

PRODUCT UPDATE

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PHARMACY CORNER

New Drug Approved for the Palliative Treatment of Prostate Cancer



Abarelix (Plenaxis™, Praecis Pharmaceuticals, Inc., Waltham, MA) is a potent antagonist of naturally occurring gonadotropin releasing-hormone (GnRH). It inhibits gonadotropin and androgen production by blocking GnRH receptors in the pituitary gland. Abarelix is indicated for the palliative treatment of men with advanced symptomatic prostate cancer who meet the following criteria: They are not candidates for luteinizing hormone-releasing hormone agonist therapy, they refuse surgical castration, and they have a risk of neurologic compromise because of metastases, ureteral or bladder outlet obstruction because of disease, or severe bone pain from skeletal metastases persisting on narcotic analgesics. Abarelix is given as an intramuscular injection every two weeks for the first month followed by once every four weeks. The most common side effects are hot flashes, problems sleeping, pain, breast enlargement or pain, and constipation. Possible adverse effects include serious or life-threatening allergic reactions, allergic skin reactions, prolongation of the QTc interval, changes in liver function, and bone density loss with extended treatment. The effectiveness of abarelix may decrease over time in some patients, and efficacy beyond 12 months has not been established. Because of the risk of serious allergic reactions, patients must be monitored for 30 minutes after each injection.

Physicians, patients, and pharmacies must enroll in the Plenaxis Prescribing Program before the drug will be released. To enroll in the program, call 866-PLENAXIS or visit www.plenaxisplus.com. For more information about the drug, call the previous number or visit www.plenaxis.com.

New Drug Treats Cancer-Related Hypercalcemia

Genta Inc. (Berkeley Heights, NJ) has announced that the U.S. Food and Drug Administration has approved Ganite™ (gallium ni-



trate) for the treatment of cancer-related hypercalcemia. Gallium nitrate originally was developed by the National Cancer Institute as a chemotherapy agent but was found to markedly reduce calcium loss from bone. The exact mechanism of action is unknown, but gallium nitrate is thought to inhibit osteoclast activity and inhibit resorption by reducing bone turnover. Genta Inc. is continuing to investigate gallium nitrate's effectiveness as a chemotherapy agent in several different types of cancer. Gallium nitrate is indicated for the treatment of clearly symptomatic cancer-related hypercalcemia that has not responded to adequate hydration.

Some clinical safety considerations and warnings exist. Gallium nitrate should not be administered to patients with severe renal impairment. Concurrent use of this drug and other drugs that are potentially nephrotoxic may increase the risk of severe renal insufficiency. Adequate hydration is necessary before and during gallium nitrate treatment, but overhydration must be avoided in patients with compromised cardiovascular status. Other potential side effects include hypocalcemia, anemia, decreased serum bicarbonate concentration, asymptomatic hypotension, and acute optic neuritis.

For more information, call 888-864-3682 or visit www.ganite.com. For Genta Inc.'s patient assistance program, visit www.genta.CARES.com.

SAHA Receives Orphan Drug Status for Multiple Myeloma

Suberoylanilide hydroxamic acid (SAHA) (Aton Pharma, Inc., Tarrytown, NY), an inhibitor of histone deacetylase, has been designated by the U.S. Food and Drug Administration (FDA) as an orphan drug for multiple myeloma. Orphan drug designation encourages research and product development by providing incentives to companies. Incentives include seven years of market exclusivity, tax credits for clinical research expenses, waiving of FDA application fees, and potential grant funding. SAHA is being investigated as an oral

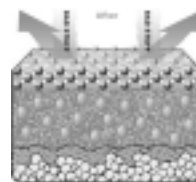
agent as well as for IV routes of administration. It has excellent oral bioavailability and a long duration of action. SAHA also is being tested in other cancers such as T cell lymphomas and metastatic squamous cell cancer of the head and neck. For more information, visit www.atonpharma.com.

Satraplatin Receives Orphan Drug and Fast-Track Status

Satraplatin (GPC Biotech, Martinsreid, Germany) is a member of the platinum family of chemotherapy agents but is administered orally. Satraplatin has been designated by the U.S. Food and Drug Administration for orphan drug and fast-track status for second-line chemotherapy for hormone-refractory prostate cancer. Satraplatin also has indications of activity for small cell lung cancer and ovarian cancer. For more information, visit www.olicode.com/site_usa/drug_pipeline/satraplatin.htm or www.gpc-biotech.com.

