Drug & Poison Information Center Bulletin

Faculty of Pharmacy - Tanta University

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Special points of interest

The FDA has granted emergency use authorization (EUA) to **a first-of-its-kind test** that can detect SARS-CoV-2 in the breath in less than 3 minutes. The COVID-19 Breathalyzer test (InspectIR Systems, LLC) will be available only in licensed test settings, therefore it is not currently meant for home use.

Inside this issue

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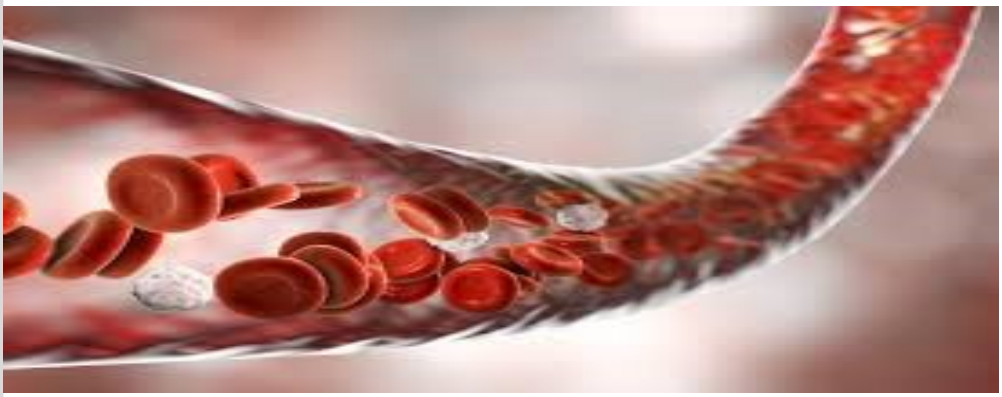
MGMT. SYS. RvA C 071

FDA approves first drug for rare inherited anemia



The US Food and Drug Administration (FDA) has approved a new drug for hemolytic anaemia in adults with pyruvate kinase (PK) deficiency that is both the first in its class and the first disease -modifying agent. **Mitapivat** (Pyrukynd, Agios Inc) was approved after clinical trials showed that it significantly reduced hemolysis and anaemia in patients with PK deficiency.

PK deficiency is rare. In clinical practice, its frequency is approximately three to nine cases per one million people, the FDA noted. However, PK deficiency likely is misdiagnosed or undiagnosed, making it difficult to determine its frequency in the general population. PK deficiency is an inherited disorder that causes premature red blood cell destruction, leading to anemia, the agency explained in its announcement. Symptoms of PK deficiency range in severity and include fatigue, unusually pale skin, jaundice, shortness of breath, and a fast heart rate. Patients can also develop an enlarged spleen, can have too much iron in their blood from repeated blood transfusions, and can develop gallstones.

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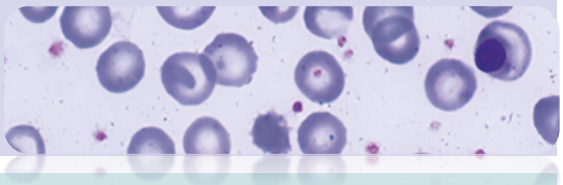

The FDA warns of drug interactions that could necessitate dose adjustments, and also the abruptly stopping mitapivat could worsen premature red blood cell destruction.

Clinical data that formed the basis of the approval came from two trials, one of which was a randomized placebo-controlled trial, and the other a single-arm study. In these studies, patients received up to 50 mg of mitapivat orally twice daily after an initial dose-titration period. The randomized trial involved 80 adults with PK deficiency who were not having regular blood transfusions. At the end of the study, 40% of participants who received mitapivat had a hemoglobin response, compared with no participants who received placebo. The single-arm study involved 27 adults with PK deficiency who were receiving regular blood transfusions. The results show that 33% of participants who received mitavipat met this reduction in transfusion burden; 22% of participants did not require any transfusions over the last 24 weeks of treatment. The most common side effects reported were decreases in estrone and estradiol in men, increased urate level, back pain, and joint stiffness. The effects of estrone and estradiol could not be reliably assessed in women because of normal changes in these hormone levels during the menstrual cycle and use of hormonal contraception.

References:

1. *FDA approves treatment for anemia in adults with rare inherited disorder. Available at: https://www.fda.gov/drugs/news-events-human-drugs/fda-approves-treatment-anemia-adults-rare-inherited-disorder. Accessed in March, 2022.*
2. *FDA Approves First Drug for Rare Inherited Anemia. Available at: https://www.medscape.com/viewarticle/968795. Accessed in March, 2022.*

By: Ph. Mai Mousa, PharmD.

