[Normal Priority] - A26392 : Otsuka— BreathTek Urea Breath Test Kits: FDA Approves Update to Product Labeling

Medical Device Ongoing Action

Published: Wednesday, May 18, 2016
Last Updated: Thursday, May 19, 2016

UMDNS Terms:

- IVD Test Reagent/Kits, Serology, Rapid Test, Bacteria, Helicobacter pylori [19468]

Product Identifier:
BreathTek Urea Breath Test (UBT) Kits *[Consumable]*

Geographic Regions: (Impact in additional regions has not been identified or ruled out at the time of this posting), U.S.

Manufacturer(s): Otsuka America Pharmaceutical Inc 2440 Research Blvd, Rockville, MD 20850, United States

Suggested Distribution: Clinical Laboratory/Pathology, Gastroenterology, Point-of-Care Coordination, Pharmacy, Materials Management

Problem:
In an April 12, 2016, letter submitted by an ECRI Institute member hospital, Otsuka states that FDA has approved updates to the product labeling for the above kits. Otsuka also states that the above kits will not be distributed with the updated package insert and how-to guide for several months. The manufacturer has not confirmed the information provided in the source material.

Action Needed:
Identify any affected product in your inventory. If you have affected product, verify that you have received the April 12, 2016, letter, the new current package insert, and how-to guide from Otsuka. The current package insert and how-to guide are also available for download from the firm's website . Be aware of the following changes to the package insert:
Warnings and Precautions (Section 4)

- The caution for administering the Pranactin-citric solution in diabetic patients was removed.
- The term "antimicrobials" was changed to "antibiotics."
- A clarification was added to recommend the use of the straw supplied in the kit to reduce likelihood of false-positive results.
- The safety of using affected product on pregnant and lactating patients is not established.
- Additional emphasis has been placed on determining infection status in pediatric patients. To obtain pediatric results, you must use a web-based calculation program provided on the website .

Patient Preparation (Section 7)

- Additional information advises patients to stop taking histamine 2-receptor antagonists (H_2RAs) 24 to 48 hours before testing.
- Additional information establishes that patients may continue to take antacids before testing.
- The term "antimicrobials" was changed to "antibiotics." Patients should stop taking antibiotics 2 weeks before testing.
- If a repeat test is required, affected product can be administered on the following day.

Step-by-Step Procedure (Section 8.2)

- After adding water to the Pranactin-citric solution, close the lid securely by pressing down until there is a click before swirling the mixture.
- Not using the straw provided in the kit may result in inaccurate results.
- The patient's breath sample may be collected no later than 30 minutes post-dose.

Notify all relevant personnel at your facility of the information in the letter, and forward a copy of the letter to any facility to which you have further distributed affected product.
For Further Information:
Otsuka
Tel.: (888) 637-3835
Email: productinfo@otsuka.com
Website: Click here

Comments:

- This alert is a living document and may be updated when ECRI Institute receives additional information. In circumstances in which we determine that it is appropriate for customers to repeat their review of an issue (e.g., when additional affected product has been identified), we will post a separate update alert. In other cases, we may add information, such as additional commentary, recommendations, and/or source documents, to the original alert. For additional information regarding the format of this alert, refer to our HDA Format Guide .

Source(s):

- 2016 May 17. Member Hospital. Download