IN THIS ISSUE

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EPVC Mission

Pharmaceutical Vigilance administration is the way through which the processes for authorizing, Regulating , monitoring and evaluating the safety of any pharmaceutical product or medical device take place, in addition to disseminating any safety information for public health programs, healthcare professionals, and the Egyptian citizen.

The Pharmaceutical vigilance administration is an integral part of the Central Administration of Pharmaceutical Care that works on the enhancement of the pharmaceutical services to guarantee safe and effective use of medications in Egypt, under the patronage of the Egyptian Drug Authority.

Newsletter

August 2026

Volume 20 Issue 7

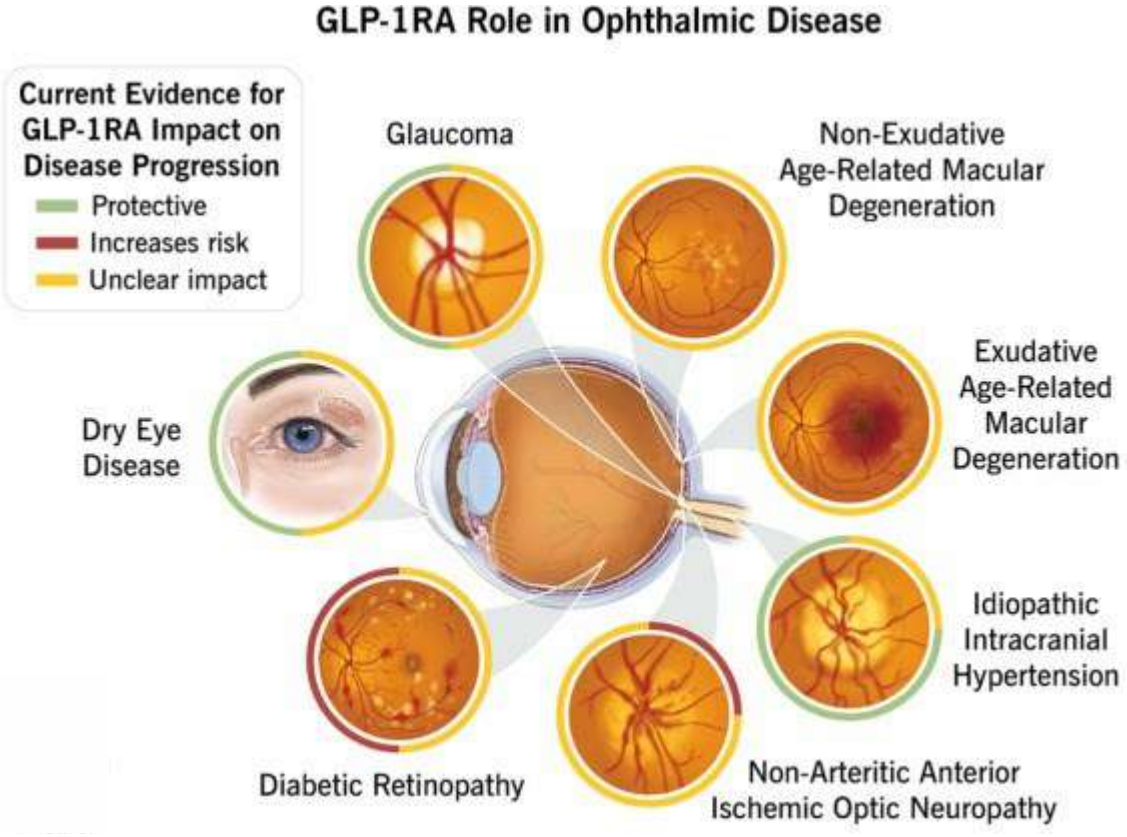
Safety Update : GLP-1 Receptor Agonists and the Risk of Vision Loss

Introduction

The regulatory Authority in Australia' (TGA) has released a class-wide safety notice regarding glucagon-like peptide-1 receptor agonist (GLP-1 RA) medications and a rare eye condition. This advisory is especially relevant due to the heavy reliance on GLP-1 RAs in Egypt for treating type 2 diabetes and obesity, as well as similar actions already taken by the MHRA and ongoing evaluations by the EMA/PRAC.