In a shocking, dapagliflozin withdrawal for type 1 diabetes in EU

Dapagliflozin is a sodium glucose co-transporter 2 (SGLT2) inhibitor that has been indicated for the treatment of type 2 diabetes since 2012. It is also indicated in adults for the treatment of symptomatic chronic heart failure with reduced ejection fraction and for patients with chronic kidney disease. Dapagliflozin was authorized in 2019 by the European Medicines Agency (EMA) as an adjunct to insulin in patients with type 1 diabetes with a body mass index (BMI) of ≥27 kg/m^2, when insulin alone does not provide adequate glycemic control despite optimal insulin therapy. Dapagliflozin was the only SGLT2 inhibitor that was available for treatment of type 1 diabetes.

On 25 October 2021, the marketing authorization holder for dapagliflozin withdrew the indication for type 1 diabetes across Europe and in the UK. A letter was sent to UK healthcare professionals to inform them of the withdrawal. As such, patients with type 1 diabetes should discontinue dapagliflozin 5 mg in consultation with their specialist diabetes physician as soon as clinically practical. After stopping dapagliflozin treatment, frequent blood glucose monitoring is recommended. Additionally, an increased insulin dose may be needed, which should be undertaken carefully to minimize the risk of hypoglycaemia or hyperglycaemia.

This withdrawal decision was voluntarily by the MOH and followed commercial considerations due to a specific European wide regulatory requirement for this authorization. The decision was not driven by any new safety concerns, such as the already known increased risk of diabetic ketoacidosis in type 1 diabetes compared with type 2 diabetes. **Other indications for dapagliflozin 5 mg and 10 mg are not affected by this licensing change and both strengths will remain on the market.**

References:

1. *Dapagliflozin (Forxiga): no longer authorised for treatment of type 1 diabetes mellitus. https://www.gov.uk/drug-safety-update/dapagliflozin-forxiga-no-longer-authorised-for-treatment-of-type-1 diabetes-mellitus. Published 10 December 2021. Accessed 27 January 2022.*
2. *Davenport L. Outrage Over Dapagliflozin Withdrawal for Type 1 Diabetes in EU. https://www.medscape.com/viewarticle/964844#vp_3. Published 15 December 2021. Accessed 27 January 2022.*

By: Ph. Bassant M. Mahboub, M.Sc.

New contact lens for ocular allergy

The FDA has approved a new contact lens that elutes the antihistamine ketotifen as a treatment for ocular allergy. The lenses are daily disposable contacts indicated for the prevention of ocular itch due to allergic conjunctivitis in people who do not have red eyes, are suitable for wearing contact lenses, and do not have more than 1.00 D of astigmatism.

Antihistamine eye drops are contraindicated for use with contact lenses because eye drop preservatives could interact with the lenses, and clinical trials generally exclude contact lens wearers. Johnson & Johnson worked for over a decade to find an antihistamine that paired well with a contact lens material, finally hitting on the combination of ketotifen and etafilcon A .

The drug is integrated into the polymer during manufacturing. In contact with the eye, the drug diffuses from the lens into the tear film and is absorbed by the ocular tissues, much like a conventional eye drop. Because the lens is kept sterilized until use, no preservatives are added to the medication. This is an advantage because preservatives cause irritation in some patients. The new contact lens "is promising for those who have contact lenses and the 20% to 40% of the American population who have allergies," said Leonard Bielory, MD, a professor of medicine, allergy, immunology, and ophthalmology at Hackensack Meridian School of Medicine in Nutley, New Jersey, who was not involved in the trial or in developing the lens.

References:

1. *New Contact Lens Elutes Antihistamine for Ocular Allergy. https://www.medscape.com/viewarticle/970151?src=. Accessed in March, 2022.*
2. *FDA-Approved Contact Lens Delivers Antihistamine for Eye Allergy Relief. Available at: https://www.everydayhealth.com/vision/new-fda-approved-contact-lens-delivers-antihistamine-for-eye-allergy-relief/. Accessed in March, 2022.*

By: Ph. Marwa EL-Sayed, PGCPD.

Surprising hidden foods

The food we eat goes through a lot of chemical processing and we often fail to understand what all ingredients are added to make the food look alluring and picture perfect on the supermarket shelf or restaurant.

