EGYPTIAN DRUG AUTHORITY

هيئة الدواء المصرية

IN THIS ISSUE

Safety Alert: : Respiratory Syncytial Virus (RSV) Vaccines – Small Increased Risk of Guillain-Barré Syndrome in Older Adults 1

Local Case Report :Combined Oral Contraceptive induced Mesenteric vascular occlusion 2-3

EPVC News 4-5

EPVC Tips 6

Prepared by:

Reem Tarek
Salma Radwan
Mohamed Sayed
Esraa Abdelhamed
Lobna Samy
Maisa Hussien

Designed by:

Reem Tarek

Chief Editor

Maha Mohamed

Head of Egyptian Pharmacovigilance Center

Under supervision of

Yassin Ragaey

Assistant to EDA chairman for Media Affairs and Investment Support and Supervisor of the Central Administration for Pharmaceutical Care

EPVC
The Egyptian Pharmaceutical Vigilance center
مركز اليقظة الصيدلية المصري

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 2025

Volume 19 Issue 8

Safety Alert: : Respiratory Syncytial Virus (RSV) Vaccines – Small Increased Risk of Guillain-Barré Syndrome in Older Adults

Summary

The regulatory authority in UK stated that there is a small increase in the risk of Guillain-Barré syndrome (GBS) following vaccination against RSV in adults aged 60 years and older. Healthcare professionals should advise all recipients in this age group to be alert for signs and symptoms of GBS, and to seek urgent medical attention if they occur, as the condition requires immediate hospital treatment.

Current evidence does not indicate an increased risk of GBS in pregnant women following RSV vaccination. Expert review by the Commission on Human Medicines (CHM) has concluded that the benefits of RSV vaccination outweigh the small risk of developing GBS in older adults.

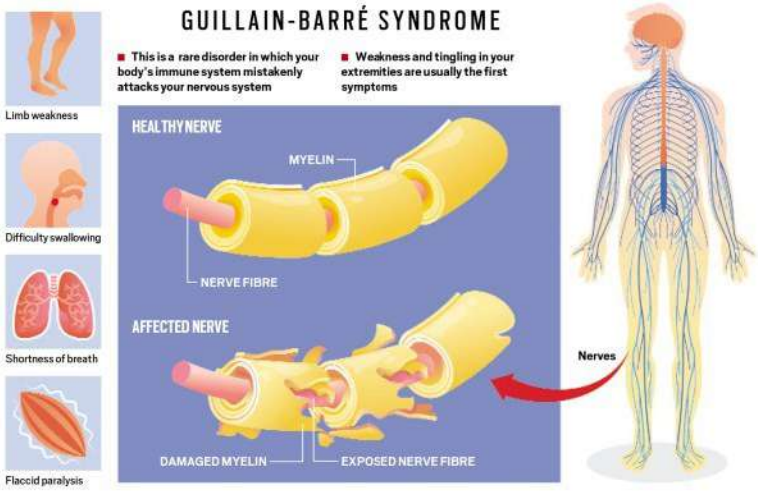
Background

RSV is an infectious disease of the airways and lungs. Infection is common in young children but can be most serious in small babies and older adults. In the UK, RSV vaccines are used in the national immunisation programme for older adults and in pregnant women to protect their infants.

Risk of Guillain-Barré Syndrome

Increased risk of GBS has been observed following RSV vaccination in adults aged 60 years and older. Up to 2 June 2025, the UK safety monitoring system received 21 reports of suspected GBS in older adults (where known, aged 75–79 years) following RSV vaccination, out of more than 1.9 million doses administered in this age group.

Post-marketing observational data from the United States suggest approximately 7–9 excess cases of GBS per million RSV vaccine doses in individuals aged 65 years and older. Preliminary unpublished data from UK studies in adults aged 75–79 years estimate 15–25 excess cases per million doses administered. The risk remains rare.



