Transcript Details
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Assessing Approvals: FDA Updates on Dexmedetomidine Hydrochloride

Announcer:
You're listening to The Drug Report on ReachMD, hosted by Linda Bernstein, Pharm.D., Clinical Professor on the Volunteer Faculty of the School of Pharmacy, University of California, San Francisco.

Dr. Bernstein:
Welcome to The Drug Report and an update on news pertaining to dexmedetomidine hydrochloride, a sedative used in anesthesia. Dexmedetomidine is a highly selective α2-adrenergic receptor agonist that is associated with sedative and analgesic sparing effects, reduced delirium and agitation, perioperative sympatholysis, cardiovascular stabilizing effects, and preservation of respiratory function. The product is indicated for sedation of initially intubated and mechanically ventilated patients during treatment in an intensive care setting and sedation of non-intubated patients prior to and/or during surgical and other procedures.

Dexmedetomidine Hydrochloride is the hydrochloride salt form of dexmedetomidine, an imidazole derivate and active d-isomer of medetomidine with analgesic, anxiolytic and sedative activities. Dexmedetomidine selectively binds to and activates presynaptic alpha-2 adrenoceptors located in the brain, thereby inhibiting the release of norepinephrine from synaptic vesicles. This leads to an inhibition of postsynaptic activation of adrenoceptors, which inhibits sympathetic activity, thereby leading to analgesia, sedation and anxiolysis.

The most common side effects of dexmedetomidine hydrochloride injection are hypotension, bradycardia and dry mouth. This drug is listed in the FDA Drug Shortage Database.

Dexmedetomidine has been the feature of a few news reports in recent months pertaining to approval of additional generic forms of the drug and a drug recall.

An abbreviated new drug application approval for Aurobindo Pharma's dexmedetomidine hydrochloride in 0.9% sodium chloride injection was announced by the US Food & Drug Administration on December 7.

The product is a therapeutic equivalent generic version of Hospira's Precedex in 0.9% Sodium Chloride Injection. The product will be launched in January 2021.

The approved product has an estimated market size of $228 million for the twelve months ending October 2020 according to IQVIA.

This approval follows that of Dr. Reddy's Laboratories Ltd. and its subsidiaries who announced on September 25th the launch of their generic version of Precedex®.

Now we move on to a November 19 voluntary recall by Fresenius Kabi USA of a single lot of Dexmedetomidine HCl in 0.9% Sodium Chloride Injection, 200 mcg/50 mL (4 mcg /mL), 50 mL fill in a 50 mL vial. Fresenius Kabi initiated this recall due to a trace amount of lidocaine present in the lot.

To date, no adverse drug experience reports have been received for the recalled lot. Administration of Dexmedetomidine HCl containing trace amounts of lidocaine to a patient with lidocaine allergy could result in a potentially life-threatening allergic reaction.

Fresenius Kabi is notifying its distributors and customers by letter and asking them to check their stock immediately and to quarantine and discontinue the use and distribution of any affected product.

Distributors should notify their customers and direct them to quarantine and discontinue distributing or dispensing any affected lots, and to return the product to Fresenius Kabi. The recall letter and response form are available at https://www.fresenius-

kabi.com/us/pharmaceutical-product-updates.

Customers with questions regarding this recall may contact the company. Consumers should contact their physician or health care provider if they have experienced any problems that may be related to taking or using this drug product.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

For The Drug Report, I'm Pharmacist, Dr. Linda Bernstein.

Announcer:
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