

Product News

Acticlate

Aqua Pharmaceuticals, LLC, announces US Food and Drug Administration approval of the new drug application for Acticlate (doxycycline hyclate) tablets. Acticlate is a tetracycline-class antibacterial indicated for the treatment of a number of infections, including adjunctive therapy in severe acne. Acticlate is available in film-coated, round 75-mg tablets and oval-shaped, dual-scored 150-mg tablets. Utilizing the latest manufacturing technology, the 150-mg tablets are formulated in a substantially reduced tablet size for Acticlate, allowing for dosing flexibility and making it easier for the patient to swallow. For more information, visit www.aquapharm.com.

ATX-101

Kythera Biopharmaceuticals, Inc, announces that its new drug application for ATX-101 (deoxycholic acid) has been accepted for filing by the US Food and Drug Administration. ATX-101 is an injectable treatment for the reduction of submental fat. The treatment contours the area under the chin by destroying fat cells while leaving surrounding tissue largely unaffected. The new drug application review should be completed by May 13, 2015. For more information, visit www.kytherabiopharma.com/pipeline/ATX-101.

EpiCeram Airless Pump

PuraCap Pharmaceutical LLC adds the EpiCeram 225-g airless pump to its product line. This airless pump gives patients more EpiCeram to treat any size area of atopic dermatitis with twice-daily application. The convenient and portable pump dispenser gives patients more control in applying EpiCeram. A 90-g tube is already available. The EpiCeram Controlled Release Skin Barrier Emulsion helps to relieve the burning and itching associated with skin conditions such as atopic dermatitis and eczema. For more information, visit www.epiceram-us.com.

Hair Regrowth System

brandMD Skin Care introduces the Hair Regrowth System, a 3-step daily regimen to prevent and improve signs of hair loss. The regimen includes the Replenish Shampoo, Restorative Conditioning Treatment, and Rapid Growth Serum. By reducing the production of dihydrotestosterone, the system stimulates hair growth and improves hair follicle anchoring. Both men and women can use the Hair Regrowth System. For more information, visit www.brandMDskincare.com.

Rasuvo

Medac Pharma Inc obtains US Food and Drug Administration approval for Rasuvo, a subcutaneous injectable methotrexate therapy delivered in a single-dose autoinjector for rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, and psoriasis. Rasuvo is available in 10 dosage strengths ranging from 7.5 to 30 mg in 2.5-mg increments. Because of the possibility of serious toxic reactions, Rasuvo should be used only in patients with psoriasis or rheumatoid arthritis with severe, recalcitrant, disabling disease that is not adequately responsive to other forms of therapy. For more information, visit www.rasuvo.com.

Restylane Silk

Valeant Pharmaceuticals International, Inc, obtains US Food and Drug Administration marketing clearance for Restylane Silk injectable gel with 0.3% lidocaine, which is indicated for submucosal implantation for lip augmentation and dermal implantation for correction of perioral rhytides in patients older than 21 years. Restylane Silk is composed of hyaluronic acid and is free from animal protein. Allergy pretesting is not necessary. Restylane Silk should not be used in patients with prior hypersensitivity to local anesthetics of the amide type, such as lidocaine. For more information, visit www.valeant.com.

Zenatane Provider Portal

Promius Pharma, LLC, launches a Web-based provider portal to follow a patient taking Zenatane (isotretinoin). It is designed to allow any authorized prescriber using the Promius Promise pharmacy program to obtain instant access to secure patient data. This portal is valuable for dermatologists to track patient adherence to guidelines for using isotretinoin. It will provide patient demographics, dates of prescriptions received and shipped, and information on pending prescription shipments. A messaging tool also allows health care providers to send questions and receive answers within the portal itself. It maintains strict privacy in accordance with the Health Insurance Portability and Accountability Act.

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