NEW PRODUCTS

Skin Treatment Offers Protection Against Dryness and Irritation



A new skin-care product is available called Gloves in a Bottle. This product forms a bond with skin to provide a protective layer to keep skin irritants away from the skin and natural moisture and oils in. Gloves in a Bottle helps the outer layer of skin to keep its moisture, which helps to protect the deeper layers of skin. Skin can breathe and perspire naturally. Gloves in a Bottle does not wash off; it wears off with exfoliating skin cells. For continued protection, it needs to be reapplied every 4–12 hours. Prices start at \$12.95 (plus shipping and handling) for

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an 8 oz. bottle that contains approximately 120 applications. For more information, call 800-600-1881 or visit www.glovesinabottle.com.

Vascular Access Imaging System Aids in Needle Placement



PunctSURE® (Inceptio Medical Technologies, L.C.) is a new ultrasonic vascular imaging system designed for anesthesiologists and cardiologists to locate and identify veins and arteries for needle placement. The system is designed to be hands free, allowing clinicians to use both hands to start an IV while viewing the blood vessels in an imaging monitor. The setup and imaging processes usually take no longer than 90 seconds and allow for needle placement on the first stick. PunctSURE can be powered by battery or AC. The company also offers sterile, disposable procedure kits that contain all of the necessary components to successfully complete each procedure. For more information, call 801-538-0777, ext. 107, or visit www.punctsure.com.

System Allows for Precise Delivery of Radiotherapy

Varian Medical Systems, Inc. (Palo Alto, CA), has announced U.S. Food and Drug Administration approval of the Trilogy™ System. At the center of the Trilogy is the 23EX Clinac linear accelerator. This new accelerator is designed to deliver stereotactic radiosurgery, intensity-modulated radiosurgery, three-dimensional conformal therapy, and traditional radiation therapy. The Trilogy system also in-

corporates Dynamic Targeting™ Image-Guided Radiation Therapy and Portal-Vision™. The system eventually will be able to accommodate an on-board imaging device and software that will give radiation oncologists radiographic, fluoroscopic, and cone-beam computed tomography images for precise patient positioning and tumor localization. For more information, call 800-544-4636 or visit www.varian.com.

Kit Cleans Chemotherapy Work Surfaces

Surface Safe® (SuperGen®, Dublin, CA) is a two-step kit used to clean and inactivate chemotherapy work surfaces. The first towelette

in the kit contains 2% sodium hypochlorite soap solution. The second towelette contains 1% sodium thiosulfate solution with 0.9% benzyl alcohol. Surface Safe towelettes are to be used in numerical order and provide enough solution to clean approximately a two-foot square area. The surface should be allowed to air dry between applications. The towelette should be disposed of in a biohazard waste container. An inactive salt residue may appear after the second application and can be cleaned with distilled water followed by alcohol (not included in the kit). Surface Safe comes in boxes of 15 kits. For more information, call 800-905-5474 or visit www.supergen.com/subpages/products/surfacesafe/surfacesafe_popup.html.

Urgent Product Recall

Janssen Pharmaceutica Products, LP, is recalling one manufacturing lot (**control number 0327192**) of the 75 mcg per hour strength of its prescription Duragesic® (fentanyl transdermal system CII) patches. A small percentage of these patches, which were distributed only in the United States, may leak medication along one edge. No other lots or dosage strengths are affected.

If the medication leaks from the patch, patients can get either too much or too little medication. Exposure to too much medication can occur if the medicine leaks directly onto the skin and the body absorbs a higher than intended amount. This overexposure may cause nausea, sedation, drowsiness, or potentially life-threatening complications. If the medication leaks out,

there may not be enough to provide adequate pain control and the patient may experience withdrawal symptoms.

Healthcare professionals, caregivers, or anyone who comes in contact with an affected patch from this lot also may be at risk. Anyone who comes in contact with the leaked medication should thoroughly rinse exposed skin with water only; do not use soap.

Those who have patches from the affected lot must contact their physician or pharmacist immediately for specific instructions and to coordinate returning affected patches and obtaining a new supply.

For information on this product recall or to report an adverse event, please visit www.Duragesic.com or call 800-JANSSEN.