



March 25, 2019

## Important Drug Safety Information

**High Level Radiation Exposure with Use of Incorrect Eluent and Failure to Follow the Quality Control Testing Procedure.**

**Use only additive-free, 0.9% Sodium Chloride Injection, USP (normal saline) to elute RUBY-FILL. Strictly adhere to the mandatory quality control testing.**

**Immediately stop the patient infusion and permanently discontinue the use of the affected RUBY-FILL generator if any solution other than additive free 0.9% Sodium Chloride Injection USP is observed during elution.**

Dear Jubilant DraxImage RUBY-FILL Rb-82 Generator User,

Jubilant DraxImage Inc. (“JDI”) would like to inform you about a serious incident caused by using the incorrect solution to elute a Rubidium Rb-82 Generator. The incorrect eluent contained calcium ( $\text{Ca}^{2+}$ ) and caused high levels of Strontium 82 (Sr-82) and Strontium 85 (Sr-85) ‘breakthrough’ into the Rubidium 82 Chloride Injection. Patients were exposed to high levels of radiation.

### *Prescriber/Operator Actions:*

- **Use only additive-free, 0.9% Sodium Chloride (NaCl) Injection, USP (normal saline) to elute RUBY-FILL as required in the labeling. Strictly adhere to RUBY-FILL’s mandatory quality control testing procedure.**
- **Immediately stop any infusion and discontinue the use of the affected RUBY-FILL (Rb-82) generator, if the incorrect eluent is observed being used to elute the generator. Immediately report the event to JDI.**
- **Evaluate the patient’s radiation absorbed dose and monitor for the effects of radiation to critical organs such as bone marrow.**

RUBY-FILL consists of Sr-82 (85-115- mCi at calibration time) adsorbed on a hydrous stannic oxide column. Use of incorrect eluent containing calcium ( $\text{Ca}^{2+}$ ), such as Lactated Ringer’s, causes the exchange of  $\text{Ca}^{2+}$  for  $\text{Sr}^{2+}$  and the release of Sr-82 and Sr-85 in the eluate. Note that Lactated Ringer’s contains **3.0 mEq/L  $\text{Ca}^{2+}$**  and RUBY-FILL contains **0.00044 mEq of  $\text{Sr}^{2+}$**  radionuclide.

JDI is going to conduct testing to evaluate the risk posed by Sr-82/85 breakthrough secondary to the use of Lactated Ringer’s, which is potentially serious. JDI is considering a range of possible additional risk mitigation options and will provide follow-up communications as appropriate.

A Jubilant Pharma Company

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Health Care Providers are encouraged to report adverse events at 1-888-633-5343 or at [Pharmacovigilance@jdi.jubl.com](mailto:Pharmacovigilance@jdi.jubl.com). Alternatively, visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch), or call 1-800-FDA-1088. Full prescribing information is available at: <https://www.draximage.com/products/us/ruby-fill/>

Sincerely,

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