From: CDERPASE CDERPASE@fda.hhs.gov
Subject: Reminder of Non-substitution of Pedmark for Pediatric Patients Receiving Cisplatin
Date: Jan 8, 2024 at 9:04:17 AM
To: CDERPASE CDERPASE@fda.hhs.gov

FDA U.S. FOOD & DRUG ADMINISTRATION

Good morning,

Pedmark (sodium thiosulfate injection), for intravenous use, is approved to reduce the risk of ototoxicity (e.g. permanent hearing loss) associated with cisplatin in pediatric patients 1 month of age and older with localized, non-metastatic solid tumors. The prescribing information states that Pedmark should not be substituted with other sodium thiosulfate (STS) products.

FDA is aware that some providers, including hospital or health-system pharmacies, may be preparing other STS products for patient use in place of Pedmark, including diluting STS products approved for other uses to match Pedmark's strength.

FDA reminds health care providers that as stated in Pedmark's prescribing information, Pedmark is not substitutable with other sodium thiosulfate products.

Such substitutions, pose potential health risks including:

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Potassium chloride exposure which, at high doses, can lead to increased risk of acute cardiac events and other serious adverse reactions.
Potassium chloride is not present in Pedmark.

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Overexposure to boric acid (a boron compound), can cause health risks including headache, hypothermia, restlessness, weariness, renal injury, dermatitis, alopecia, anorexia and indigestion. Although Pedmark also contains boric acid, it is at a lower concentration than other STS products.

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Overexposure to sodium nitrite, which can lead to health risks including methemoglobinemia. Sodium nitrite is copackaged with sodium thiosulfate as a separate vial in some products; it is not present in Pedmark.

Please contact FDAOncology@fda.hhs.gov with any questions.

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