EGYPTIAN DRUG AUTHORITY

هيئة الدواء المصرية

The Egyptian Pharmaceutical Vigilance center

مركز اليقظة الصيدلية المصري

IN THIS ISSUE

Prepared by:

Reem Hossam

Dina Gawish

Ola Fahmy

Mariam Morkos

Designed by:

Reem Tarek

Chief editor

Aalaa Afdal

Head of Egyptian Pharmacovigilance Center

Under supervision of

Dr. Sherin Abdel Gawad

Head of the C.A for Pharmaceutical Care

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.

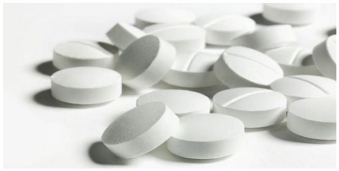
Newsletter

March 2022

Volume 13 **Issue 3**

Direct Healthcare Professional Communication (DHPC): Dapagliflozin 5mg Should No Longer be Used for the Treatment of Type 1 Diabetes Mellitus

EPVC in agreement with market authorization holders (MAH) of products containing Dapagliflozin would like to inform you of the following:



Summary:

* Dapagliflozin 5mg is no longer authorized for the treatment of patients with type 1 diabetes mellitus (T1DM) and should no longer be used in this population. This is based on the decision to remove the T1DM indication for Dapagliflozin 5mg.
* Diabetic ketoacidosis (DKA) is a known side effect of Dapagliflozin. In T1DM studies with Dapagliflozin, DKA was reported with common frequency (occurring in at least 1 per 100 patients).
* Additional risk minimization measures for healthcare professionals and patients, implemented to mitigate the risk of DKA with the use of Dapagliflozin in T1DM will no longer be available.
* Discontinuation of Dapagliflozin in patients with T1DM must be made by or in consultation with a physician specialized in diabetes care and be conducted as soon as clinically practical.
* After stopping Dapagliflozin treatment, frequent blood glucose monitoring is recommended, and the insulin dose should be increased carefully to minimize the risk of hypoglycaemia.

Background on the safety concerns

Dapagliflozin 5mg should no longer be used for the treatment of patients with T1DM as an adjunct to insulin in patients with BMI ≥ 27 kg/m2, when insulin alone does not provide adequate glycaemic control despite optimal insulin therapy.

The decision was taken to remove the T1DM indication for Dapagliflozin. Other Dapagliflozin 5mg and 10mg indications are not affected by this change. Dapagliflozin remains authorized in adults for the treatment of type 2 diabetes mellitus, and for the treatment of symptomatic chronic heart failure with reduced ejection fraction.

The use of Dapagliflozin 5mg for the treatment of T1DM required specific additional risk minimization measures for DKA, such as a patient alert card and a Health Care professional Guide. As a result of the Dapagliflozin 5 mg T1DM indication removal, the additional risk minimization measures will no longer be available.

References:

EMA (Click here)

Case Report from Cairo: Alendronic Acid - Case of Osteonecrosis of the Jaw

The regional center in Cairo received a report via EDA Hotline concerning a 78 years old female patient that took Alendronic Acid for a year for Osteoporosis, bone weakness and pain in lower back. The patient went to the dentist for teeth implantation, but the dentist told her that her jaw bones are eroded and transplantation can't be done now. When asked about her drug regimen, dentist told the patient that Alendronic acid was the reason for this condition and she should stop it for 3 months to restore jaw bones to be able to transplant teeth. The patient also was taking Ramipril and Amlodipine+ Valsartan + Hydrochlorothiazide for hypertension. She had taken Alendronic acid for 2 years 5 years ago, but she never discovered then that she had a jaw problem.

Background:

Alendronic acid belongs to a group of non-hormonal medicines known as bisphosphonates, which prevent bone loss from the body. Alendronic acid is used to treat osteoporosis (brittle bones). This condition is common in women after the menopause. The earlier a woman reaches the menopause, the greater the risk of her developing osteoporosis. Without treatment, osteoporosis can cause thinning and weakening of the bones in the skeleton which can then lead to fractures, usually of the hip, backbone and wrists. Fractures can occur easily in people suffering from osteoporosis including during normal everyday activities such as heavy lifting or from a minor injury or fall. Alendronic acid helps to prevent bone loss and to build up bone which may have been lost due to osteoporosis. It can therefore reduce the risk of back and hip fractures.[1]

Labeled information:

According to Alendronic acid Summary of product Characteristics (SmPC)[2] it was stated Under section (4.4 Special warnings and precautions for use) that:

"Osteonecrosis of the jaw, generally associated with tooth extraction and/or local infection (including osteomyelitis) has been reported in patients with cancer receiving treatment regimens including primarily intravenously administered bisphosphonates. Many of these patients were also receiving chemotherapy and corticosteroids. Osteonecrosis of the jaw has also been reported in patients with osteoporosis receiving oral bisphosphonates."

