EGYPTIAN DRUG AUTHORITY

هيئة الدواء المصرية

The Egyptian Pharmaceutical Vigilance center

مركز اليقظة الصيدلية المصري

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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

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Reminder of Risk: Risk of encephalitis with varicella vaccines

The Regulatory Authority in Europe (PRAC)) is reviewing the known risk of encephalitis (inflammation of the brain) with varicella (chickenpox) vaccines, , following a report of a fatal outcome after vaccination with Varilrix.

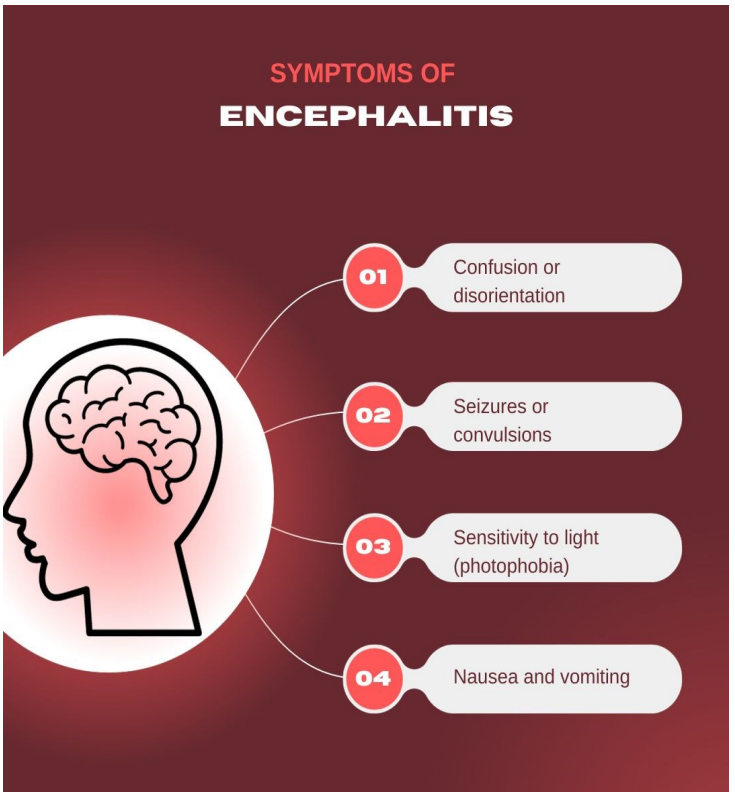
varicella (chickenpox) vaccines is authorised for vaccination of adults and children from 12 months of age, and in certain populations from 9 months of age, against chickenpox. They contain live attenuated (weakened) varicella virus.

Varicella is caused by the varicella-zoster virus, which also causes shingles (herpes zoster). Varicella mainly affects children aged 2-8 years where it is usually a mild disease and children recover quickly. In some cases, varicella can cause complications including bacterial infection of the skin or blood, pneumonia (infection and inflammation of the lungs) and encephalitis. Encephalitis can also be caused by other viral or bacterial infections. While most people with encephalitis recover, the condition can be life-threatening.

This review was initiated by the PRAC following a case report in Poland of a child who developed encephalitis a few days after receiving the varicella (chickenpox) vaccines.

The patient died of the consequences of encephalitis several days later. As a precaution, the Polish medicines agency has suspended the distribution of vaccines from the batch in question.

These vaccines are widely used across the EU, and encephalitis is listed as a side effect in their product information based on rare reports during Post-Marketing surveillance.



The committee will now assess all available evidence to better understand the risk of encephalitis and to determine if any regulatory action is necessary.

While EMA is investigating the issue, the vaccines can continue to be used in line with the approved product information.

References

1. PRAC: (click here)

Local Case Safety Report: Fournier Gangrene Following Empagliflozin Administration

1. Reason for Publishing

The Cairo Regional Center for Pharmacovigilance received a serious adverse drug reaction (ADR) report concerning a 68-year-old male patient with multiple comorbidities: chronic kidney disease (serum creatinine: 2 mg/dL), ischemic heart disease, hypertension, newly diagnosed type 2 diabetes mellitus, and pulmonary edema . The patient was prescribed Empagliflozin 10 mg orally once daily, initiated on 6 June 2025 for glycemic control. Concomitant medications included Furosemide 40 mg, Pantoprazole, Atorvastatin 40 mg, and Amlodipine 10 mg.

On 14 June 2025, the patient presented with leukocytosis (WBCs: 20.5 $\times 10^9$/L) and was diagnosed with Fournier's gangrene (penile). The condition was classified as serious and life-threatening, requiring urgent medical intervention.

