هيئة الدواء المصرية

IN THIS ISSUE

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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

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Safety Notification ! Medicines containing Garcinia gummi-gutta (Garcinia cambogia) or hydroxycitric acid (HCA)

The Regulatory Authority in Australia has published the following safety notification:

Key messages

Medicines and herbal supplements containing Garcinia gummi-gutta (Garcinia cambogia) or hydroxycitric acid (HCA) may cause liver injury in rare cases. The risk also relates to other ingredients that contain HCA: Garcinia quaesita, hydroxycitrate complex, calcium hydroxycitrate, sodium hydroxycitrate, or potassium hydroxycitrate. You should immediately stop taking medicines or herbal supplements containing these ingredients and seek medical advice if you experience any of the following symptoms:

Yellowing of the skin or eyes , Dark urine , Nausea , Vomiting , Unusual tiredness , Weakness , Stomach or abdominal pain , Loss of appetite.

If you currently have or have had liver problems, you should avoid medicines and herbal supplements containing Garcinia related ingredients

Rare link with liver injury

We have become aware of an increasing number of cases of liver injury reported in scientific literature, by consumers who had taken products containing Garcinia gummi-gutta/HCA. Older literature reports mostly involved additional ingredients that may have contributed to the liver injury, but recently more cases have been published with Garcinia gummi-gutta (Garcinia cambogia)/HCA as the only suspected ingredient in the liver injury. Many of these cases were severe and required hospitalisation. Of particular concern, 5 cases resulted in liver transplantation, one of which was an Australian case. We are also aware of several cases of liver injury reported to regulators in other countries. We have also received a small number of reports of possible liver-injury involving Garcinia ingredients. However, most reports contained limited information about the medicines consumed and some cases involved other ingredients that may have contributed to liver injury. In response to this safety concern, we completed an investigation into the risk of liver injury for the ingredient Garcinia gummi-gutta (Garcinia cambogia) and its naturally occurring component HCA. Available evidence shows that there may be a rare risk of liver injury from taking Garcinia gummi-gutta (Garcinia cambogia) or HCA. Liver injury concerns also apply to the other HCA-containing ingredients. We will continue to monitor this issue and are currently considering further regulatory action, including consultation on proposed requirements for a label warning. We will publish the outcome of this consultation including the details of any new labelling requirements in late 2024.

About Garcinia species

Medicines and herbal supplements containing Garcinia gummi-gutta (sometimes also called Garcinia cambogia) and other HCAingredients can be bought in supermarkets, health food shops and pharmacies without a prescription and without the advice of a health professional. The fruit rind of Garcinia gummi-gutta and Garcinia quaesita naturally contains HCA. HCA can be extracted and used in listed medicines as an active ingredient and is present in the other Garcinia-related ingredients.

Safety Notification ! Medicines containing Garcinia gummi-gutta (Garcinia cambogia) or hydroxycitric acid (HCA)

Information for consumers

If you take medicines or herbal supplements containing Garcinia-related ingredients, you should be aware of the possible risk for liver injury. While liver injury is a rare side effect, it can be severe. However, the risks are reduced if you recognise the early signs and stop taking the medicine or herbal supplement.

Patients should immediately stop taking it and seek medical advice if you experience any of the following symptoms:

1. Yellowing of the skin or eyes
2. Dark urine
3. Nausea
4. Vomiting
5. Unusual tiredness
6. Weakness
7. Stomach or abdominal pain
8. Loss of appetite.

As a precaution, if you currently have or have had liver problems, you should avoid medicines and herbal supplements containing Garcinia-related ingredients. If you have any concerns or questions about this issue, you should discuss them with your health professional. You can report any suspected side effects from medicines or herbal supplements to us or your health professional. Please note that some reports of liver damage involved products purchased online from overseas. You should exercise caution when considering buying medicines online . Medicines bought online from overseas are not regulated by us for quality and safety. The benefits of purchasing complementary medicines that are regulated by us include that you have assurances that those products contain the ingredients listed on the label and are made under strict manufacturing standards. If you buy unregulated medicines, either from a local retailer or online, you may be wasting your money and risking your health.

Information for sponsors

Sponsors of products containing Garcinia-related ingredients should be aware of this issue and take appropriate risk mitigation action if the available evidence alters the risk-benefit profile for their products. Sponsors are also reminded of their obligation to report all serious adverse events and significant safety issues to us within required timeframes.

