



IMPORTANT DRUG WARNING

December 7, 2020

Subject: Detection of trace amounts of Lidocaine in CISplatin Injection, CARBOplatin Injection, and Octreotide Acetate Injection.

Administration of the below batches to a patient with lidocaine allergy could result in allergic reactions, including rare but life-threatening anaphylactic reactions.

Dear Healthcare Provider and Prescribers,

The purpose of this communication is to inform you about the potential risk of allergic reactions, including rare but life-threatening anaphylactic reactions, associated with traces of **lidocaine** detected in the below-listed batches of CISplatin Injection, CARBOplatin Injection, and Octreotide Acetate Injection.

<u>Product Name/Product size</u>	<u>NDC Number</u>	<u>Product Code</u>	<u>Affected Batch Number</u>
CISplatin Injection 200mg 200mL MDV	63323-103-64	100364	6122356 6123906 6122357 6121943*
CISplatin Injection 100mg 100mL MDV	63323-103-65	100365	6124136 6124138 6121945 6122722
CISplatin Injection 50mg 50mL MDV	63323-103-51	100351	6122624*
CARBOplatin Injection 600 mg 60 mL MDV	63323-172-60	107260	6123843 6124062
Octreotide Acetate Injection 1000 mcg 5mL MDV	63323-378-05	370805	6122440*

The maximum amount of lidocaine detected in the above referenced batches ranges between 10-times to 200-times below the calculated Permitted Daily Exposure (PDE) for lidocaine of 0.2 mg/day. The PDE represents a dose that is unlikely to cause an adverse effect if an individual is exposed, by any route of administration, at or below this dose every day for a lifetime.

However, administration of these batches to a patient with a lidocaine allergy, could result in allergic reactions, including rare but life-threatening anaphylactic reactions.

Lidocaine Hypersensitivity

Allergies and hypersensitivity reactions to lidocaine have been reported in the literature as a rare event. IgE mediated allergies to lidocaine are extremely rare and are estimated to account for less than 1% of suspected allergic reactions to local anesthetics (LA). Amide-linked local anesthetics, and



lidocaine in particular, are reported to have a lower risk of allergic reactions than ester-linked local anesthetics.

Prescriber Action

Prescribers and healthcare providers are asked to be aware of the possibility of allergic reactions when prescribing or administering CISplatin Injection, CARBOplatin Injection, or Octreotide Acetate Injection to their patients.

Please refer to the CISplatin Injection, CARBOplatin Injection, or Octreotide Acetate Injection package inserts for full prescribing information.

Reporting Adverse Events

You are encouraged to report adverse events or quality problems experienced with the use of these products. Call Fresenius Kabi USA Vigilance or Medical Affairs at 1-800-551-7176, Monday – Friday, between the hours of 8 a.m. and 5 p.m. (CST), or e-mail adverse.events.USA@fresenius-kabi.com or productcomplaint.USA@fresenius-kabi.com.

Fresenius Kabi USA CONTACT NUMBERS: Please use the following contact numbers as appropriate:

Reason To Call	Department	Number
Adverse Event Reporting	Vigilance Department	1-800-551-7176
Clinical/Technical Info. Or Product Complaint	Medical Affairs Department	
Product Availability & Ordering	Customer Service Department	1-888-386-1300

You are encouraged to report adverse reactions or quality problems experienced with the use of this product to the FDA’s MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report Online: www.fda.gov/medwatch/report.htm
- Regular Mail or Fax: Download form <https://www.fda.gov/safety/medical-product-safety-information/medwatch-forms-fda-safety-reporting> or call 1 800 332 1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178 (1-800-332-0178).

This communication and product information is available on the Fresenius Kabi USA web site at <https://www.fresenius-kabi.com/us/pharmaceutical-product-updates> .

Sincerely,

Melanie Power-Burns
Sr. Vice President, Quality