Background

GLP-1 RAs are used to manage type 2 diabetes mellitus and obesity. The TGA has identified a potential association between this drug class and non-arteritic anterior ischaemic optic neuropathy (NAION), a rare but serious condition that can cause sudden, potentially permanent vision loss, including blindness. No treatment has been shown to improve visual acuity outcomes once NAION occurs. This follows MHRA's February 2026 drug safety update on semaglutide flagging the same risk, and an ongoing EMA/PRAC review concluding NAION is a recognised risk associated with the class.



Management

TGA has mandated a class-wide update to the Product Information (PI) and Consumer Medicine Information (CMI) for all GLP-1 RAs marketed in Australia containing : dulaglutide , semaglutide, tirzepatide, liraglutide.

New warning added under "Eye disorders" in the PI, advising that a sudden loss of vision should prompt urgent ophthalmological examination.

References

1. ***TGA:*** *Click here*
2. ***Pic:*** *Click here*

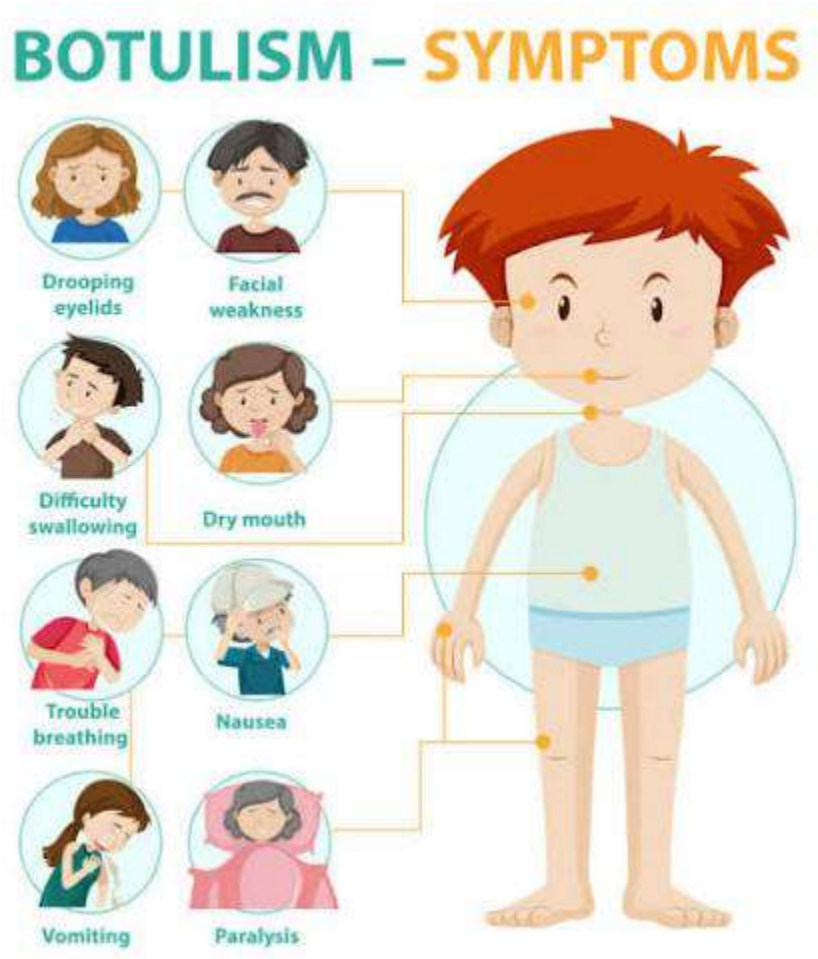
Safety Update : Safety Warnings on Iatrogenic Botulism Risk after cosmetic use of Botulinum Toxin Type A

Introduction

The regulatory Authority in UK issued a class-wide safety update strengthening warnings for all botulinum toxin type A products, published 15 July 2026, following rare reports of iatrogenic botulism. Given the wide cosmetic and therapeutic use of botulinum toxin products in Egypt, this update warrants evaluation for local labeling and public-awareness relevance.

