



هيئة الدواء المصرية

IN THIS ISSUE

Emerging Safety Issue: Statin potential risks of myasthenia gravis and ocular myasthenia	1
Case Study: A female got ischemic stroke while taking the combined hormonal contraceptive pill	2-3-4
EPVC News	5-6-7
EPVC Tips	8

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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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Emerging Safety Issue

Statin potential risks of myasthenia gravis and ocular myasthenia

The PRAC has recommended a change to the product information for statins to include potential risks of myasthenia gravis and ocular myasthenia.

Statins are HMG-CoA reductase inhibitors and include atorvastatin, fluvastatin, lovastatin, pitavastatin, pravastatin, rosuvastatin and simvastatin.

In few cases, statins have been reported to induce de novo or aggravate pre-existing myasthenia gravis or ocular myasthenia. Treatment with statins should be discontinued in case of aggravation of symptoms. Recurrences when the same or a different statin was (re-) administered have been reported.

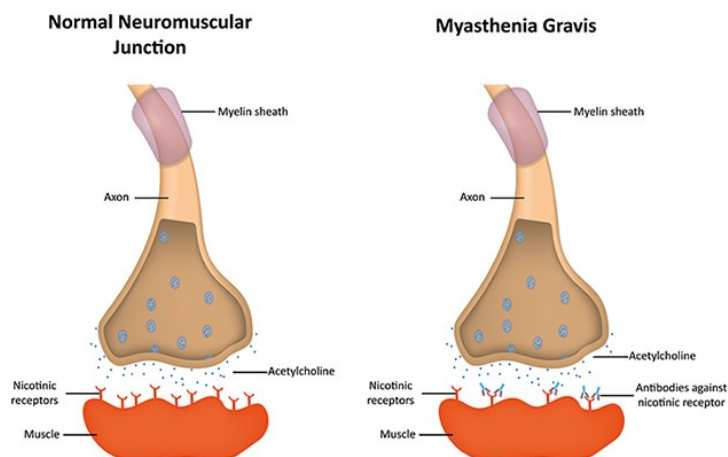


References:

EMA: ([Click here](#))

MYASTHENIA GRAVIS

Grave muscular weakness





Local Case Report

Case Study: A FEMALE GOT ISCHEMIC STROKE WHILE TAKING THE COMBINED HORMONAL CONTRACEPTIVE PILL

1. Background

1.1 Combined Hormonal Contraception:

The primary mechanism of action of Combined oral contraceptive CHC is prevention of ovulation. CHC acts on the hypothalamic pituitary-ovarian axis to suppress luteinizing hormone (LH) and follicle-stimulating hormone (FSH) and thus inhibit ovulation. Changes to cervical mucus, endometrium and tubal motility that result from progestogen exposure may also contribute to the contraceptive effect.

When taken correctly, it is more than 99% effective - fewer than one in every 100 women who use it will get pregnant in one year - but it's around 91% effective based on "typical use".

1.2 Combined Hormonal Contraception Regimens

The majority of Combined oral contraceptives are designed to be taken as 28-day cycles, with 21 consecutive daily active pills followed by a 7-day hormone-free interval prior to starting the next packet of pills. Traditionally women have then either had seven pill-free days or taken seven placebo tablets; during this hormone-free interval, most women will have a withdrawal bleed due to endometrial shedding. It should be made clear to women that this bleed does not represent physiological menstruation and that it has no health benefit.

Tailored (non-standard) regimens include Continuous use of CHC (no hormone-free interval), Extended use of CHC (less frequent hormone-free interval), and CHC regimens in which the hormone-free interval is shortened.



1.3 Combined oral contraceptives: the risk of ischemic stroke:

In a Cochrane Review, a meta-analysis of 28 publications to assess the risk of myocardial infarction or ischemic stroke in women using Combined oral contraceptives. Overall, the risk of myocardial infarction or ischemic stroke was 1.6-fold increase in women that used Combined oral contraceptive compared with non-users.

Another Cochrane Review to compare between continuous or extended cycle CHCs in regimens of greater than 28 days of active hormone compared with traditional cyclic dosing (21 days of active hormone and 7 days of placebo, or 24 days of active hormones and 4 days of placebo) the review included 12 randomized controlled trials. Study findings were similar between 28-day and extended or continuous regimens regarding contraceptive efficacy (i.e., pregnancy rates) and safety profiles.