2. Background

Empagliflozin: A selective SGLT2 inhibitor, Empagliflozin is approved for:

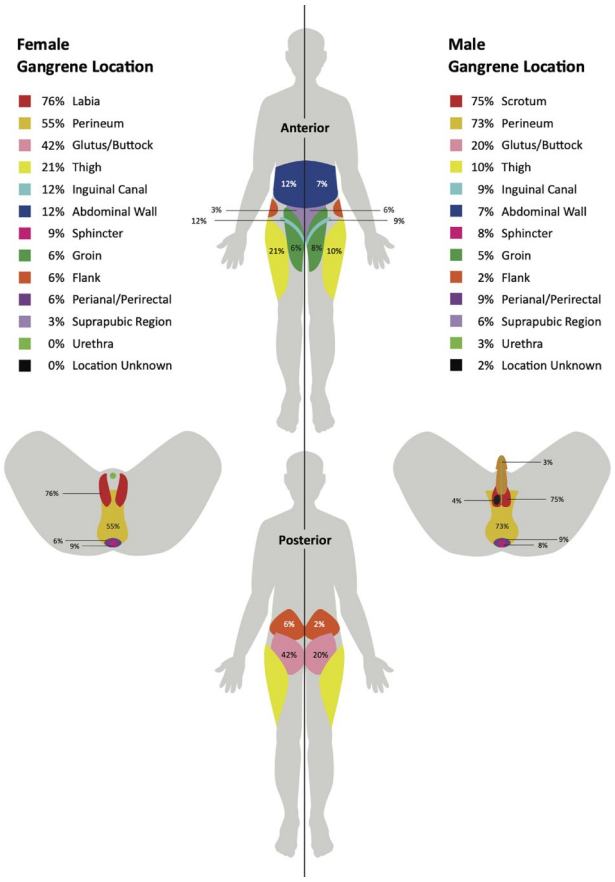
- Glycemic control in type 2 diabetes (age >10 years) alongside diet and exercise
- Treatment of symptomatic chronic heart failure in adults
- Management of chronic kidney disease (CKD) in adults

Mechanism of Action: By inhibiting SGLT2 in the proximal renal tubules, Empagliflozin reduces renal glucose reabsorption, leading to glycosuria, osmotic diuresis, and modest natriuresis. Its insulin-independent mechanism may additionally contribute to cardiovascular and renal benefits.

Fournier's Gangrene

A rare but rapidly progressing **necrotizing fasciitis** affecting the perineum, genitals, or perianal region. It is life-threatening, requiring early recognition and urgent management.

- **Incidence**: ~1.6 per 100,000 males annually in the U.S., higher in ages 50–79 (3.3 per 100,000)



- **Pathophysiology**: Infection spreads through fascial planes following minor skin breaches, leading to obliterative endarteritis and thrombosis. The testes are typically spared due to separate blood supply.

Symptoms: Sudden pain/swelling, skin discoloration, necrosis, crepitus, fever, shock.

Progression: Can be fulminant (within hours) or evolve subacutely over days to weeks.

Onset Timeline:

Prodromal Phase: Non-specific (e.g., fever, lethargy)

Initial Local Signs: Pain, swelling, color change, crepitus

Advanced Stage: Rapid necrotic spread with systemic toxicity

Risk Factors

- Diabetes mellitus (especially uncontrolled)
- Chronic kidney disease
- Advanced age
- Cardiovascular disease
- Immunosuppression
- Obesity
- Poor perineal hygiene
- Use of nephrotoxic or immunosuppressive medications

Nutritional Status is also critical—malnutrition is linked to poor outcomes due to impaired healing and immune response.

Empagliflozin SmPC Highlights:

Section 4.4 – Warnings and Precautions: Reports of Fournier's gangrene in both male and female patients receiving SGLT2 inhibitors.

Section 4.8 – Undesirable Effects: Fournier's gangrene listed as a rare but serious post-marketing infection with outcomes including hospitalization, multiple surgeries, and death

3. Recommendations

1. **Strict Glycemic Control**: Essential for reducing infection risk in diabetic patients.
2. **Personal Hygiene**: Emphasize genital and perineal hygiene in patient education.
3. **Patient Awareness**: Inform patients about early signs of Fournier's gangrene—pain, swelling, discoloration, foul odor.
4. **Urgent Reporting**: Encourage patients to report genital pain, swelling, or systemic signs (fever, malaise) immediately.
5. **Avoid Trauma**: Advise against harsh cleansing methods or irritant products in the genital area.
1. **High-Risk Patient Monitoring**: Use SGLT2 inhibitors cautiously in patients with multiple comorbidities.
2. **Post-Initiation Surveillance**: Close monitoring after starting, increasing, or stopping Empagliflozin.
3. **Immediate Action if Suspected**: Discontinue Empagliflozin immediately and initiate broad-spectrum antibiotics and surgical debridement if Fournier's gangrene is suspected.
4. **Regular Skin Inspections**: Especially in elderly, obese, or CKD patients.
5. **Regular Follow-Up**: For individuals with vascular disease, on immunosuppressants, or with poor renal function.

