EGYPTIAN DRUG AUTHORITY

هيئة الدواء المصرية

The Egyptian Pharmaceutical Vigilance center

مركز اليقظة الصيدلية المصري

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

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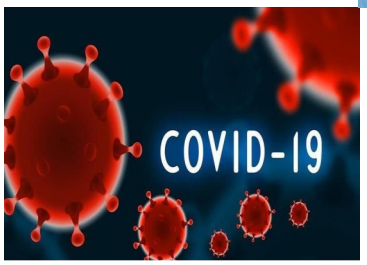
Pholcodine Containing Antitussive Drugs and Risk of Allergic Reaction to Neuromuscular Blocking Agents in the Context of the COVID-19 Epidemic

In the context of COVID-19 pandemic, EPVC would like to highlight the potential risk of cross-allergic reactions between pholcodine, used in cough syrups, and curares (neuromuscular blocking agents), used in anesthesia/ resuscitation. As a precaution, we recommend that doctors do not prescribe a medicinal product containing pholcodine for the symptomatic treatment of cough and that patients do not use them on their own.



NMBA

Neuromuscular Blocking Agents

Background on the safety concerns

Pholcodine, used as an active ingredient in cough syrups, has been the subject of discussions on its potential risk of cross-allergy with muscle relaxants such as neuromuscular blocking agents. Indeed, cases of allergic reactions to neuromuscular blocking agents after use of pholcodine, rare but serious (anaphylactic shock), have been reported.

Healthcare Professionals: In the current context of the COVID-19 pandemic, it is therefore advisable, as a precautionary measure, not to prescribe a pholcodine-based medicinal product in the treatment of cough symptoms. This is to reduce the risk of a cross-allergic reaction in the event of a change to a serious form of COVID-19 requiring admission of the patient to the intensive care unit.

Patients: It is also recommended that patients not use pholcodine-based medication for current cough symptoms, and more generally avoid self-medicating in the case of any symptom suggestive of a COVID-19 infection: if you have a cough, associated with fever, difficulty breathing, muscle pain, loss of taste and/or smell, contact your doctor.

It is also important to highlight that, based on currently available data, the benefit-risk balance of pholcodine-containing products in the treatment of non-productive cough is positive under normal conditions of use.

References:

1. *ANSM* (Click here)
2. *EMA* (Click here)

Direct Healthcare Professional Communication (DHPC): Glatiramer acetate-Rare Cases of Severe Liver Damage

EPVC in agreement with market authorization holders (MAH) of products containing Glatiramer acetate would like to inform you of rare cases of severe liver damage (including Liver failure, hepatitis with jaundice and in isolated cases Liver transplant). Therefore Liver function tests are recommended before and during treatment with Glatiramer acetate-containing drugs.

Summary:

Rare cases of severe liver damage (including liver failure, hepatitis with jaundice and in Individual cases of liver transplantation) have been reported with the use of glatiramer acetate. Most cases of severe liver damage decreased with discontinuation of treatment. In order to reduce the risk of severe liver damage, a recommendation to monitor the liver was made.

Monitoring liver function and criteria for discontinuing therapy:

* Liver function tests should be done before starting treatment with glatiramer acetate and regularly thereafter (e.g. every 6-12 Months). It is recommended to use serum aminotransferase or alkaline phosphatase in all patients and determine the total bilirubin level.
* Patients should be monitored for signs of liver damage during treatment. If clinically relevant liver damage is suspected, the treatment with glatiramer acetate should be discontinued.

Please inform your patients:

* How to recognize signs and symptoms that indicate liver damage, such as nausea, loss of appetite, repeated vomiting, diffuse itching, dark colored urine and light-colored stools, yellowing of the skin or the whites of the eyes and increased tendency to bleeding.

* Contact a doctor immediately if one of the above symptoms appear.

Background on the safety concerns

Glatiramer acetate is used to treat relapsing multiple sclerosis (MS). Glatiramer acetate is a synthetic, complex mixture of polypeptides and acts as a disease-modifying agent which leads to a significant reduction in the number of attacks.

Rare cases of severe liver damage have been reported. The possible mechanism that leads to liver damage is current not known. The drug-induced liver injury (DILI) pattern is considered idiosyncratic.

The pattern of reported events was similar for the two dosages 20mg / ml and 40mg / ml. Hepatic events occurred within days to years from starting treatment with glatiramer acetate. In these cases, among other things, the following co-factors were reported: excessive alcohol consumption, existing or known history of liver damage and use of other potentially hepatotoxic drugs.

