

PROMIUS® PHARMA LLC ANNOUNCES ZENATANE™ (Isotretinoin Capsules USP) 30MG

Princeton, NJ – March 16th, 2015 – Promius Pharma, LLC has announced that **ZENATANE™ (Isotretinoin Capsules USP)** are now available in a 30mg dose. **Zenatane**, *AB rated equivalent* to Accutane 30mg, has been introduced in response to dermatologists who have continued to request this strength of the drug.

Zenatane 30mg will also be supported by **The Promius Promise**, a pharmacy service designed specifically to support **Zenatane** prescribers and patients. **The Promius Promise** program is designed to assist with patient education about treatment requirements and deliver **Zenatane** within 24 hours to US locations, at a reduced, if not zero, out of pocket expense, for eligible patients*.

“We wanted to deliver what the dermatology community expressed a need for and hopefully meet the needs of patients at the same time,” said Victor Caliman, Associate Director of Marketing for Promius Pharma. “The 30mg size is very popular and generally comprises up to 35% of overall SKU utilization for isotretinoin brands offering it. At this time, Zenatane is one of the only generic isotretinoin products with a 30mg option available. Prescribers can send their prescriptions to the Promius Promise knowing that the 30mg size will be available. Eligible patients will have a money saving rebate automatically applied, and will receive free shipping anywhere in the US. Our trained customer service team is on hand to answer questions for patients until 11pm EST 5 days a week, and from 9am – 3pm EST on Saturdays. The Promius Promise will also assist with insurance questions and challenges if necessary. The Promius Promise is committed to providing the highest level of service possible for patients and providers alike.”

#

Zenatane™ (Isotretinoin Capsules USP) 30 mg Capsules

INDICATIONS AND USAGE

Severe Recalcitrant Nodular Acne

Zenatane™ is indicated for the treatment of severe recalcitrant nodular acne. Nodules are inflammatory lesions with a diameter of 5 mm or greater. The nodules may become suppurative or hemorrhagic. “Severe,” by definition², means “many” as opposed to “few or several” nodules. Because of significant adverse effects associated with its use, Zenatane™ should be reserved for patients with severe nodular acne who are unresponsive to conventional therapy, including systemic antibiotics. In addition, Zenatane™ is indicated only for those female patients who are not pregnant, because Zenatane™ can cause severe birth defects (see **BOXED CONTRAINDICATIONS AND WARNINGS**).



CONTRAINDICATIONS AND WARNINGS

Zenatane™ must not be used by female patients who are or may become pregnant. There is an extremely high risk that severe birth defects will result if pregnancy occurs while taking Zenatane™ in any amount, even for short periods of time. Potentially any fetus exposed during pregnancy can be affected. There are no accurate means of determining whether an exposed fetus has been affected.

Birth defects which have been documented following Zenatane™ exposure include abnormalities of the face, eyes, ears, skull, central nervous system, cardiovascular system, and thymus and parathyroid glands. Cases of IQ scores less than 85 with or without other abnormalities have been reported. There is an increased risk of spontaneous abortion and premature births have been reported.

Documented external abnormalities include: skull abnormality; ear abnormalities (including anotia, micropinna, small or absent external auditory canals); eye abnormalities (including microphthalmia); facial dysmorphia; cleft palate. Documented internal abnormalities include: CNS abnormalities (including cerebral abnormalities, cerebellar malformation, hydrocephalus, microcephaly, cranial nerve deficit); cardiovascular abnormalities; thymus gland abnormality; parathyroid hormone deficiency. In some cases death has occurred with certain of the abnormalities previously noted.

If pregnancy does occur during treatment of a female patient who is taking Zenatane™, Zenatane™ must be discontinued immediately and she should be referred to an Obstetrician-Gynecologist experienced in reproductive toxicity for further evaluation and counseling.

Special Prescribing Requirements

Because of Zenatane™ teratogenicity and to minimize fetal exposure, Zenatane™ is approved for marketing only under a special restricted distribution program approved by the Food and Drug Administration. This program is called iPLEDGE™. Zenatane™ must only be prescribed by prescribers who are registered and activated with the iPLEDGE program. Zenatane™ must only be dispensed by a pharmacy registered and activated with iPLEDGE, and must only be dispensed to patients who are registered and meet all the requirements of iPLEDGE (see PRECAUTIONS).

Please see Full Prescribing Information at www.Zenatane.com

About Promius Pharma, LLC

Promius Pharma is a wholly owned, branded specialty company, of Dr. Reddy’s Laboratories, Inc. It is located in Princeton, NJ. Promius Pharma is a focused, leading-edge company that develops and markets innovative solutions for challenging dermatological conditions with an eye to the future to redefine therapeutic options for physicians and patients. For more information visit www.promiuspharma.com.

*See rebate card for full explanation of eligibility requirements.

For information about the iPLEDGE™ program, call 1.866.495.0654 or visit www.ipledgeprogram.com
iPLEDGE™ is a trademark of McKesson Specialty Arizona Inc.

CONTACT: Suzanne Lane
 Lane Communications Group
 212.757.6880, slane@thelcgroup.com