Advice for Healthcare Professionals

- Be aware of the small increased risk of GBS following RSV vaccination in adults aged 60 years and older.
- There is currently no evidence of increased GBS risk in pregnant women receiving RSV vaccine.
- Monitor all recipients for signs and symptoms of GBS to enable early diagnosis, appropriate supportive care, and exclusion of other causes.
- Early medical intervention can reduce severity and improve outcomes.

References

1. MHRA : (click here)

Local Case Safety Report: Combined Oral Contraceptive induced Mesenteric vascular occlusion

Reason for publishing

On June 29, 2025, the Cairo Regional Pharmacovigilance Center received a report about a 33 years old female patient with previous cesarean delivery.

In 6/2024, she started administering (Ethinylestradiol-Gestodene) combination, indicated for contraception with dose of 1 tablet once daily orally. During a whole year of administration, she was experiencing intermittent episodes of abdominal pain and gaseous distension.

On 16/6/2025, she developed mesenteric vascular occlusion which resulted in small intestinal resection.

The reaction considered serious as it was life threatening and required surgical intervention which was the resection of all small intestines. The patient has no history of vascular disorder or any identifiable risk factor.

Background

Combined estrogen-progestin oral contraceptives also known as birth control pills, provide reliable contraception as well as several non-contraceptive benefits. COCs contain an estrogen component and one of a dozen different progestins.

According to the local product information, combined oral contraceptives are associated with a risk of venous thromboembolism (VTE). Although extremely rare, cases of thrombosis have also been reported in other blood vessels, including the hepatic, mesenteric, renal, cerebral, and retinal veins and arteries.

Mesenteric venous thrombosis: Acute mesenteric ischemia refers to the sudden onset of intestinal hypoperfusion, one cause of which can be mesenteric venous occlusion. Mesenteric venous thrombosis can present acutely or in a subacute or chronic manner. At one time, acute mesenteric venous thrombosis was thought to be the principal cause of acute mesenteric ischemia; however, with increasing recognition of and differentiation from the occlusive and nonocclusive forms of acute arterial mesenteric ischemia, the proportion of cases attributed to mesenteric venous thrombosis has decreased to approximately 10 percent of all cases of acute mesenteric ischemia.

Common risk factors for mesenteric venous thrombosis:

- Abdominal mass (eg, tumor, pseudocyst) leading to venous compression
- Abdominal inflammatory processes (eg, acute pancreatitis, diverticulitis)
- Myeloproliferative disorders (e.g., JAK-2 V617F mutation)
- Portal hypertension and cirrhosis (increased portal venous pressure)
- Personal or family history of venous thromboembolism
- Acquired thrombophilia (e.g., malignancy, oral contraceptives)
- Inflammatory bowel disease
- Mesenteric adenopathy/viral infection (eg, influenza)
- Inherited thrombophilia – Factor V Leiden mutation, prothrombin G20210A mutation, protein S deficiency, protein C deficiency, antithrombin III deficiency, activated protein C resistance, and antiphospholipid syndrome
- Endoscopic sclerotherapy
- Obesity surgery

Intestinal ischemia which can affect the small or large intestine, can be caused by any process that reduces intestinal blood flow, such as arterial occlusion, venous occlusion, or arterial vasospasm. For patients with acute symptoms, a rapid diagnosis is imperative since the clinical consequences can be catastrophic, including sepsis, bowel infarction, and death.

In this patient's case, it's theorized that the use of a combined oral contraceptive led to mesenteric vascular thrombosis, which then resulted in mesenteric occlusion and an intestinal ischemia.

Literature review:

One case report was found with similar reaction, A case of a 38-year-old obese female patient who presented with acute abdominal pain. A bowel infection was first diagnosed and treated with antibiotics. Contrast-enhanced tomography of the abdomen revealed diffuse ischemia of the small intestine with superior mesenteric thrombosis. Laparotomy with segmental resection of both small and large bowel was performed. No predisposing factor of mesenteric

Recommendations

Although rare, the use of combined oral contraceptives (COCs) can lead to mesenteric thrombosis, potentially resulting in intestinal ischemia and necrosis. Clinicians should consider this diagnosis in women taking COCs who present with sudden, severe abdominal pain of unclear origin.

