Drug & Poison Information Center Bulletin

Faculty of Pharmacy - Tanta University

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FDA approves a novel, dual-targeted medication for Type 2 Diabetes

On May 13th, the United States Food and Drug Administration (FDA) approved Tirzepatide (Mounjaro™) injection to improve glycemic control in adult patients with type 2 diabetes as an adjunct to diet and exercise. Tirzepatide is not indicated for use in patients with type 1 diabetes mellitus. Tirzepatide has dual mechanism of action, as it is a glucagon-like peptide-1 (GLP-1) receptor and glucagon-dependent insulintropic peptide (GIP) receptor agonist. Tirzepatide selectively binds to and activates both the GLP-1 and GIP receptors, the targets for native GLP-1 and GIP respectively. GLP-1 and GIP are hormones involved in glycemic control. Tirzepatide is a first-in-class medication that activates the receptors of both hormones which leads to improved glycemic control. The drug enhances first- and second-phase insulin secretion and reduces glucagon levels, both in a glucose-dependent manner.

Dosage & administration:

Tirzepatide is administered by subcutaneous injection once weekly, with the dose adjusted as tolerated to meet treatment goals. The recommended starting dose of tirzepatide is 2.5 mg injected subcutaneously once weekly. This dose is for treatment initiation and not for achieving glycemic control. After 4 weeks, the dose is increased to 5 mg injected subcutaneously once weekly. If additional glycemic control is needed the dose can be increased by 2.5 mg increments after at least 4 weeks on the current dose. The maximum dose is 15 mg injected subcutaneously once weekly.

Clinical data:

The effectiveness of tirzepatide as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus was established in five trials. In these trials tirzepatide was studied as a monotherapy, as an add-on to metformin, sulfonylureas, and/or sodium-glucose co-transporter 2 inhibitors (SGLT2 inhibitors); and in combination with basal insulin with or without metformin. Three different doses of tirzepatide (5 mg, 10 mg, and 15 mg given subcutaneously once weekly) was compared with placebo, semaglutide 1 mg, insulin degludec, and/or insulin glargine.

On average, patients randomized to receive the maximum recommended dose of tirzepatide (15 milligrams) had lowering of their hemoglobin A1c (HbA1c) level by 1.6% more than placebo when used as stand-alone therapy, and 1.5% more than placebo when used in combination with insulin glargine. In trials comparing tirzepatide to other diabetes medications, patients who received the maximum recommended dose of tirzepatide had lowering of their HbA1c by 0.5% more than semaglutide, 0.9% more than insulin degludec and 1.0% more than insulin glargine. Tirzepatide's effect on weight was also studied, as obesity was common among study participants with body mass index (BMI) ranging from 32 kg/m2 to 34 kg/m2 reported at the time of enrollment. Patients randomized to the maximum recommended dose, the average weight loss with tirzepatide was 6.8 kilograms more than placebo when neither were used with insulin and 10.4 kilograms more than placebo when both were used with insulin. The average weight loss with the maximum recommended dose of tirzepatide was 5.4 kilograms more than semaglutide, 13.1 kilograms more than insulin degludec and 12.2 kilograms more than insulin glargine. Those patients receiving insulin without tirzepatide tended to gain weight during the study.

Safety:

Tirzepatide's most common adverse effects are: nausea, diarrhea, decreased appetite, vomiting, constipation, dyspepsia, and abdominal pain.

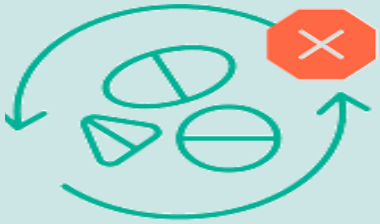
In both sexes of rats, tirzepatide caused a dose-dependent and treatment-duration-dependent increase in the incidence of thyroid C-cell tumors (adenomas and carcinomas) in a 2-year study at clinically relevant plasma exposures.

Acute pancreatitis, including fatal and non-fatal hemorrhagic or necrotizing pancreatitis, has been observed in patients treated with GLP-1 receptor agonists. Tirzepatide has not been studied in patients with a prior history of pancreatitis. It is unknown if patients with a history of pancreatitis are at higher risk for the development of pancreatitis on tirzepatide.

Contraindications:

Tirzepatide is contraindicated in patients with a personal or family history of medullary thyroid carcinoma (MTC) or in patients with multiple endocrine neoplasia syndrome type 2 (MEN 2).

Drug interactions: Tirzepatide delays gastric emptying, and thereby has the potential to impact the absorption of concomitantly administered oral medications. Moreover, if tirzepatide is concomitantly used with insulin secretagogue or insulin, reducing the dose of concomitantly administered insulin secretagogues or insulin should be considered to reduce the risk of hypoglycemia.



Use in pediatrics & geriatrics :

Safety and effectiveness of tirzepatide have not been established in pediatric patients (younger than 18 years of age). For geriatric patients, no overall differences in safety or efficacy were detected between these patients and younger patients during clinical trials.

References:

- *FDA News Release concerning Tirzepatide: Available at: https://www.fda.gov/news-events/press announcements/fda-approves-novel-dual-targeted-treatment-type-2-diabetes. Accessed in May, 2022.*
- *Tirzepatide's label at Drugs@FDA. Available at https://www.accessdata.fda.gov/ drugsatfda_docs/label/2022/215866s000lbl.pdf. Accessed in May, 2022.*
- *Tirzepatide retail price from Medscape Medical News. Avialble at: https://www.medscape.com/ viewarticle/974390. Accessed in May, 2022.*

By: Amr Noweir, B.Sc

June 2022 - FDA Drug Safety Communication

Due to safety concerns, the U.S. Food and Drug Administration (FDA) has withdrawn its approval for the cancer medicine Ukoniq (umbralisib). Ukoniq was approved to treat two specific types of lymphoma: marginal zone lymphoma (MZL) and follicular lymphoma (FL). Updated findings from the UNITY-CLL clinical trial continued to show a possible increased risk of death in patients receiving Ukoniq. The drug's manufacturer, TG Therapeutics, announced that it was voluntarily withdrawing Ukoniq from the market for the approved uses in MZL and FL.