Local Case Report

Case Study: A FEMALE GOT ISCHEMIC STROKE WHILE TAKING THE COMBINED HORMONAL CONTRACEPTIVE PILL (Continued)

The Case Report:

A female patient of 38-year-old and 80 Kg as body weight, she has no chronic illnesses. On 1.3.2023, the patient started combined oral contraceptive pills, she desired to fast Ramadan uninterrupted. As a result, she planned to skip her menstrual period for one month. Considering this, she was taking the pill continuously without break (No hormonal free intervals regimen). No concomitant medications were administered.

On 12.4.2023, the patient developed sudden left arm weakness, mouth deviation to right side (Facial droop), and vomiting. The patient was admitted to the hospital and upon investigation the following was detected:

- Blood pressure was 170/100 mmHg,
- Normal immune tests including antinuclear autoantibodies (ANA), Anti double strand DNA, ANCA, Anti- Phospholipid IgG, and Antiphospholipid IgM,
- Magnetic resonance imaging MRI on Brain showed Recent Right tempo partial infraction,
- Normal carotid Doppler.

Finally, the patient was diagnosed with Ischemic stroke.

The reaction was considered serious as life-threatening and required hospitalization.

The physician prescribed: Aspirin 75mg oral tablets once daily, Capoten 25mg oral tablet three times daily, and pantoprazole 40mg oral tablet once daily. The combined oral contraceptive pills were stopped, and the patient was recovering. The case was discharged on 15.4.2023 on her medication and physiotherapy sessions.

Recommendations:

Recommendations for Healthcare Professionals:

Use of combined oral contraceptive is contraindicated in patients at high risk of arterial or venous thrombotic diseases, such as those with: cerebrovascular disease; coronary artery disease; patients >35 years of age with diabetes mellitus; diabetes mellitus with hypertension, vascular disease, or end-organ damage; diabetes mellitus for >20 years duration; deep vein thrombosis or pulmonary embolism (current or history of); hypertension (uncontrolled); hypertension with vascular disease; headaches with focal neurological symptoms; migraine headaches with aura or migraine headaches if >35 years of age; patients >35 years of age who smoke; hyper-coagulopathies (inherited or acquired); thrombotic valvular or thrombotic rhythm diseases of the heart (eg, subacute bacterial endocarditis with valvular disease, atrial fibrillation).



Case Study: A FEMALE GOT ISCHEMIC STROKE WHILE TAKING THE COMBINED HORMONAL CONTRACEPTIVE PILL (Continued)

Patient counselling tips:

- Before using this medication, tell your doctor or pharmacist your medical history, especially of: blood clots (for example, in the legs, eyes, lungs), blood clotting disorders (such as protein C or protein S deficiency), high blood pressure, abnormal breast exam, cancer (especially endometrial or breast cancer), high cholesterol or triglyceride (blood fat) levels, depression, diabetes, family or personal history of a certain swelling disorder (angioedema), gallbladder problems, severe headaches or migraines, heart problems (such as heart valve disease, irregular heartbeat, previous heart attack), history of yellowing eyes/skin (jaundice) during pregnancy or while using hormonal birth control (such as pills, patch), kidney disease, liver disease (including tumors), stroke, swelling (edema), thyroid problems, unexplained vaginal bleeding.
- Tell your doctor if you just had or will be having surgery or if you will be confined to a bed or chair for a long time (such as a long plane flight). These conditions increase your risk of getting blood clots, especially if you are using hormonal birth control. You may need to stop this medication for a time or take special precautions.
- This medication may rarely cause serious (sometimes fatal) problems from blood clots (such as deep vein thrombosis, heart attack, pulmonary embolism, stroke).
- Get medical help right away if any of these side effects occur: chest/jaw/left arm pain, confusion, sudden dizziness/fainting, pain/swelling/warmth in the groin/calf, trouble speaking, sudden shortness of breath/rapid breathing, unusual headaches (including headaches with vision changes/ lack of coordination, worsening of migraines, sudden/very severe headaches), unusual sweating, weakness on one side of the body, vision problems/changes (such as double vision, partial/complete blindness).
- The patient should be advised to follow the specific dosing instructions on the package and avoid the misuse of the drug. The standard regimen to take this pill is to take 1 every day for 21 days, then have a break for 7 days, and during this week you have a bleed like a period.

References:

1. Combined oral contraceptives background: ([Click here](#)) ([Click here](#)) ([Click here](#))
2. Combined Hormonal Contraception Regimens ([Click here](#))
3. Risk of ischemic stroke with combined oral contraceptives: ([Click here](#))
4. Recommendations for Healthcare Professionals ([Click here](#)) ([Click here](#))
5. Patient counseling tips: ([Click here](#))

Disclaimer : The method of case handling depends on the evaluation of the treating physician according to individual patient's need.