Conclusion

This case emphasizes the importance of vigilant monitoring when prescribing **Empagliflozin**, particularly in elderly patients with diabetes and comorbidities. Fournier's gangrene, although rare, is a known and serious risk requiring swift diagnosis and treatment. Pharmacovigilance systems play a vital role in detecting such life-threatening ADRs and guiding clinical practice through data-driven risk minimization strategies.

References

1. FDA: (click here)
2. Fournier Gangrene: (click here)
3. Empagliflozin SmPC: (click here)
4. Fournier Gangrene Microbiology and Risk Factors (click here)
5. Recommendation : (click here)

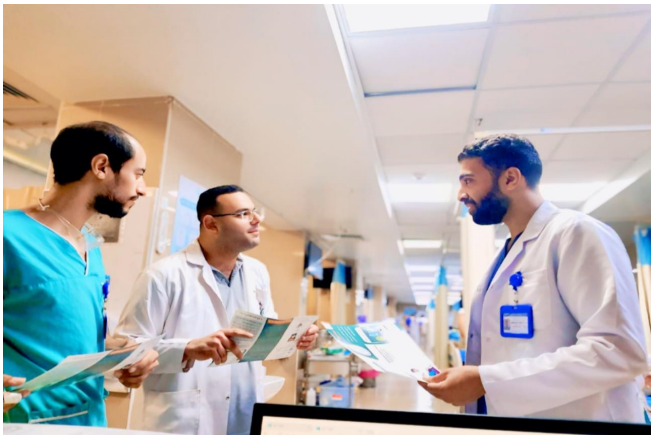
The Egyptian Pharmaceutical Vigilance Centre (EPVC) like to extend a sincere appreciation and to express gratitude to General Authority for Healthcare, EHA for enhancing pharmacovigilance practices.

EPVC is pleased to encourage and acknowledge the efforts made by port said governorate, their outstanding performance in promoting pharmacovigilance was done through continuous awareness campaigns and patient education activities.

The aim of the campaigns was to raise awareness about the importance of reporting adverse drug reactions and what are the reporting mechanism or available channels.

The Pharmacovigilance Coordinators in collaboration with pharmacy department at port said delivered number of 4 campaigns at the following facilities:

- Hemodialysis Unit at Al-Hayat Hospital
- Al-Jarabaa Family Health Unit
- Specialized Ophthalmology Hospital
- Umm Khalaf Family Health Unit



This comes within the framework of EHA's commitment to spreading awareness about the safe use of medicines and achieving the highest quality standards in healthcare services provided.

EPVC always support and appreciate all contributions to enhance medication safety and empower patients with the knowledge needed to make informed health decisions.

Ultimately, EPVC extends a sincere appreciation to all our partners that have collaborated in PV activities We commend the organizations for the ongoing commitment to enhance the monthly cases reporting continuously in addition to achieve excellence in enhancing the role of healthcare providers across the country

"Together for Safe Medicine" Initiative News:

We are happy to announce that we will start the activities for the 7th wave of the EPVC initiative "Together for safe medicine". On Thursday, 17 July 2025 as we will start with an introductory online lecture about the initiative, its different stages, the expected outcomes, and the Pharmacovigilance definition.

EPVC Tips

On Pharmacovigilance

Stay Safe, Stay Informed: Understanding Vaccinovigilance

Vaccinovigilance is concerned by monitoring the safety of vaccines after they are given to the public. It helps make sure that vaccines continue to be safe and effective for everyone.

Even though vaccines go through strict testing before approval, some adverse events following immunization may appear later in a few people Mostly are mild. That's why it's important to report any unusual symptoms after getting vaccinated.

By reporting Adverse events following immunization , you help health authorities protect others, improve vaccine safety, and respond quickly to any concerns.

* Get vaccinated at authorized centers only
* Inform your provider about allergies, medications, or past vaccine reactions.
* Stay for 15–30 minutes after the shot to monitor for Adverse events following immunization .
* Watch for Adverse events following immunization like fever, pain, rash, or breathing issues.
* Report any unusual or delayed symptoms to your healthcare provider.
* Keep your vaccination card and share it during medical visits.
* Do not skip doses unless advised by your doctor.
* Stay informed: use trusted sources like WHO, Ministry of Health, or EDA

Your voice matters if you feel unwell after a vaccine, speak up. It's part of keeping your community safe!

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*

The Egyptian Pharmaceutical Vigilance center
مركز اليقظة الصيدلية المصري

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

The Egyptian Drug Authority (EDA)
Pharmaceutical Care Administration
The Egyptian Pharmaceutical Vigilance Center (EPVC)

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