Drug errors associated with opium tincture and paregoric

Since 1997, the Food & Drug Administration has received eight cases of medication errors involving opium tincture and paregoric. Among the six cases in which a product was administered, three resulted in fatal outcomes, one required treatment at an emergency room, one required prolonged treatment in a hospital, and one involved an unknown outcome.

In six of the eight cases, the wrong drug product (n=3), drug concentration (n=2), or dose/drug volume (n=1) was given to the patient. In the other two cases, the medication was either not administered or it could not be determined whether the medication was administered. The medication errors involved adults (n=3), infants less than one year of age (n=3), or an age was not reported (n=2).

An initial analysis of the medication errors indicates several factors have contributed to the errors. One contributing factor to medication errors is that over the years additional names have been associated with the two products, and these additional names are listed below:

Opium tincture, USP:
Opium tincture, deodorized
Opium tincture (laudanum)
Deodorized tincture of opium
Opium
Tincture of opium
DTO

Paregoric, USP:
Tincture of opium, camphorated
Tincture of paregoric

Also, some healthcare practitioners have mistakenly used the abbreviation "DTO" to indicate diluted tincture of opium. However, the letters *DTO* are actually an abbreviation for deodorized tincture of opium.

In 2001, the agency received a report in which the abbreviation DTO caused confusion. A 13-day-old infant was transferred from an obstetrics hospital with a diagnosis of opiate withdrawal. A transfer order was written as "DTO 0.7 mL PO q4h." The pharmacist processing the order identified the abbreviation DTO to represent deodorized tincture of opium. When the pharmacist attempted to verify the dose with common reference sources, he determined the dose to be excessive. The pharmacist contacted the obstetrics hospital pharmacy personnel to clarify the transfer order and discovered the abbreviation DTO was meant to indicate a 25-fold dilution of deodorized tincture of opium. If deodorized tincture of opium had been dispensed, then the infant would have received a 42-mg daily dose, instead of the prescribed 1.68-mg daily dose. Vigilance by the pharmacist prevented an abbreviation error from causing patient harm. It is important to remember there is no abbreviation for *diluted tincture of opium*, and all medication abbreviations should be avoided when prescribing.

The presentation of the product strength on the container label and package insert is another source of confusion. The presentation does not easily allow the reader to determine opium tincture is *25 times more concentrated* than paregoric. This 25-fold concentration difference is the reason opium tincture is dosed in drops (or a fraction of a milliliter) and paregoric is dosed as 5-10 milliliters (or one to two teaspoonfuls). There is no pediatric dosing guideline for opium tincture because of the high morphine concentration. However, paregoric can be used to treat diarrhea in children at a dose of 0.25-0.5 ml/kg one to four times a day.

Another contributing factor to the medication errors is the overlapping indications, which do not aid in differentiating the products. Both products are indicated for the treatment of diarrhea. Reference sources also indicate both products can treat the same unlabeled indications of use, which include the relief of pain, neonatal abstinence syndrome, and the management of short bowel syndrome.

Three cases of medication errors involving adult patients, as well as one case involving a patient of unknown age, and three additional cases involving infants are summarized in the table on the right. All four cases involving adults were errors that resulted in the administration of the wrong product, three of which contributed to the death of the patient. The three additional cases involving infants were errors that resulted in the administration of the wrong dose or concentration.

These medication-error reports indicate the risk for patient harm and injury is increased if opium tincture is dispensed or administered in error. This would be expected since opium tincture is 25-fold more concentrated than paregoric.

The FDA will be working with the manufacturers on container label and package insert labeling revisions. However, in the interest of minimizing potential user error and maximizing patient safety, we recommend increasing your staff's awareness of the confusion between these products.

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MEDWATCH

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To report a problem with an FDA-regulated product, please call 1-800-FDA-1088.

Med-error reports associated with opium tincture and paregoric

Patient age and date received	Abbreviated narrative of cases involving adults
Unknown 5/97	A patient was ordered 8 mL of Paregoric every eight hours to be added to a tube feeding bag. A recent graduate pharmacist did not realize that Paregoric and Deodorized Tincture of Opium were not the same drug. The container was labeled "Deodorized Tincture of Opium (Paregoric) 1 g/100 mL." The reporter stated the patient received an extra 120 mg of morphine. The outcome was unknown.
91 years old 6/00	The patient was given a dose of 10 mL of Opium Tincture (deodorized) in a nursing home. Patient passed away shortly after the dose administration. The dose prescribed was "5-10 mL by mouth every 6 hours as needed." The nursing home pharmacy printer would "print the highest dose on the prescription label and therefore it gave a dose of 10 mL." A prescription was faxed to the pharmacy department at the nursing home but was not verified by the pharmacy department.
51 years old 4/02	The patient was prescribed camphorated Tincture of Opium to treat chronic diarrhea. The pharmacy dispensed Opium Tincture, which contains 25 times the amount of Morphine as Paregoric. After taking the Opium Tincture in the morning, the patient became weak and complained of feeling tired and achy. Later the patient was found unresponsive and could not be revived. The medical examiner's office found that the patient's death was caused by morphine intoxication.
85 years old 5/03	A patient was prescribed Opium Tincture camphorated, 5 mL p.o. b.i.d./t.i.d. 2-3x/day until diarrhea stops. That evening, the patient just lay in bed with difficulty breathing. He could not talk or even open his eyes. Three days later, the patient passed away. The foster care had all of the prescriptions delivered from a community pharmacy. A family member learned that evening pharmacy personnel came back with a new bottle of Opium and took the original bottle. The new bottle was labeled Opium 10% Tincture 0.6 mL 2-3 times a day until diarrhea stops.

Patient age and date received	Abbreviated narrative of cases involving infants
9 months 1/1996	A prescription for Paregoric was written for 10-15 drops every 4-6 hours for pain. The prescription label was dispensed as 10-15 cc per dose. The mother called the physician to verify the dose before the medication was administered to the infant.
Newborn 1/02	A full-term baby was to go through a weaning process from opiate dependency over 21 days. However, on the 19th or 20th day of therapy, it was discovered a wrong concentration was prepared. The physician ordered 0.35 mL q4h of a 0.4 mg/mL solution. However, the baby received a 0.35 mL q4h of a 10 mg/mL solution. The baby required an additional 3 months of weaning.
One month 3/03 & 4/03	An outpatient pharmacy dispensed Opium Tincture, USP to the infant. The report stated the pharmacist was unfamiliar with the concentration and failed to dilute the product properly. The report indicated the infant was treated in the emergency room and required patient monitoring.