



July 19, 2019

Important Safety Information

Open in a well-ventilated hood shipments of DraxImage Sodium Iodide I-131 Capsules, Diagnostic shipped without charcoal bags

Dear Valued Customer,

We are informing you that effective immediately, you will receive orders of DraxImage **Sodium Iodide I-131 Capsules, Diagnostic** (NDC 65174-461) (Sodium Iodide I 131 Capsule USP Diagnostic - Oral) without the charcoal bags. Due to the current shortage of this product, Jubilant DraxImage Inc., coordinated with the US Food and Drug Administration to release this product without the charcoal bags.

The product's quality, safety, efficacy and patient benefit/risk ratio are unaffected by the absence of the charcoal bag (the adsorbent desiccant) listed in the supplied/storage and handling section of the prescribing information. The charcoal bag adsorbs radioactive iodine gas that may potentially be present during shipping. In addition, these charcoal bags are not required by the Nuclear Regulatory Commission.

Prescriber Actions

As always, it is mandatory to adhere to the radiation safety controls as mandated per USNRC licensing requirements when handling Sodium Iodide I-131 Capsules, Diagnostic.

Specifically, we remind you to avoid exposure to radioactive iodine gas by opening shipments of Sodium Iodide I-131 Capsules, Diagnostic in a well ventilated hood.

We are sorry for the inconvenience caused by this temporary shortage of DraxImage **Sodium Iodide I-131 Capsules, Diagnostic** (Sodium Iodide I 131 Capsule USP Diagnostic - Oral).

A Jubilant Pharma Company

OUR VALUES



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Reporting Adverse Events

Health care providers and patients are encouraged to report adverse events in patients taking DraxImage Sodium Iodide I-131 capsules, Diagnostic to Jubilant DraxImage Inc. at 1-888-633-5343.

Adverse events or quality problems experienced with the use of this product may also be reported 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 www.fda.gov/MedWatch/getforms.htm

On behalf of Jubilant DraxImage Inc., we thank you for your continued support.
Kind regards,



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