COCs should be prescribed and monitored under appropriate medical supervision.

If the overall risk-benefit assessment for venous thromboembolism (VTE) is unfavorable, combined hormonal contraceptives (CHCs) should not be prescribed.

Health care professionals must remain vigilant and informed about the risk factors associated with mesenteric vascular occlusion.

References

1. ***Combined-estrogen-progestin-oral-contraceptives-***(click here).

2. ***Ethinylestradiol-Gestodene SPC*** (click here).

3. ***VTE definition*** (click here).

4. ***Mesenteric venous thrombosis Definition***(click here).

5. ***Risk factors for mesenteric occlusion***(click here).

6. ***Intestinal ischemia Definition***(click here).

The Egyptian Drug Authority Participates in Pharmacovigilance Scientific Event at Saudi-German Hospital in Alexandria

The Egyptian Drug Authority (EDA), through the Egyptian Pharmacovigilance Center (EPVC) under the Central Administration for Pharmaceutical Care, participated in a pharmacovigilance scientific event hosted by the Saudi-German Hospital (SGH) in Alexandria. The event, held on Tuesday, July 8, was organized by the hospital's Medical Education Unit and Pharmaceutical Services Department.

The gathering brought together prominent figures, including the President of the Alexandria Pharmacists Syndicate, deans and professors from leading universities such as Alexandria University, Alameen University, University of Hertfordshire, Arab Academy for Science, Technology & Maritime Transport, and Egypt Japan University of Science & Technology, alongside the hospital's director and senior management.

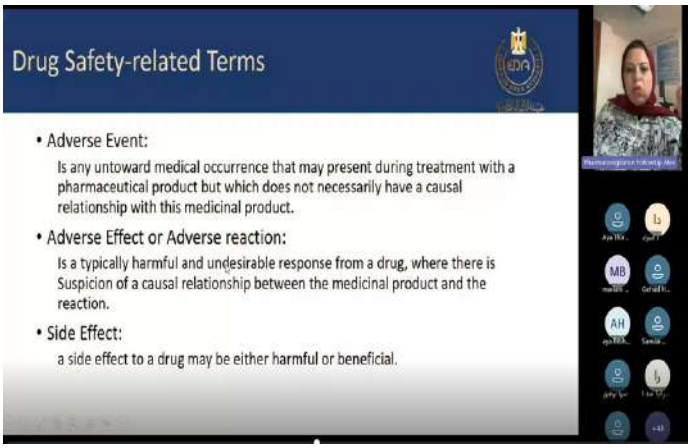
The event commenced with a productive discussion involving SGH's leadership team — the Hospital Executive Director, Hospital Medical Director, Chief Quality Officer, Manager of Pharmaceutical Services, and HR Manager — as well as officials from the Medical Education Unit, pharmacy faculty members, deans, and EPVC representatives. Key topics included the development of pharmacovigilance in Egypt and the awareness levels among students, graduates, and healthcare professionals.

Following the meeting, lectures were delivered at the hospital with active participation from pharmacy students of the Arab Academy. The EPVC team presented four key sessions:

- Structure and achievements of Egypt's pharmacovigilance system
- Reporting of Adverse Drug Reactions (ADRs) and available reporting methods
- Introduction to Adverse Events Following Immunization (AEFIs)
- Handling and processing of Individual Case Safety Reports (ICSRs)

The EDA's participation underscores its commitment to fostering collaboration between institutions, promoting safe medication practices, and equipping future pharmacists with the knowledge and skills needed to strengthen public health and ensure patient safety.