Recommendations for Healthcare Professionals

1. The following risk factors should be considered when evaluating an individual's risk of developing osteonecrosis of the jaw:
   - ⇒ Potency of the bisphosphonate (highest for Zoledronic acid), route of administration and cumulative dose.
   - ⇒ Cancer, chemotherapy, radiotherapy, corticosteroids, smoking
   - ⇒ A history of dental disease, poor oral hygiene, periodontal disease, invasive dental procedures and poorly fitting dentures.
1. A dental examination with appropriate preventive dentistry should be considered prior to treatment with bisphosphonates in patients with poor dental status.
2. While on treatment, these patients should avoid invasive dental procedures if possible. For patients who develop osteonecrosis of the jaw while on bisphosphonate therapy, dental surgery may exacerbate the condition. For patients requiring dental procedures, there are no data available to suggest whether discontinuation of bisphosphonate treatment reduces the risk of osteonecrosis of the jaw.
3. Clinical judgement of the treating physician should guide the management plan of each patient based on individual benefit/risk assessment.
4. During bisphosphonate treatment, all patients should be encouraged to maintain good oral hygiene, receive routine dental check-ups, and report any oral symptoms such as dental mobility, pain or swelling. [2]
5. Hypocalcemia reported with use of bisphosphonates; correct hypocalcemia prior to therapy; ensure adequate calcium and vitamin D intake[4].
6. Risk of osteonecrosis of the jaw may increase with duration of exposure to bisphosphonates. The optimal duration of therapy with alendronate has not been established. Periodically re-evaluate the need for therapy. Discontinuation of therapy should be considered by doctors after 3 to 5 years in patients at low risk of fracture[5].

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

References:

1. *EMC (Click here)*
2. *EMC (Click here)*
3. *Medscape (Click here)*
4. *Drugs.com (Click here)*

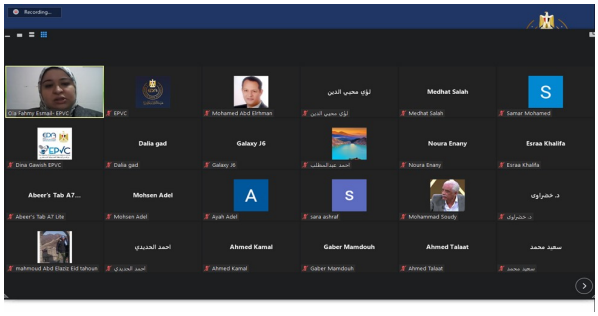
The Egyptian Pharmaceutical Vigilance center
مركز اليقظة الصيدلية المصري

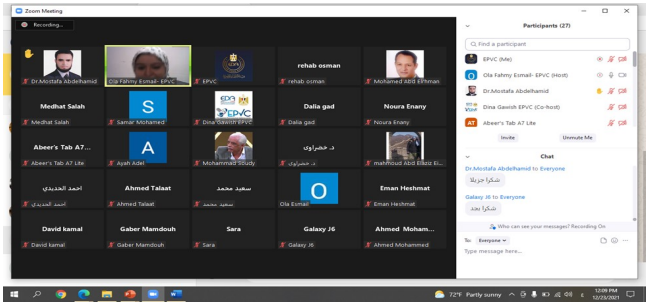
Together for Safe Medicine Initiative Progress

The Egyptian Pharmaceutical Vigilance Center (EPVC) is delighted to announce the completion of the introductory phase of the Egyptian Drug Authority (EDA) initiative "Together for Safe Medicine" which targets the community pharmacies all over Egypt. The initiative aimed to raise the professional competence of Egyptian pharmacists in order to ensure the application of the highest levels of pharmaceutical care in a manner that ensures the patient's safety and security through enhancing the ADRs and other safety information reporting which comes in accordance with Egypt's 2030 vision for upgrading the Egyptians quality of life.

During this two-week introductory phase, the participants completed an online pre-test, attended online pre-recorded lectures, and finished an online post-test. They also completed three projects aimed at raising pharmaceutical vigilance knowledge among Egyptian patients in community pharmacies.

Those who finished this phase were upgraded to the implantation phase which will last for 3 months and includes an intensive follow-up with participants that aims at implementing pharmaceutical vigilance activities in each participant community pharmacy in order to be finally a member of "EPVC Community Club" and given certificate for their excellence and "EPVC Community Club" poster.





Special Acknowledgment to the International Medical Center

EPVC would like to express it's gratitude to the International Medical Center represented by Pharmacist Samah Sallam for their efforts and effective participation in reporting adverse drug reactions occuring from the use of medicines within the International Medical Center regularly, which contributes to the progress towards achieving the goal of safe and effective medicine to patients.

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
مركـــز اليـــقظة الصـــيدلية المـــصري

Address: 21 Abd El Aziz AlSoud Street. El-Manial, Cairo, Egypt, PO Box: 11451
Hotline: 15301
Fax: +202 – 23610497
Email: pv@edaegypt.gov.eg,
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)