PIPELINE PREVIEWS

Pipeline Previews brings to you information on the newest drugs and medical products as they become available to the dermatologic community. This department may include additional information from the manufacturers, plus reports from physicians who wish to share their clinical experience with these new products. In addition, we will inform our readers about the latest drugs receiving Food and Drug Administration (FDA) approval.

FDA Boxed Warning for Tygacil

The FDA is warning that an analysis shows an increased risk of death when intravenous (IV) Tygacil (tigecycline) is used for FDA-approved uses as well as for non-approved uses. As a result, the FDA approved a new Boxed Warning about this risk to be added to the Tygacil drug label and updated the Warnings and Precautions and the Adverse Reactions sections. A Boxed Warning is the strongest warning given to a drug. These changes to the Tygacil label are based on an additional analysis that was conducted for FDA-approved uses after issuing a Drug Safety Communication (DSC) about this safety concern in September 2010.

Health care professionals should reserve Tygacil for use in situations when alternative treatments are not suitable. Tygacil is FDA-approved to treat complicated skin and skin structure infections (cSSSI), complicated intra-abdominal infections (cIAI), and community-acquired bacterial pneumonia (CABP). Tygacil is not indicated for treatment of diabetic foot infection or for hospital-acquired or ventilator-associated pneumonia. Patients and their caregivers should talk with their health care professionals if they have any questions or concerns about Tygacil.

In the 2010 DSC, the FDA informed the public that a combined analysis, or meta-analysis, of 13 Phase 3 and 4 trials showed a higher risk of death among patients receiving Tygacil compared to other antibacterial drugs: 4.0% (150/3788) vs. 3.0% (110/3646) respectively. The adjusted risk difference for death was 0.6% with corresponding 95% confidence interval (0.1, 1.2). The increased risk was greatest in patients treated with Tygacil for ventilator-associated pneumonia, a use for which the FDA has not approved the drug.

Since issuing the 2010 DSC, the FDA analyzed data from 10 clinical trials conducted only for FDA-approved uses (cSSSI, cIAI, CABP), including trials conducted after the drug was approved. This analysis showed a higher risk of death among patients receiving Tygacil compared to other antibacterial drugs: 2.5% (66/2640) vs. 1.8% (48/2628), respectively. The adjusted risk difference for death was 0.6% with corresponding 95% confidence interval (0.0%, 1.2%). In general, the deaths resulted from worsening infections, complications of infection, or other underlying medical conditions.

FDA Clears Nu Skin Facial Spa Device for Market

Nu Skin Enterprises, Inc. has announced that it has received FDA clearance to market a facial spa device for over-the-counter cosmetic use. The company's 510(k) application was filed approximately one year ago. The company estimates that the facial spa will become available for sale some time during the first half of 2014.

FDA Approves Botox Cosmetic for Crow's Feet

The FDA has approved a new use for Botox Cosmetic (onabotulinumtoxinA) for the temporary improvement in the appearance of moderate to severe lateral canthal lines, known as crow's feet, in adults. Botox Cosmetic is the only FDA approved drug treatment option for lateral canthal lines.

The FDA approved Botox Cosmetic in 2002 for the temporary improvement of glabellar lines in adults. Botox Cosmetic's safety and effectiveness for treating lateral canthal lines were established in two clinical efficacy and safety studies. The studies enrolled 833 adult participants with moderate to severe lateral canthal lines who were randomly assigned to receive Botox or placebo. Results showed that those treated with Botox had greater improvement compared to placebo in the appearance of lateral canthal lines.

The most common adverse reaction associated with the use of Botox Cosmetic for treatment of lateral canthal lines is eyelid edema, a condition in which the eyelids are swollen and contain excessive fluid.

OnabotulinumtoxinA is marketed as Botox and Botox Cosmetic. The FDA approved Botox for the treatment of chronic migraine, severe underarm sweating, blepharospasm (eyelid spasm) and strabismus (misalignment of the eyes when one or both eyes turn inward or outward). Botox and Botox Cosmetic have a boxed warning that says the effects of the botulinum toxin may spread from the area of injection to other areas of the body, causing symptoms similar to those of botulism. Those symptoms include swallowing and breathing difficulties that can be life-threatening. There has not been a confirmed serious case of toxin spread when Botox or Botox Cosmetic has been used at the recommended dose for the approved indications.

FDA Approves Generic Hydrocortisone Butyrate Cream

Glenmark Generics has received abbreviated new drug approval (ANDA) from the FDA for hydrocortisone butyrate cream USP, 0.1 per cent, a generic version of Locoid Lipocream. Glenmark is entitled to 180 days of exclusivity with respect to its hydrocortisone butyrate cream, as it is the first generic company to file an ANDA for the product. Hydrocortisone butyrate cream is indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses in adults and the treatment of mild to moderate atopic dermatitis in patients three months to 18 years of age.