GE Healthcare
Life Sciences, Pharmaceutical Diagnostics

100 Results Way
Marlborough, MA 01752

November 15, 2018

IMPORTANT PRESCRIBING INFORMATION

Subject: Introducing an Alternative Excipient: Cobalt Chloride Stabilizer Solution for Ceretec™

Dear Healthcare Provider:

The purpose of this letter is to introduce an alternative excipient (cobalt stabilizer solution) for Ceretec. GE Healthcare will begin to offer cobalt stabilizer solution with Ceretec. Concurrently, we will continue to provide Ceretec packaged with the stabilizing components methylene blue, sodium phosphate buffer, and syringe filter. However, on March 31, 2019, GE Healthcare will discontinue offering methylene blue, and only offer Ceretec packaged with cobalt stabilizer solution.

Ceretec is indicated for use in adult and pediatric patients from 2 to17 years of age for leukocyte-labeled scintigraphy and cerebral scintigraphy. Use of both stabilizer solutions is optional for the preparation of Tc-99m exametazime injection for cerebral scintigraphy. DO NOT use either stabilizer in the preparation of Tc-99m exametazime-labeled leukocytes.

To enhance your understanding of the two "presentations" of Ceretec, it is important that you review the following Product Comparison table, which describes the differences between the two product presentations. The full Prescribing Information for each presentation of Ceretec is attached.

Product Comparison

New: Ceretec packaged With Cobalt Solution Stabilizer	**Ceretec packaged With Methylene Blue and Sodium Phosphate Buffer Stabilizer**
PRODUCT DESCRIPTIONS: DOSAGE FORM AND STRENGTHS	
Kit for Ceretec is supplied with five units. Each unit contains two vials to prepare technetium Tc-99m exametazime intravenous injection. Five 10-mL vials of Ceretec: a lyophilized mixture of 0.5 mg exametazime. Five 10-mL vials of Cobalt stabilizer solution: 200 mcg cobalt chloride 6-hydrate stabilizer solution in 2 mL of water for injection.	Kit for Ceretec is supplied with five units. Each unit contains three vials to prepare technetium Tc-99m exametazime intravenous injection. Five 10-mL vials of Ceretec: a lyophilized mixture of 0.5 mg exametazime. Five 1-mL vials of methylene blue injection USP 1% containing 10 mg methylene blue USP in water for injection. Five 4.5-mL vials of 0.003 M monobasic sodium phosphate USP and dibasic sodium phosphate USP in 0.9% sodium chloride injection USP.
PRODUCT EXPIRY AFTER RECONSITITUTION	
Use the reconstituted, stabilized product containing cobalt solution within five hours after preparation.	Use the reconstituted, stabilized product containing methylene blue and sodium phosphate buffer between 30 minutes and four hours after preparation.

ADMINISTRATION	
Cobalt solution stabilized Ceretec is clear and a syringe filter is not required for reinjection. Visually inspect the reconstituted technetium Tc-99m exametazime injection prior to use, and do not use if there is evidence of particulate matter or discoloration.	Methylene blue stabilized Ceretec is blue in color. A syringe filter is required before reinjection because the color limits visual inspection for particulate matter.
HOW SUPPLIED	
The kit for Ceretec contains: • Five individual 10-mL vials of exametazime • Five individual 10-mL vials of cobalt stabilizer solution • Ten radiation labels • One copy of Prescribing Information	The kit for Ceretec contains: • Five individual 10-mL vials of exametazime • Five individual 1-mL vials of methylene blue injection USP 1% • Five individual 4.5-mL vials of 0.003 M monobasic sodium phosphate USP and dibasic sodium phosphate USP • Ten radiation labels • Five radiochemical purity worksheets • Five labeling efficiency worksheets • Fifteen 0.45 µM syringe filters • One copy of Prescribing Information
PRODUCT NDC NUMBER	
17156-**025**-05	17156-**023**-05

Prescriber Action

1. After March 31, 2019, GE Healthcare will discontinue offering methylene blue and only offer Ceretec packaged with cobalt stabilizer solution.
2. Both stabilizer solutions are optional for cerebral scintigraphy. Do not use methylene blue or cobalt stabilizer solution for leukocyte-labeled scintigraphy.

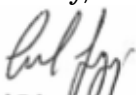
Reporting Adverse Events

Healthcare Providers and patients are encouraged to report adverse events in patients receiving Ceretec to GE Healthcare Adverse Event reporting at 800 654 0118 (option 2, then option 1). You are encouraged to report negative side effects of prescription drugs to the FDA at www.fda.gov/medwatch or by calling 800 FDA 1088.

You can also contact our Medical Affairs department at 800 654 0118 (option 2, then option 3) if you have any questions about the information contained in this letter or the safe and effective use of Ceretec.

This letter is not intended to be a complete description of the benefits and risks related to the use of Ceretec. Please refer to the enclosed full Prescribing Information for each product. For additional information, please call GE Healthcare at 800 292 8514.

Sincerely,



Axel Grippo, General Manager, US Nuclear Pharmacy Services

Enclosures: Full Prescribing Information for each presentation of Ceretec