Most cases of severe liver damage decreased with discontinuation of treatment.

Direct Healthcare Professional Communication (DHPC): Glatiramer acetate- Rare Cases of Severe Liver Damage Continued

Recommendations for Healthcare Professionals :

1. The early detection of possible liver damage from the use of Glatiramer acetate is essential so that timely measures can be taken and, if clinically relevant, the treatment can be discontinued.
2. Healthcare professionals should test serum aminotransferase, alkaline phosphatase and total bilirubin level of all patients before starting treatment thereafter (for example every 6-12 months) .
3. Patients should be monitored for signs and symptoms of liver damage, such as:
   - ⇒ Nausea
   - ⇒ Loss of appetite
   - ⇒ Repeated vomiting
   - ⇒ Diffuse itching
   - ⇒ Dark colored urine and light-colored stools
   - ⇒ Yellowing of the skin or the whites of the eyes
   - ⇒ Increased tendency to Bleeding.

   and trained to recognize such symptoms and seek medical advice if symptoms occur.

References:

Swissmedic *(Click here)*

The Egyptian Pharmaceutical Vigilance center
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Case Report from Cairo: A Case of Guillain-Barre Syndrome Following Janssen COVID-19 Vaccine

The regional center in Cairo received a spontaneous report concerning a 37 years old male who was administered COVID-19 vaccine Janssen. Five or six days later, the patient started to develop numbness in his left leg followed by swelling at the tibia, as a result, he suspected a DVT and did an ultrasound which revealed absence of DVT.

Within 10 days, his right leg developed the same signs, followed by burning sensation and he felt that he doesn't feel with his leg, followed by his hands.

The patient was admitted to the Hospital where he was diagnosed as Guillain Barre syndrome and he was prescribed and administered SoluMedrol 400mg once daily for 5 days, the patient was then discharged.

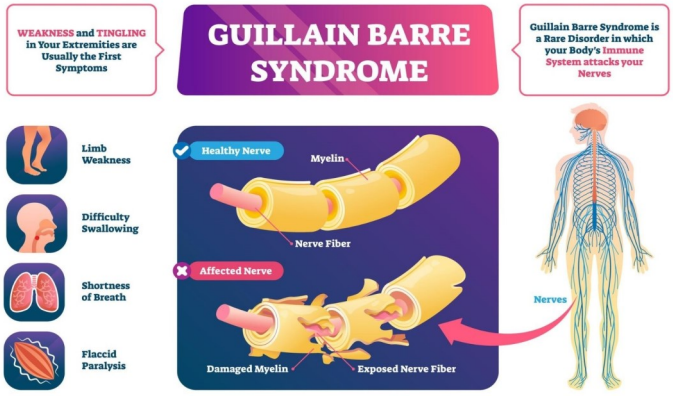
One day later, he started to develop swelling of the left side of his face, dropped face and vision difficulty, as a result he went to the ER in another hospital, at the evening of the same day he was referred to Naser Institute where he was admitted and they were planning to give him IVIG or to perform plasmapheresis.

Examination Report revealed that the patient suffers from mild demyelinated sensory neuropathy of both lower limbs. On follow up we were informed that the patient was recovering.

Background:

On February 2021, the U.S. Food and Drug Administration issued an emergency use authorization (EUA) for the Janssen COVID-19 Vaccine for the prevention of coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 18 years of age and older.

Based on information provided by the manufacturer, the Johnson & Johnson vaccine, or Ad26.COV2.S, has shown to be 66.9% effective in an ongoing, large-scale clinical trial. [2]



GBS is a neurological disorder in which the body's immune system damages nerve cells, causing muscle weakness, or in the most severe cases, paralysis. Based on an analysis of Vaccine Adverse Event Reporting (VAERS) data, there have been 100 preliminary reports of GBS following vaccination with the Janssen vaccine after approximately 12.5 million doses administered. Of these reports, 95 of them were serious and required hospitalization. There was one reported death.

Labeled information:

According to THE JANSSEN COVID-19 VACCINE FACT SHEET FOR RECIPIENTS AND CAREGIVERS [3] it was stated that: "Guillain Barré syndrome (a neurological disorder in which the body's immune system damages nerve cells, causing muscle weakness and sometimes paralysis) has occurred in some people who have received the Janssen COVID-19 Vaccine. In most of these people, symptoms began within 42 days following receipt of the Janssen COVID-19 Vaccine. The chance of having this occur is very low."