Health care professionals should stop prescribing Ukoniq and switch patients to alternative treatments. Inform patients currently taking Ukoniq of the increased risk of death seen in the clinical trial and advise them to stop taking the medicine. In limited circumstances in which a patient may be receiving benefit from Ukoniq, TG Therapeutics plans to make it available under expanded access.

Patients should talk to your health care professionals about alternative treatments and stop taking Ukoniq. It is best to dispose of unused Ukoniq using a drug take-back location such as in a pharmacy, but if one is not available, you can dispose of Ukoniq in your household trash by doing the following:

⇒ *Mix the medicine with an unappealing substance such as dirt, cat litter, or used coffee grounds; do not crush them.*

⇒ *Place the mixture in a container such as a sealed plastic bag.*

⇒ *Throw away the container in your home trash.*

⇒ *Delete all personal information on the prescription labels of empty medicine bottles or packaging, then throw away or recycle them.*

- ***For more detailed information, contact FDA at: 855-543-DRUG (3784) and press 4 druginfo@fda.hhs.gov .***
- ***FDA approval of lymphoma medicine Ukoniq (umbralisib) is withdrawn due to safety concerns. Available at: https://www.fda.gov/drugs/drug-safety-and-availability/fda-approval-lymphoma-medicine-ukoniq-umbralisib-withdrawn-due-safety-concerns. Accessed in June, 2022.***

By: Marwa Elsayed, PGCPD.

Sneaky sources of gluten

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If you have **celiac disease**, even traces of gluten (a protein found in wheat, barley, rye and sometimes oats) can devastate on your intestinal tract. Some food could have this traces like:-

- **Medications and supplements:** Gluten may be used as a filler or coating in medications and supplements. Always review the ingredients list on any over-the-counter medications, or vitamin/mineral supplements.
- **Meat, fish and poultry** processed lunch meats and deli meats like cold cuts, hot dogs, salami and sausage may contain gluten. Other foods like self-basting poultry or seasoned turkey breast may also contain gluten.
- **Meat and fish substitutes:** watch for gluten in veggie burgers, sausage, bacon and crumbles, and in imitation seafood.
- **Chips and fries potatoes and corn** are naturally gluten-free, but potato chip seasoning may contain malt vinegar and wheat starch. Also be aware that tortilla chips and French fries may be fried in the same oil/fryer as foods that contain gluten. This will contaminate the oil and may cause harm to someone with celiac disease.
- **Oats** are naturally gluten-free whole grain that contain important vitamins, minerals and fiber. But oats are at high risk for cross contamination. They're sometimes grown next to wheat or packaged in facilities that have gluten-containing products. When shopping, beware of bulk bins. Only choose oats that are labeled "certified gluten-free."
- **"Gluten-free" pizza and baked goods** these may be contaminated by other grains.
- **Sweet treats** (candy, desserts) and snacks.
- **Soy sauce + miso**, a traditional Japanese seasoning.
- **Salad fixings.**
- **Ezekiel bread:** the popular sprouted bread is made from wheat and barley**.**
- **Soups and gravies:** Gluten may be used as a thickener, even in bouillon.

References:

- *How to Spot Those Sneaky Sources of Gluten. Available at: https://health.clevelandclinic.org/spot-secret-sources-gluten-infographic/. Accessed in May, 2022.*
- *Hidden gluten and endometriosis. Available at: https://www.endo-resolved.com/hidden-gluten-endometriosis-diet.html/. Accessed in May, 2022.*
- *Marziali, M., Venza, M., Lazzaro, S., Lazzaro, A., Micossi, C., & Stolfi, V. M. (2012). Gluten-free diet: a new strategy for management of painful endometriosis related symptoms?. Minerva chirurgica, 67(6), 499–504.*

By: Nahla H. Eldeep, B.Sc

جائزة جامعة طنطا للتميز الداخلي
Tanta University Excellence Award

Latest news & achievements

جائزة مصر للتميز الحكومي
Egyptian Government Excellence Award

For the first time and with our honor, **Faculty of Pharmacy, Tanta University** has been awarded the ***Tanta University Excellence Award 2022 (1st Place)***. Our faculty demonstrated special, attractive, and unique file full with unique activities and achievements in different fields. This competition was held between faculties of Tanta University under the patronage of:

- **President Abdel Fattah El-Sisi.**
- The Ministry of Planning, Monitoring and Administrative Reform. The President of Tanta University, **Prof. Mahmoud Zaki.**
- The Dean of Faculty of Pharmacy, **Prof. Nahla EL-Ashmawy.**
- The vice dean of our faculty, **Prof. Amal Abo Qamar, Prof. Sahar El-Haggar, and Prof. Amal Kabbash.**
- The Quality Assurance Unit Manager, **Prof. Mona EL-Aaser**

The Drug and Poison Information Center (DPIC) presented by the DPIC director, Ph. Bassant Maher, with other center's staff had the honor to be effectively participated in the file preparation under supervision of Dr. Peter Sidhom, Head of Excellence Management Unit, Tanta Faculty of Pharmacy.

Congratulations to our great Faculty

Contact us

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We are on the web

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