ToxTidbits

Maryland Poison Center
UNIVERSITY OF MARYLAND SCHOOL OF PHARMACY

December 2014 Poison Center Hotline: 1-800-222-1222

The Maryland Poison Center's Monthly Update: News, Advances, Information

Compounded Pain Creams and Ointments

The Maryland Poison Center was called for advice in managing a 48 year old woman who was transported to the emergency department by EMS after intentionally ingesting a pain cream compounded for her. She was unresponsive, BP 85/55, HR 36, was intubated and ventilated. EMS gave 2mg naloxone with no response. The cream was labeled "K(CIII)BGFANC".

Topical creams, ointments and lotions are increasingly being prescribed for patients suffering from a variety of chronic pain syndromes, often as an alternative to opioids and other analgesics. These topical products are compounded by pharmacies, often in other states at a cost of > $1000/container, and may not be in child resistant containers. The creams and ointments contain a variety of drugs in high concentrations that can cause toxic effects when overused topically or when ingested. The compounded preparations may contain any combination of the following drugs and more:

- Ketamine, opioids, menthol (analgesics)
- Baclofen, cyclobenzaprine (muscle relaxants)
- Clonidine, gabapentin, tricyclic antidepressants (neuropathic analgesics)
- Lidocaine, bupivacaine, prilocaine (anesthetics)
- Nifedipine, verapamil (vasodilators)
- Mefenamic acid, diclofenac, ketoprofen, flurbiprofen (nonsteroidal anti-inflammatory agents)

In the above case, "K(CIII)BGFANC" was an abbreviation for the following ingredients: ketamine 7%, baclofen 4%, gabapentin 6%, flurbiprofen 7%, amitriptyline 2%, nifedipine 2%, and clonidine 0.2%. As little as one teaspoonful when ingested (containing 350 mg ketamine, 200 mg baclofen, 300 mg gabapentin, 350 mg flurbiprofen, 100 mg amitriptyline, 100 mg nifedipine and 10 mg clonidine) would be likely to produce severe neurological, respiratory and cardiovascular effects. Numerous case reports of toxicity have recently been published in the medical literature. A 23 year old man rubbed a compounded pain cream over his entire body. The cream contained 0.2% clonidine and five other drugs. He presented with hypertension, bradycardia, and altered mental status, and developed a subarachnoid hemorrhage. The serum clonidine concentration was 5,200 ng/mL; therapeutic is generally accepted as <4 ng/mL *(J Med Toxicol 2014;10:61-4)*. Twenty minutes after a compounded pain ointment was applied to an 18 month old for diaper rash, he was unresponsive with constricted pupils, had a pulse of 57 and blood pressure of 74/35 *(Ped Emerg Care 2013;29:1220-2).* A 14 month old was found with his grandmother's compounded pain ointment on his face and hands. He was responsive only to painful stimuli, had pinpoint pupils, bradycardia, and hypotension, and required intubation and vasopressors *(Clin Toxicol 2014;52:801).* Lethargy and hypotension were observed in a 26 month old after ingesting a compounded pain lotion *(Clin Toxicol 2014;52:801-2).*

Treatment of toxicity due to compounded pain creams, ointments and lotions consists of dermal decontamination for topical exposures, activated charcoal for recent oral ingestions in patients who can protect their airway, and supportive care. Naloxone may reverse the toxicity associated with opioids and clonidine. Most of the drugs in these products will not be tested for on routine urine toxicology screens.

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Did you know?

Compounded pain creams and ointments are not FDA-approved.

A compounded drug is one in which a licensed pharmacist or physician combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient. The FDA does not verify the quality, safety or effectiveness of compounded drugs, including pain creams and ointments. State boards of pharmacy have primary responsibility for the day-to-day oversight of state-licensed pharmacies that compound drugs. Some containers may not be labeled with adequate directions or warnings. Creams and ointments may not be viewed by users as dangerous if misused or if small children gain access to them. Patients should be educated about proper use, adverse effects, risk of toxicity, and safe storage of pain creams and ointments.

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