Case Report from Cairo: A Case Guillain-Barre Syndrome Following Janssen COVID-19 Vaccine Continued

Warnings and Recommendations:

1. The U.S. Food and Drug Administration (FDA) recently issued a warning that the single-dose vaccine is associated with an increased risk of developing Guillain-Barré syndrome (GBS), a rare autoimmune disorder that attacks the body's nerves. Although the available evidence suggests an association between the Janssen vaccine and increased risk of GBS, it is insufficient to establish a causal relationship. FDA continues to work with its partner in vaccine safety surveillance, the CDC, to monitor reports of GBS following vaccination with the Janssen COVID-19 Vaccine. [5]
2. Although cases of GBS after vaccination with COVID-19 Vaccine Janssen have been reported very rarely, healthcare professionals should be alert to signs and symptoms of GBS, in view of the seriousness of this condition, to allow for early diagnosis, supportive care and treatment. [6]
3. Patients should seek medical attention right away if they develop any of the following symptoms after receiving the Janssen COVID-19 Vaccine [4]:
   - ⇒ Weakness or tingling sensations, especially in the legs or arms, that's worsening and spreading to other parts of the body.
   - ⇒ Difficulty walking.
   - ⇒ Difficulty with facial movements, including speaking, chewing, or swallowing.
   - ⇒ Double vision or inability to move eyes.
   - ⇒ Difficulty with bladder control or bowel function.
4. In addition to rare risk of Guillian–barre syndrome; thrombosis and thrombocytopenia (TTS), in some cases accompanied by bleeding, has been observed very rarely following vaccination. COVID-19 Vaccine Janssen is also now contraindicated in individuals who have previously experienced episodes of capillary leak syndrome (CLS) [7] .
5. However, the benefits of COVID-19 Vaccine Janssen continue to outweigh the risks of the vaccine [6].

References:

1. *FDA (Click here)*
2. *WHO (Click here)*
3. *FDA (Click here)*
4. *FDA (Click here)*
5. *FDA (Click here)*
6. *EMA (Click here)*
7. *EMA (Click here)*

Egyptian Pharmaceutical Vigilance Center Announce Access of EPVC News and Guidelines on EDA's Website

The Egyptian Pharmaceutical Vigilance Center would like to inform you that the Egyptian Drug Authority (EDA) website currently hosts our guidelines and all Direct Healthcare Professional Communications for 2021 which can be accessed through the following link *(Click here)* .

Pharmacovigilance Training Session at the Medical Services Sector of the Egyptian Ministry of Interior

In continuation of the Role of the Egyptian Pharmaceutical Vigilance Center (EPVC) in spreading the awareness of Pharmacovigilance and the culture of reporting of adverse events among Healthcare professionals, and to complement the cooperation with the Medical Services Sector of the Egyptian Ministry of Interior for the second year, Cairo Regional center has taken part in Cycle (2) of "Basics of Clinical Pharmacy Practice" Training Course conducted at the Institute of Specialized Medical Training.

The training included two lectures 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. Also, a lecture about Case Studies and Regulatory actions taken in these cases. The workshop included how to Report a case on yellow cards and how to access the Electronic Reporting Link Online.

Attendees were 12 pharmacists, who are affiliated to the Ministry of Interior hospitals in Cairo. They showed a great interest in the importance of Reporting Adverse Events and practicing Pharmacovigilance in their institutes, for better patient safety and rational drug use.

Sohag Pharmacovigilance Center Training Session of Faculty of Pharmacy - Sohag University Students for Awareness of Adverse Events Reporting

In efforts of pharmacovigilance center to provide pharmaceutical care to the patient to obtain a safe and effective medicine, the pharmacovigilance center in Sohag accepted the invitation of the Egyptian Pharmaceutical Students' Federation at the Faculty of Pharmacy at Sohag University to hold an introductory workshop about the importance of the role of Pharmacovigilance and to raise awareness of how to report the adverse effects of drugs.

The workshop was held inside the Faculty of Pharmacy at the university and was attended by 29 students from the Faculty of Pharmacy at Sohag University, The workshop resulted in students' interaction and reporting of some reports on the adverse effects of drugs.

The Egyptian Pharmaceutical Vigilance center
مركـــز اليـــقظة الصـــيدلية المـــصري

One report counts

A call for reporting

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

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)

The Egyptian Pharmaceutical Vigilance center
مركز اليقظة الصيدلية المصري

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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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