Together for safer medicine initiative News



The Egyptian Pharmacovigilance Center (EPVC) is proud to announce the launch of its "Together for Safe Medicine – Wave 7" activities in July 2025.

As part of this initiative, the EPVC team organized three online lectures attended by over 60 pharmacists from community and governmental pharmacies. During these sessions, EPVC team members introduced participants to:

- The fundamentals of pharmacovigilance
- The concept and importance of adverse drug reaction (ADR) reporting
- Various reporting methods, including E-reporting, the EDA hotline, the Arabic reporting link on the EDA website, and VigiFlow accounts in governmental organizations

At the end of the program, participants were briefed on their assignments, which aim to promote pharmacovigilance awareness across Egypt—whether by engaging with the public or by reaching out to healthcare professionals (HCPs).

VigiTest Competition: The Journey of Challenge Continues!

Healthcare heroes, the journey is far from over! The VigiTest competition returns, offering another opportunity to refine your pharmacovigilance expertise.

After witnessing exceptional participation and brilliant minds in the first and second rounds, we're excited to keep the challenge alive. Each month, we'll continue to test your knowledge and skills in pharmacovigilance. Ready to stay on top of your game?

How to Join: It's simple. Scan the QR code provided in the newsletter or tap the link below to access the competition questions. Answer correctly with your knowledge and skill, and you could be one of our monthly winners. Monthly Winners: Every month, the top participants will be celebrated for their expertise.

Annual Winners: At the end of the year, the top consistent winners will be recognized for their brilliance throughout the year and win certificate of appreciation for their participation and outstanding performance. Follow the next release, and stay tuned for the results and winners

The next challenge is just ahead. Don't miss your chance to participate!

Scan the QR code or tap the link below, follow the instruction and answer the questions.

https://forms.gle/j7M32GVhYSb3sR9B7

SCAN ME

EPVC Tips

On Pharmacovigilance

Stay Safe, Stay Informed: Understanding Vaccinovigilance

Some medicines, especially those that suppress the immune system (such as high-dose corticosteroids, chemotherapy, or certain biologics), may reduce a vaccine's effectiveness or increase the risk of side effects. Always inform your healthcare provider about all medications you are taking before getting vaccinated, so they can advise on the best timing and type of vaccine for you.

1. Tell Your Doctor Everything : Always share a complete list of your medications, supplements, and herbal remedies before vaccination.
2. Immune System Medicines : Drugs that weaken your immune system (e.g., chemotherapy, high-dose steroids, biologics) can make vaccines less effective — your doctor may adjust the timing.
3. Live Vaccines & Medications : Some medicines (like certain antivirals or antibiotics) can interfere with live vaccines. Your healthcare provider will decide if a delay is needed.
4. Blood Thinners : If you're on anticoagulants (e.g., warfarin), you can still get vaccinated, but inform the vaccinator to reduce the risk of injection site bleeding.
5. Recent Drug Changes :If you've recently started or stopped any medicine, tell your healthcare provider — it might affect vaccine choice or timing.
6. Don't Stop Medicine Without Advice : Never stop or change a prescribed medication on your own just because you're getting a vaccine.

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.

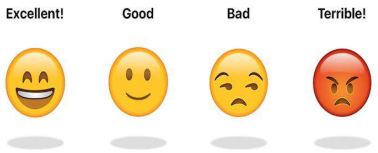
What is the Egyptian Pharmaceutical Vigilance Center?

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)

Address: 21 Abd El Aziz AlSoud Street. El-Manial, Cairo, Egypt, PO Box: 11451
Hotline: 15301
Fax: +202 – 23610497
Email: pv.followup@edaegypt.gov.eg
Reporting link: www.edaegypt.gov.eg
https://sites.google.com/view/epvc-reporting/healthcare-professional-public-adverse-drug-event-reporting/reporting-other-adverse-drug-event-cases

هيئة الدواء المصرية (الرعاية الصيدلية)