A-Surprising Sources of Hidden Caffeine

Some food or drinks may contain traces of caffeine which has effect on blood pressure and sleeping issues, for examples:-

⇒ Decaffeinated coffee

⇒ Non-cola soft drinks

⇒ Chocolate the darker the chocolate, the higher the caffeine content.

⇒ Many pain relievers incorporate caffeine to ease the pain, but if you take more than the label suggests, you could be taking more than you need. Two Excedrin Migraine tablets have 130 milligrams of caffeine

⇒ Some Chewing gum

Caffeine content of drinks and foods

DRINKS/FOODS	VOLUME	CAFFEINE (MG) MEAN (RANGE)
Filtered coffee	125ml	85 (60–135)
Espresso	30ml	60 (35–100)
Soluble instant coffee	125ml	65 (35–105)
Decaffeinated coffee	125ml	3 (1–5)
Tea (leaves or bag)	150ml	32 (20–45)
Iced tea	330ml	20 (10–50)
Hot chocolate	150ml	4 (2–7)
Caffeinated soft drinks	330ml	39 (30–48)
Sugar-free caffeinated soft drinks	330ml	41 (26–57)
Energy drinks	330ml	80 (70–120)
Chocolate bar	30g	20 (5–36)
Milk chocolate	30g	6 (1–15)
Dark chocolate	30g	60 (20–120)

Data adapted from Illy et al., Harland et al., and Heckman et al[2,3,4].

B-Surprising Sources of Hidden Salt

Salt is naturally present at low levels in all foods but around 80% of our salt intake is hidden in processed food. Most of the salt children and adults eat is hidden in processed and convenience foods, and the rest comes from salt added during cooking and any salt added at the table. Apple sauce, apple juice, dried apples, jams made from apples and guavas are also sodium-rich

Do you know where salt is hiding in your food?

⇒Frozen meals.

⇒Canned or pickled foods.

⇒Snack foods.

⇒Cheese.

⇒Salty nuts.

⇒Condiments, sauces and dressings.

⇒Breads.

⇒Cereals.

⇒Soda (including diet soda).

⇒Sausage and bacon.

⇒Yeast extract.

⇒Corn &potato snacks.

⇒Cakes and pastries.

⇒Canned food.

⇒Breads and rolls: Each piece can have up to 230 mg of sodium.

⇒Pizza: One slice can have up to 760 mg of sodium.

⇒Cold cuts and cured meats: Two slices of bologna has 578 mg of sodium.

⇒Poultry: Especially chicken nuggets. Just 3 ounces have nearly 600 mg of sodium.

⇒Canned soups: One cup of canned chicken noodle soup can have up to 940 mg of sodium.

C-Surprising sources of hidden sugar

It is very important for diabetics to regulate blood sugar; considering their food and drinks. So regarding these kinds of food is a necessary

Pasta Sauces	Granola Bars
Yogurt	Salad Dressing
Instant Oatmeal	Breakfast Cereals
Energy Drinks	Packaged Fruits
Coleslaw	Lemon-flavored iced tea
Dried Fruit	Ketchup
Barbecue (BBQ) sauce	Fruit juice
Spaghetti sauce	Sports drinks
Chocolate milk	Flavored coffees
Protein bars	Premade soup
Breakfast cereal	canned baked beans
Peanut Butter	Flavored milk

References:

- *Food facts. Available at: https://www.nhs.uk/healthier-families/food-facts/. Accessed in April, 2022*
- *17 Foods and Drinks That Are Surprisingly High in Sugar. Available at: https://www.healthline.com/nutrition/18-surprising-foods-high-in-sugar. Accessed in April, 2022.*

By: Ph. Nahla EL-Deep, B.Sc.

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https://pha.tanta.edu.eg/units/Drug%20Information/Default.aspx

Vision

The vision of Tanta University DPIC is to improve national healthcare service through provision of evidence-based, unbiased, patient oriented drug information services & adverse drug reporting system.

Mission

* Responding to drug inquiries related to the use of the drug and providing the health care professionals and patients with drug information related to the patient's care to achieve the optimal use of the drug in addition to the provision of other toxicological managing information.
* Educational activities to support the rational optimal use of drugs as well, supporting research activities.
* Continuous medical education and training courses in various fields of pharmacy for students, undergraduates, postgraduate students, and researchers.
* Issuing a Drug Information Bulletin periodically to take a look at medical & pharmaceutical news.
* Supporting the National Pharmaceutical Vigilance Program by following up and monitoring side effects and problems related to use of pharmaceutical preparations within regional hospitals.
* Contributing to the establishment of various treatment protocols and prescription booklet services in regional hospitals.

Editorial board