Background

Botulinum toxin type A is a prescription-only medicine widely used for both medical and cosmetic indications. In rare cases, the toxin's effect can spread beyond the intended injection site, resulting in iatrogenic botulism — a serious, potentially life-threatening condition affecting the nervous system. This risk has been reflected in product information since 2007, but the MHRA has now strengthened and clarified the warning across the entire product class following recent case reports.



- Risk: spread of toxin effect beyond the treatment area, leading to iatrogenic botulism.
- Symptoms: difficulty swallowing, slurred speech, breathing difficulties/shortness of breath, muscle weakness, drooping eyelids, blurred or double vision. Onset can occur within days or be delayed up to 4 weeks post-treatment. Severe cases may require mechanical ventilation and intensive care.
- Risk factors highlighted by MHRA: underlying neurological disorders, history of dysphagia/ aspiration, off-label use at unapproved injection sites, and use of counterfeit or unauthorized botulinum toxin products.
- Regulatory action: MHRA has worked with manufacturers to update the SmPC and Patient Information Leaflet (PIL) for all UK-authorized botulinum toxin type A products, to more clearly highlight the risk of iatrogenic botulism and advise patients to seek immediate medical attention if symptoms occur.
- Scope: class-wide — applies to all licensed botulinum toxin type A

References

1. ***GOV.UK :*** *Click here*
2. ***MHRA :*** *Click here*

Safety Signal : Potential Risk of Nephrolithiasis (Kidney Stones) Associated with Sertraline Use

The Safety Signals Management Unit within the Pharmaceutical Vigilance General Administration (PVGA) identified and evaluated reports of nephrolithiasis (kidney stones) in patients taking sertraline to assess a potential causal link and potential risk factors.

Background

Sertraline is an antidepressant medication within the selective serotonin reuptake inhibitors (SSRIs) class. Sertraline is an antidepressant with primarily inhibitory effects on presynaptic serotonin reuptake. Serotonin in the central nervous system plays a role in regulating mood, personality, and wakefulness, which is why blocking serotonin reuptake is beneficial in disorders such as major depression [1]. The metabolites are excreted in feces and urine in equal amounts. Only a small amount of unchanged sertraline is excreted in the urine [2]. Nephrolithiasis (kidney stone/ or renal stone) is a common condition characterized by the formation of urinary stones, often presenting with hematuria and abdominal, flank, or groin pain. It affects approximately 1 in 11 individuals during their lifetime. Stone formation is related to reduced urine volume or increased excretion of stone-forming substances, including calcium, oxalate, uric acid, cystine, xanthine, and phosphate. Calcium-containing stones account for 60–80% of cases, followed by struvite (10–15%), uric acid (5–10%), cystine (1%), and other rare stone types, including drug-induced calculi [3-4].

Methodology

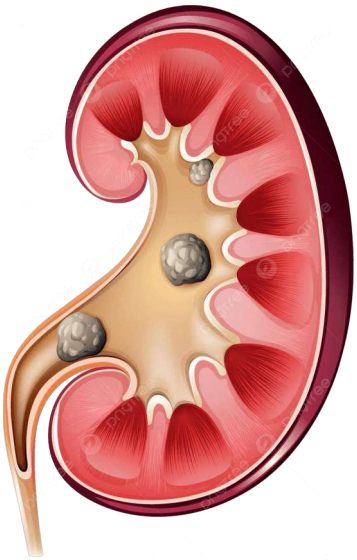
A quantitative signal of significant disproportionate reporting (SDR) between nephrolithiasis (Kidney Stones) and sertarline, with a total of 66 case reports, was retrieved from the WHO global database of adverse event reports for medicines and vaccines (VigiBase) till 08/02/2026. A case series causality assessment using the Bradford Hill criteria method was conducted, alongside a review of the scientific literature for supportive evidence.

