitamin D

Food	IUs per serving*	Percent DV**
Cod liver oil, 1 tablespoon	1,360	340
Swordfish, cooked, 3 ounces	566	142
Salmon (sockeye), cooked, 3 ounces	447	112
Tuna fish, canned in water, drained, 3 ounces	154	39
Orange juice fortified with vitamin D, 1 cup (check product labels, as amount of added vitamin D varies)	137	34
Milk, nonfat, reduced fat, and whole, vitamin D-fortified, 1 cup	115-124	29-31
Yogurt, fortified with 20% of the DV for vitamin D, 6 ounces (more heavily fortified yogurts provide more of the DV)	80	20
Margarine, fortified, 1 tablespoon	60	15
Sardines, canned in oil, drained, 2 sardines	46	12
Liver, beef, cooked, 3 ounces	42	11
Egg, 1 large (vitamin D is found in yolk)	41	10
Ready-to-eat cereal, fortified with 10% of the DV for vitamin D, 0.75-1 cup (more heavily fortified cereals might provide more of the DV)	40	10

*IUs = International Units **DV = Daily Value
United States Department of Agriculture, Agriculture Research Service

New Direct Oral Anticoagulant Reversal Agent

Laura Read, RPh, CSPI, Regional Poison Control Center

In 2010 the U.S. Food and Drug Administration approved the first direct oral anticoagulant (DOAC), dabigatran (Pradaxa®), to provide more stable pharmacokinetic and pharmacodynamic options for oral anticoagulation. Examples of DOACs include direct thrombin inhibitors (DTIs) dabigatran (Pradaxa) and direct factor Xa inhibitors ("Xabans") rivaroxaban (Xarelto®), apixaban (Eliquis®), edoxaban (Lixiana®, Savaysa®) and betrixaban (Bevyxxa®). The DOACs act directly upon Factors IIa (DTIs) or Xa ("Xabans") without using antithrombin as a co-factor. It should be noted that each direct factor Xa inhibitor has the letters "Xa" in its spelling. DOACs are associated with lower risks of major bleeding than warfarin, making reversal of an overdose infrequently necessary. DOAC benefits also include absence of dietary interactions and a smaller number of drug-drug interactions which leads to greater patient safety and compliance.

Up until May 2018, idarucizumab (Praxbind®) was the only FDA-approved reversal agent for direct oral anticoagulants, working only on dabigatran (Pradaxa). Andexanet alfa (Andexxa®) is a new direct oral anticoagulant reversal agent specifically indicated for patients treated with rivaroxaban (Xarelto) and apixaban (Eliquis). Andexxa was approved under the FDA's Accelerated Approval pathway. It is also being studied to reverse other anticoagulants, betrixaban (Bevyxxa), edoxaban (Savaysa®), and enoxaparin (Lovenox®).

Andexanet alfa is a biologic agent that functions as a decoy receptor to which factor Xa inhibitors bind in preference to natural factor Xa. Adverse effects associated with the use of Andexxa may include, but are not limited to, urinary tract infections and pneumonia. The Andexxa label has a Boxed Warning concerning the possibility of arterial and venous thromboembolic events and ischemic events, including myocardial infarction and ischemic stroke. Preliminary data suggest bleeding stops within 12 hours of giving Andexxa for most patients. Andexxa can cost about $25,000 to $50,000 per patient.

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