What's in News

News from Regulatory Corner: Safety Communication and Recent Drug Approvals

**Dapsone Causes Falsely Low Values of Glycosylated Hemoglobin in Diabetics**

Dapsone is still used very commonly as a part of multidrug therapy for leprosy and also for other dermatologic indications such as dermatitis herpetiformis, linear immunoglobulin A bullous dermatosis, chronic bullous dermatosis of childhood, bullous systemic erythematosus lupus, and erythema elevatum diutinum among other indications.\(^1\)

Diabetes is an important health problem in India and abroad. In patients with diabetes who are also receiving dapsone, one should be aware that dapsone causes falsely low hemoglobin A1c (HbA1c) values due to the accelerated red blood cell turnover. Monitoring fructosamine levels avoids this potential confounder.\(^2-4\)

Dapsone leads to a falsely low HbA1c through three mechanisms. One of the mechanisms by which dapsone can cause a misleadingly low HbA1c is by inducing hemolysis. Second, dapsone promotes the oxidation of hemoglobin to methemoglobin, which interferes with the high-performance liquid chromatography assay used to measure HbA1c since it will not spike in the correct HbA1c location, and hence, will give a falsely low value. Finally, dapsone is thought to reduce erythrocyte survival independent of its hemolytic effect.\(^5-9\)

**Griseofulvin and Conception**

Regarding griseofulvin-nowadays, with the rampant surge in treatment failure that is observed in cutaneous dermatophytoses, griseofulvin is also used in cutaneous dermatophytoes apart from terbinafine, fluconazole, and itraconazole. There are conflicting reports of teratogenicity and griseofulvin. As griseofulvin interferes with chromosomal distribution during cell division, it has been suggested that males should wait at least 6 months after completing griseofulvin therapy before fathering a child.\(^10,11\) As per Fuller et al., the drug is contraindicated in pregnancy, and men are cautioned against fathering a child for 6 months after treatment.\(^12\) However, a study by Czeizel et al. do not indicate a detectable teratogenic risk of oral griseofulvin treatment during pregnancy; however, the numbers of cases and controls were limited in the study.\(^13\) Amidst these conflicting reports, a caution must be exercised while prescribing griseofulvin to patients of childbearing age suffering from fungal infection.

**Biotin Supplementation Can Affect Results of Thyroid Tests**

A lot of patients seen by dermatologists receive biotin supplements for purported benefit for hair and nail diseases. Patients also take multivitamin preparations on their own and may be also prescribed multivitamins by their internal physicians. These other multivitamins may also contain biotin. High-dose biotin can interfere with the results of thyroid and other tests leading to wrong diagnosis and even erroneous treatment.\(^14,15\)

**Over-the-counter (Otc) Consumer Antiseptic Wash Products Containing Certain Active Ingredients Can No Longer be Marketed**

September 2, 2016

The U.S. Food and Drug Administration today issued a final rule establishing that over-the-counter consumer antiseptic wash products containing certain active ingredients can no longer be marketed. This final rule applies to consumer antiseptic wash products containing one or more of 19 specific active ingredients, including the most commonly used ingredients—triclosan and triclocarban. These products are intended for use with water and are rinsed off after use. This rule does not affect consumer hand “sanitizers” or wipes, or antibacterial products used in health-care settings. (Source: www.usfda.gov.press announcements).

**Eucrisa (Crisaborole) Ointment to Treat Mild to Moderate Eczema (Atopic Dermatitis)**

December 14, 2016

The U.S. Food and Drug Administration today approved Eucrisa (crisaborole) ointment to treat mild-to-moderate eczema (atopic dermatitis) in patients 2 years of age and older. Crisaborole is a phosphodiesterase 4 (PDE-4) inhibitor. PDE-4 inhibition results in increased intracellular cyclic adenosine monophosphate levels. The specific mechanism by which crisaborole exerts its therapeutic action for the treatment of atopic dermatitis is not well defined. (Source: https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/207695s000lbl.pdf).

**SiliQ (Brodalumab) to Treat Adults With Moderate-to-Severe Plaque Psoriasis**

February 15, 2017

The U.S. Food and Drug Administration today approved Siliq (brodalumab) to treat adults with moderate-to-severe plaque psoriasis.

Brodalumab is a human monoclonal IgG2 antibody that selectively binds to human IL-17RA and inhibits its
interactions with cytokines interleukin (IL)-17A, IL-17F, IL-17C, IL-17A/F heterodimer, and IL-25. IL-17RA is a protein expressed on the cell surface and is a required component of receptor complexes utilized by multiple IL-17 family cytokines. Blocking IL-17RA inhibits IL-17 cytokine-induced responses, including the release of pro-inflammatory cytokines and chemokines. (Source: https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/761032lbl.pdf).

**DUPIXENT (DUPILUMAB) SUBCUTANEOUS INJECTION TO TREAT ADULTS WITH MODERATE-TO-SEVERE ECZEMA (ATOPIC DERMATITIS)**

March 28, 2017

The U.S. Food and Drug Administration today approved Dupixent (dupilumab) subcutaneous injection to treat adults with moderate-to-severe eczema (atopic dermatitis). Dupixent is intended for patients whose eczema is not controlled adequately by topical therapies, or those for whom topical therapies are not advisable. Dupixent can be used with or without topical corticosteroids.

Dupilumab is a human monoclonal IgG4 antibody that inhibits IL-4 and IL-13 signaling by specifically binding to the IL-4Rα subunit shared by the IL-4 and IL-13 receptor complexes. Dupilumab inhibits IL-4 signaling through the Type I receptor and both IL-4 and IL-13 signaling through the Type II receptor. Blocking IL-4Rα with dupilumab inhibits IL-4 and IL-13 cytokine-induced responses, including the release of proinflammatory cytokines, chemokines, and IgE. Source: https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/761055lbl.pdf.

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**Conflicts of interest**

There are no conflicts of interest.

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