Results

The analysis included 32 females and 30 males, with gender unknown in 4 case reports, and a mean patient age of 44.4 years. In 31.8% of reports, cases were medically confirmed by physicians. Reports originated from 11 countries, suggesting consistent different geographical regions. In Egypt, physician-reported cases showed recovery following sertraline withdrawal, with most patients receiving doses ranging from 100–150 mg/day.

Published evidence suggests that serotonergic modulation associated with SSRIs may increase sympathetic activity while reducing parasympathetic control of bladder emptying. This may increase post-void residual urine volume and contribute to urinary retention, potentially creating conditions conducive to urinary crystal formation and subsequent nephrolithiasis.

This potential association may be more relevant during prolonged treatment, with a reported median time to onset of acute renal colic of 55 days [5–8]. ▪ Furthermore, urinary disorders listed in the local PI and EU SmPC, including pollakiuria, urinary retention, polyuria, and nocturia, provide additional biological plausibility for a potential association between as a member of the SSRI class, and the development of nephrolithiasis (kidney stones).



Conclusion and recommendation for actions

The weighted available evidence from the case series analysis and published literature supports a potential safety signal of nephrolithiasis associated with sertraline and the SSRI group, possibly secondary to drug-induced urinary retention and voiding dysfunction. Accordingly, the PVGA has imposed risk-minimization measures to enhance healthcare professionals' awareness of the potential risk of nephrolithiasis (Kidney Stones) associated with sertraline and other SSRIs to facilitate early recognition, appropriate clinical assessment, timely management, and prompt reporting of suspected cases to the PVGA, particularly in patients receiving long-term therapy, higher doses, or those with predisposing risk factors.

References

1. ***Sertraline monograph*** : *Click here*
2. ***Sertraline monograph*** : *Click here*
3. ***Nephrolithiasis, Renal calcul:*** *Click here*
4. ***Nephrolithiasis, Renal calcul:*** *Click here*

Local Case Safety Report: Drug Administration Error Leading to Skin Necrosis and Tissue Breakdown

The Cairo Regional Pharmacovigilance Center received an Individual Case Safety Report

(ICSR) concerning suspected adverse drug reactions in a 21 year old male patient presented to the Emergency Room with Consciousness disturbed and Hepatic encephalopathy

The patient began receiving an intravenous dose of Ceftriaxone (2 g once daily) on May 16, 2026, in order to treat spontaneous bacterial peritonitis.

The suspected drug was injected over the course of two minutes after being diluted in 20 milliliters of normal saline.

Following a single dosage The suspected medication was stopped when the patient had skin disintegration and necrosis. Reaction outcome not recovered

Background:

Ceftriaxone is a third-generation cephalosporin with broad-spectrum gram-negative activity; has lower efficacy against gram-positive organisms but higher efficacy against resistant organisms; highly stable in presence of beta-lactamases (penicillinase and cephalosporinase) of gram-negative and gram-positive bacteria

Mechanism of action:

Ceftriaxone bactericidal activity results from inhibiting cell-wall synthesis by binding to 1 or more penicillin-binding proteins; exerts antimicrobial effect by interfering with synthesis of peptidoglycan (major structural component of bacterial cell wall); bacteria eventually lyse because activity of cell-wall autolytic enzymes continues while cell-wall assembly is arrested

Spontaneous bacterial peritonitis (SBP):

is the infection of ascitic fluid in the absence of any intra-abdominal, surgically treatable source of infection

Skin necrosis is characterized by transmural necrosis affecting the epidermis, dermis, and possibly the subcutis. It is infrequently diagnosed as a primary lesion. Necrosis most commonly occurs secondary to damage of the epidermis and frequently extends into the dermis and subcutis.

Labeled information:

According to Summary of product Characteristics (SmPC) of Ceftriaxone, Posology and method of administration stated that: Ceftriaxone can be administered by intravenous infusion over at **least 30 minutes (preferred route) or by slow intravenous injection over 5 minutes**

It was also stated in special warnings and precautions for use: Severe cutaneous adverse reactions (Stevens Johnson syndrome or Lyell's syndrome/toxic epidermal necrolysis) and drug reaction with eosinophilia systemic symptoms (DRESS)) which can be life-threatening or fatal have reported in association with ceftriaxone treatment; however, the frequency of these events is not known.

