
A^{PhA} **DrugInfoLine[®]**

July 2019

[OTC Medicines Corner](#)

Advising on this article: Tara Whetsel

July 2, 2019

New study shows systemic absorption of topical sunscreen products

Key Point

Application of four commercially available topical sunscreen products under maximal use conditions resulted in plasma concentrations that exceeded FDA-established thresholds for waiving nonclinical toxicology studies, suggesting additional research is needed to assess the safety of these products, according to results of a pilot study published in JAMA.

Source URL:

<http://www.aphadruginfoline.com/otc-medicines-corner/new-study-shows-systemic-absorption-topical-sunscreen-products>

[Neurology](#)

Advising on this article: Jack J. Chen

July 2, 2019

AAN releases practice guideline on management of tics

Key Point

The American Academy of Neurology (AAN) published in *Neurology* a guideline on management of tics in patients with Tourette syndrome and chronic tic disorders that focuses on behavioral interventions, pharmacotherapy, and suggestions for future research.

Source URL:

<http://www.aphadruginfoline.com/neurology/aan-releases-practice-guideline-management-tics>

[Drug Interactions Corner](#)

Advising on this article: Daniel S. Streetman

July 8, 2019

Drug interaction alerts and override reasons can be substantially improved

Key Point

An assessment of drug–drug interaction (DDI) alert override reasons in electronic health records (EHRs) found that override reasons were variable, with many not actionable and some irrelevant to the DDI. The report, published in the Journal of the American Medical Informatics Association, suggests that both the quality of alerts and alert override reasons need substantial improvement and should be more specific to the interaction and the patient.

Source URL:

<http://www.aphadruginfoline.com/drug-interactions-corner/drug-interaction-alerts-and-override-reasons-can-be-substantially-improved>

[Endocrinology](#)

Advising on this article: Frank Pucino

July 8, 2019

Guideline recommends against thyroid hormones for subclinical hypothyroidism

Key Point

Many adults with subclinical hypothyroidism, defined as elevated thyroid stimulating hormone (TSH) levels and normal thyroxine (T4) levels, may not need thyroid hormone supplementation with drugs such as levothyroxine, according to a new clinical practice guideline published by an international panel in the British Medical Journal.

Source URL:

<http://www.aphadruginfoline.com/endocrinology/guideline-recommends-against-thyroid-hormones-subclinical-hypothyroidism>

Supplemental Approvals

Generic Name (Trade Name—Company)

July 1, 2019

Bevacizumab-bvzr

(Zirabev—Pfizer)

Pfizer gains approval for its oncology biosimilar, bevacizumab-bvzr

Uses/Notes

Pfizer has received FDA [approval](https://www.pfizer.com/news/press-release/press-release-detail/pfizer_receives_u_s_fda_approval_for_its_oncology_biosimilar_zirabev_bevacizumab_bvzr) for bevacizumab-bvzr, a biosimilar to bevacizumab (Avastin), for treatment of five types of cancer: metastatic colorectal cancer; unresectable, locally advanced, recurrent, or metastatic nonsquamous non-small cell lung cancer (NSCLC); recurrent glioblastoma; metastatic renal cell carcinoma (RCC); and persistent, recurrent, or metastatic cervical cancer. It works by inhibiting the formation of new blood cells (angiogenesis) by specifically recognizing and binding to vascular endothelial growth factor (VEGF) protein. FDA approval was based on review of a comprehensive data package that demonstrated biosimilarity of bevacizumab-bvzr to the reference product. The most common adverse reactions are epistaxis, headache, hypertension, rhinitis, proteinuria, taste alteration, dry skin, rectal hemorrhage, lacrimation disorder, back pain, and exfoliative dermatitis. See the [prescribing information](http://labeling.pfizer.com/ShowLabeling.aspx?id=11860) for dosage instructions.

Source URL:

<http://www.aphadruginfoline.com/supplemental-approvals/pfizer-gains-approval-its-oncology-biosimilar-bevacizumab-bvzr>

Supplemental Approvals

Generic Name (Trade Name—Company)

July 1, 2019

Avatrombopag

(Doptelet—Dova Pharmaceuticals)

Avatrombopag has new indication for treatment of chronic immune thrombocytopenia

Uses/Notes

FDA [approved](http://investors.dova.com/news-releases/news-release-details/dova-pharmaceuticals-announces-fda-approval-supplemental-new) an expanded use of avatrombopag for treatment of thrombocytopenia in adults with chronic immune thrombocytopenia (ITP) who have had an insufficient response to a previous treatment.

Avatrombopag was previously approved for treatment of thrombocytopenia in adult patients with chronic liver disease (CLD) who are scheduled to undergo a procedure.

The drug is an oral thrombopoietin receptor agonist administered with food.