EPVC News

Pharmacovigilance and Reporting Awareness Training

In the context of the vision and mission of the Egyptian Pharmaceutical Vigilance Center (EPVC) in spreading awareness of pharmacovigilance and the culture of reporting side effects among Healthcare professionals to promote the safe and effective use of different pharmaceutical products and to promote the pharmaceutical care, the center conducted training on pharmacovigilance organized by Alexandria main University Hospital, attendees were 60 HCPs as 34 pharmacists, 20 nurses, and 6 Physicians had attended from different healthcare units from six hospitals of Alexandria university as Alexandria Main University Hospital, New University Hospital, Borg El Arab University Hospital, Alexandria University Children Hospital (El Shatby), Smouha University Hospital For Pediatrics and Pediatric Surgeries, El Hadara University Hospital (Nariman).

The training included a lecture and workshop on the basics of Pharmacovigilance, its importance, and how to report adverse events and other safety information related to the different pharmaceutical products such as medicines, vaccines, biological products, and medical devices.

Egyptian Pharmaceutical Vigilance Center (EPVC) Vigiflow expansion project Trainings for Raising Reporting Awareness

The Egyptian Pharmaceutical Vigilance Center (EPVC) is thrilled to announce the continuation of Vigiflow Expansion training in collaboration with the Health Insurance Organization (HIO) and the Specialized Medical Centers (SMCEgy).

In line with our commitment to pharmacovigilance, this training program aims to educate pharmacists employed in coordinating institutions on how to effectively report using the national database reporting system. Additionally, it endeavors to enhance the reporting system itself and provide the organization an access to a strong database.

EPVC Regional Centers provided the training in May 2023 as two days of online lectures, followed by another day of tutorials on the National Database.

Simultaneously, as the training sessions progress, EPVC remains actively engaged in receiving cases through the national database. We diligently review these cases, offer feedback to the coordinating organizations, and assess the need for further training. This ongoing effort aims to elevate the quality of the cases entered into the database.



EPVC News

Together for Safe Medicine Initiative Progress

We are happy to announce that EDA had organized an event on 25 May 2023 to celebrate the Success of the first three waves of the Central Administration of pharmaceutical care Initiative “Together for Safe Medicine” In the presence of Professor Dr. Aiman ElKhattib Deputy Chairman of EDA, Dr. Shereen Abdel Gawad Head of Central Administration of pharmaceutical care, Dr. Alaa Afdal Manager of General Administration for Pharmaceutical Vigilance and Representatives of various medical Institutions as Health care Authority, Specialized Medical Centers(SMC), Supreme council of universities hospitals and MUP& Pharco PV unit managers



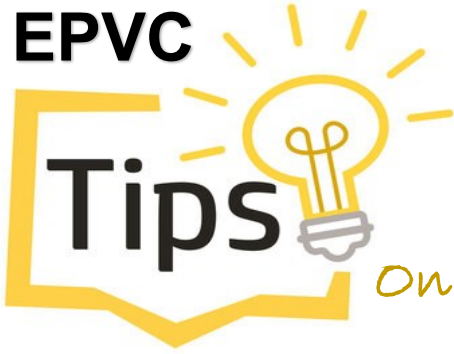
EPVC News

Together for Safe Medicine Initiative Progress

Professor Dr. Aiman ElKhattib had Rewarded the top achievers' pharmacists of the three waves who attended the celebration and the Pharmacovigilance team responsible for Initiative by giving them a shield of distinction as an appreciation of their valuable efforts in applying, practicing, and spreading the science of Pharmacovigilance and increasing the ADRs reporting rate through their community and governmental Pharmacies trying to improve Drug safety in the Egyptian Market.



EPVC



On Pharmacovigilance



Hormonal contraception Side Effects and Risks

Combined Hormonal Contraception: could cause minor symptoms, especially in the first few months of starting it, such as: Nausea, headaches, breast tenderness and irregular periods.

However, Birth control methods with estrogen hormone could also make increase the risk of blood clots. For this reason, Doctors don't suggest these methods if your age is above 35 years and you are a smoker. But if you're in good health and don't smoke, these types of birth control can be used until menopause. Also, Progestin-Only Pills (Minipills) may cause: Irregular periods, tender breasts, depression, nausea and ovarian cyst.



Visit EDA website to find all any 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](#)



EPVC
The Egyptian Pharmaceutical Vigilance center
مركز المراقبة الصيدلانية المصري



One report counts

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

A call for reporting

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

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>



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