GBS
Group Benefit Services

Compliance Alert

November 23, 2010

Recall of Fentanyl Patches

Recently, Actavis announced a recall of 25mcg per hour fentanyl patches. The company is encouraging consumers to return patches from 18 lots of 25 mcg per hour fentanyl patches. These patches could release drug faster than specifications, which could lead to adverse events for at-risk patients, including excessive sedation, respiratory depression, hypoventilation, and apnea. The lot numbers can be found on the bottom of the box and on the black and white side of each individual patch packaging, in the lower left corner.

Lot	Expiration		Lot	Expiration		Lot	Expiration
30041	12/2011		30241	02/2012		30391	03/2012
30049	12/2011		30256	02/2012		30392	04/2012
30066	12/2011		30257	03/2012		30429	04/2012
30096	01/2012		30258	03/2012		30430	04/2012
30097	02/2012		30349	03/2012		30431	04/2012
30123	01/2012		30350	03/2012		30517	04/2012

Patients should not use the recalled 25 mcg/hr fentanyl patches and should contact ***Actavis at 1-877-422-7452*** for return instructions. No other strengths, lots or manufacturers of fentanyl patches are involved in this recall

Voluntary Recall of Methotrexate Injection Vials

Sandoz has announced a voluntary recall of all lots of Sandoz and Parenta brand Methotrexate Injection 50mg/2mL and 250mg/10mL vials. The vials are being recalled because they may contain small glass flakes. Methotrexate Injection is an antimetabolite used to treat a variety of conditions including cancer, rheumatoid arthritis and psoriasis. There is a small risk that severe adverse events including disability and death could occur if a patient is injected with Methotrexate from an affected lot. Intrathecal administration could result in neurologic damage, intravenous administration could result in local damage to blood vessels in the lung and localized swelling, intramuscular administration could result in localized pain and inflammation, and intra-arterial administration could result in damage to blood vessels in the extremities or organs. To date, Sandoz has not received any reports of adverse events from any lot of Methotrexate, including vials that contain small glass flakes. As a precautionary measure, Sandoz is recalling this product to the consumer level to minimize any potential risk to patients.

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Anyone with this product should not use it and should call the toll free Methotrexate Recall Hotline at 1-888-896-4565 or send an email to Sandoz.methotrexaterecall@gencopharma.com to arrange for the return and reimbursement of the product. Medical questions can be directed to Sandoz at 1-800-525-8747. Patients can also contact their doctor or pharmacist if they have any questions.

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