In the pivotal Phase III study, administration of avatrombopag resulted in a platelet count of at least 50,000 per μL at day eight of therapy in the majority of patients. Efficacy was superior to placebo in maintaining platelet counts in the target range during the 6-month treatment period.

The most common adverse reactions in patients with chronic immune thrombocytopenia are headache, fatigue, contusion, epistaxis, upper respiratory tract infection, arthralgia, gingival bleeding, petechiae, and nasopharyngitis.

Full prescribing information is available at [www.Dova.com](https://www.globenewswire.com/Tracker?data=CZw4OZrUi7sttPNPF0oW6CFy8e35tE_q_ip2Ur2g2YAjJ3yDRk9F7vgf7Y6o-gwdyCqsOhULGd-vzeE4CWIV5ivO862plq-unWV92bjMcrUKKEbA16ez48xbWavANnP).

Source URL:

<http://www.aphadruginfoline.com/supplemental-approvals/avatrombopag-has-new-indication-treatment-chronic-immune-thrombocytopenia>

New Drug Approvals

Generic Name (Trade Name—Company)

July 8, 2019

Selinexor

Uses/Notes

FDA granted https://www.fda.gov/news-events/press-announcements/fda-approves-new-treatment-refractory-multiple-myeloma?utm_campaign=FDA%20approves%20new%20treatment%20for%20refractory%20multiple%20myeloma%20Drug%20Inform&utm_medium=email&utm_source=Eloqua accelerated approval to selinexor tablets in combination with the corticosteroid dexamethasone for treatment of adult patients with relapsed refractory multiple myeloma (RRMM) who have received at least four prior therapies and whose disease is resistant to several other forms of treatment, including at least two proteasome inhibitors, at least two immunomodulatory agents, and an anti-CD38 monoclonal antibody.

Efficacy was evaluated in 83 patients with RRMM who were treated with selinexor in combination with dexamethasone. At the end of the study, the overall response rate was measured at 25.3%. The median time to first response was 4 weeks, with a range of 1 to 10 weeks. The median duration of response was 3.8 months. The efficacy evaluation was supported by additional information from an ongoing, randomized trial in patients with multiple myeloma.

Common adverse effects of patients taking selinexor in combination with dexamethasone included leukopenia, neutropenia, thrombocytopenia, and anemia. Patients also reported vomiting, nausea, fatigue, diarrhea, fever, decreased appetite and weight, constipation, upper respiratory tract infections, and low blood sodium levels.

Health professionals are advised to monitor patients for low blood counts, platelets, and sodium levels. Patients should avoid taking selinexor with other medications that may cause dizziness or confusion and avoid situations where dizziness may be a problem. Health professionals also are advised to optimize the patient's hydration status, blood counts, and other medications to avoid dizziness or confusion.

Females of reproductive age and males with a female partner of reproductive potential should use effective contraception during treatment. Women who are pregnant or breastfeeding should not take selinexor because it may cause harm to a developing fetus or newborn baby. Selinexor must be dispensed with a patient Medication Guide that

(Xpovio—Karyopharm Therapeutics)

FDA approves new treatment for refractory multiple myeloma

describes important information about the drug's uses and risks.

Source URL:

<http://www.aphadruonline.com/new-drug-approvals/fda-approves-new-treatment-refractory-multiple-myeloma>

Supplemental Approvals

Generic Name (Trade Name—Company)

July 8, 2019

Tiopronin

(Thiola—Retrophin)

New formulation of tiopronin treatment for cystinuria can be taken with or without food

Uses/Notes

[Retrophin](http://ir.retrophin.com/news-releases/news-release-details/retrophin-announces-fda-approval-thiolar-ec-tiopronin-100mg-and) [announced](http://ir.retrophin.com/news-releases/news-release-details/retrophin-announces-fda-approval-thiolar-ec-tiopronin-100mg-and) [FDA](http://ir.retrophin.com/news-releases/news-release-details/retrophin-announces-fda-approval-thiolar-ec-tiopronin-100mg-and) approval of 100-mg and 300-mg tablets of tiopronin, a new enteric-coated formulation, for treatment of cystinuria. This rare inherited disorder causes a buildup of cystine levels in the urine, resulting in the formation of recurring cystine kidney stones.

The new formulation can be administered with or without food, whereas the original formulation of 100 mg tiopronin is recommended to be taken at least 1 hour before or 2 hours after meals.

The recommended initial dosage of tiopronin in adult patients is 800 mg per day. In clinical studies, the average dose was approximately 1,000 mg, or 10 tablets per day.

The most common adverse reactions are nausea, diarrhea or soft stools, oral ulcers, rash, fatigue, fever, arthralgia, proteinuria, and emesis.

Source URL:

<http://www.aphadruginfoline.com/supplemental-approvals/new-formulation-tiopronin-treatment-cystinuria-can-be-taken-or-without-food>

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