Conclusion:

This case highlights the importance of adherence to the recommended Method of administration of ceftriaxone 2g

Recommendations for Healthcare Professionals:

- Administer ceftriaxone strictly according to the approved route and rate of administration.
- Ensure secure IV access and verify patency before and during administration.
- Stop administration immediately if extravasation or significant injection-site symptoms are suspected..
- Assess and document suspected tissue injury promptly.
- Distinguish local injection-site injury from severe cutaneous adverse reactions.
- Monitor patients for serious cutaneous reactions during ceftriaxone treatment.
- Report suspected adverse reactions, including administration-related events, to the General Administration of Pharmaceutical Vigilance (PVGA).

References

1. **Ceftriaxone :** (click here)
2. **Spontaneous bacterial peritonitis:** (click here)
3. **Skin necrosis:** (click here)

Vigitest Competition 2026 – Round 3 & R4 with Live Pharmacovigilance Challenge winners

We appreciate your attendance and engagement in Round 4 simultaneously with R3 of VigiTest 2026, we reached 57 participants.

Thank you for participating, and please join us in congratulations our top 5 winners on their achievement:

	Name	Title	Affiliation
1	Alaa Elgnainy	PV Specialist	National Hepatology and Tropical Research Institute
2	Aya Hefnawy	PV Specialist	---
3	Amira Khaled	PV Specialist	Fidia pharma
4	Norhan Hassan	Pharmacist	---
5	Sondos Adel	PV Specialist	Fidia Pharma

Don't miss the opportunity to be part of next rounds - Vigitest Game 2026 where knowledge meets action!

EPVC Tips On Pharmacovigilance

Protect Your Kidneys from Medicine Overuse

Too much medicine can hurt your kidneys!
Some medicines, especially certain painkillers, can affect kidney function when used too often, in high doses, or for a long time.
Remember:

* Always follow the recommended dose and duration.
* Do not take painkillers repeatedly without medical advice.
* Avoid taking several medicines containing the same active ingredient.
* Drink enough fluids unless your doctor has advised you to restrict them.
* Ask your doctor or pharmacist before using medicines if you have kidney problems or take several medicines.

Your medicine should help you—not harm you.

You can report any ADR on:
Email: pv.followup@edaegypt.gov.eg
Hotline: 15301
Website: (click Here)
Or report through your pharmacy / product distributor / company hotline — they are required to forward it to EDA.

Why Your Report Matters

Every report _ to us counts when it comes to the safety of medicines and patients worldwide

Visit EDA website to find all medicine- related news, updates and alerts *Click here*

You will find all EPVC Newsletters and DHPCs here

You will also find all alerts regarding counterfeited and falsified products released by Central Administration of Operations *here*

One report counts

A call for reporting

Please remember that you can report safety information of medicines to EPVC using the following communication information:

What is Pharmacovigilance

Pharmacovigilance (PV) is defined as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug- related problem.

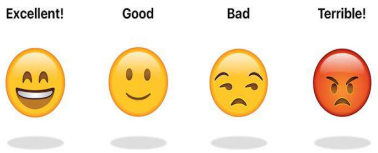
What is the Egyptian Pharmaceutical Vigilance Center?

With the increasing demand for patient's safety which is becoming more stringent, . The Egyptian Pharmaceutical Vigilance Center was established to be responsible for the safety monitoring of the pharmaceutical products throughout its lifecycle and it is the regulatory authority regarding Pharmacovigilance and its applications .

EPVC monitors the safety of all types of pharmaceutical products, including human medicines, biological products, supplements, cosmetics, veterinary medicines, medical devices, Biocides and pesticides

Participate with us

We invite you to take a quick survey on how much our communication with you is effective
We value your feedback! Help us enhance our communication by taking a quick survey. Your insights are crucial in ensuring we meet your expectations.
Survey Link: (Click Here)



Thank you for your valuable input

Communication information

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Reporting link: (click Here)

هيئة الدواء المصرية (الرعاية الصيدلية)