References:

TGA : *(Click Here)*

The Egyptian Pharmaceutical Vigilance center
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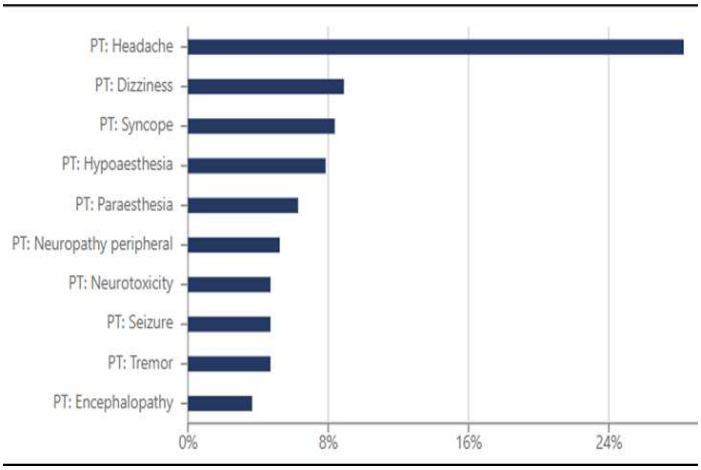
Local Case Report: Cytarabine induced CNS adverse reactions

Since the beginning of 2024, the Egyptian Pharmaceutical Vigilance Centre has received 4 ICSRs of Cytarabine induced neural adverse reactions. Two out of four ICSRs were serious, life-threatening and caused prolonged hospitalization.

Reaction (MedDRA)	
Headache	Reported in two cases
Seizure and/or Convulsion	Reported in two cases
Consciousness disturbed	Reported in one case
Seriousness	
2 cases were serious	Life threatening or caused/prolonged hospitalization
2 cases were non-serious	

The following is one of those simple case scenarios:

M.M is a female patient with 27 years old and weighting 54 Kg, suffering from Acute myeloid leukaemia (AML). The patient administrated Cytarabine 1-gram intravenous use for three days (twice daily) Two days after starting cytarabine regimen the case experienced seizure as an adverse cytarabine related reaction. The physician did not stop the medication cycle and added Levetiracetam oral tablets 500 mg twice daily to her medical plan and continued her cycle safely. Fortunately, the case recovered, and the reaction is considered serious because it was a life threatening in addition requiring an intervention to stop damage.



Cytarabine is metabolized to Ara-CTP, a known cerebellar and cerebral toxin when given in doses over 1 g/m2. Risk factors for developing cerebellar toxicity include:

Age over 50 years

Impaired renal function (CrCl <60 mL/min)

And total dose received, high dose cytarabine is defined as 2,000-3,000 mg/m2

Prior CNS disease may also be a risk factor.

Neurotoxicity (8-10%) typically occurs 3-8 days after initiating therapy.2,4,15,25 Cerebellar dysfunction is characterized by difficulty with speech, trouble standing or walking, and tremors.

Cerebral dysfunction may be seen concomitantly and is characterized by somnolence, confusion, personality changes, cognitive dysfunction, memory loss, psychosis, or seizures. Seizures are usually self-limited. In most patients, neurologic dysfunction resolves in 5-10 days.

There is a high incidence (approximately 60%) of recurrent cerebellar toxicity in patients who have already experienced toxicity. It is not conclusively known if cytarabine therapy should be discontinued if neurological toxicity develops.

Peripheral motor and sensory neuropathies involving both upper and lower extremities have occurred. Neuropathies may manifest as muscle weakness, gait disturbances, paresthesias, myalgia, hypoalgesia, and hypoesthesia. Dose adjustments may be required to avoid irreversible complications.

Cytarabine and Nervous system disorders as mentioned in SPCs

Common	At high doses cerebellar or cerebral influence with deterioration of the level of consciousness, dysarthria, nystagmus
Uncommon	Headache, peripheral neuropathy and paraplegia at intrathecal administration
Not known	Dizziness, neuritis or neural toxicity and pain, neurotoxicity rash

Management of Cytarabine induced neural toxicity:

A. Prevention

Ongoing neurological assessment of patients will lead to early identification of symptoms, prompt intervention (drug dose reduction, delay, or drug discontinuation), and prevention of severe, irreversible toxicity. In most cases, this toxicity is reversible but if cytarabine is continued without dose reduction, severe, irreversible and possibly fatal effects may occur. Methods used to decrease the risk of neurotoxicity in these patients include decreasing the dose, utilizing a once-daily rather than twice-daily schedule, shortening the course of treatment, and modifying the dose based on the CrCl, Dosing:

Altered Kidney Function:

Low dose Cytarabine	
No dose adjustment needed	
High- and intermediate-dose cytarabine: (≥1,000 mg/m2/ dose)	
CrCl ≥60 mL/minute	No dosage adjustment necessary.
CrCl 31 to 59 mL/minute	Consider alternative agents. If necessary, administer 50% of the usual recommended dose; monitor closely for neurotoxicity. Some protocols cap single doses at 1,000 mg/m2.
CrCl ≤30 mL/minute	Consider alternative agent

Treatment

In the event of a change in neurological status discontinue cytarabine infusion immediately.

Stopping therapy usually results in recovery within several weeks. However, only 30% of patients have complete resolution of symptoms. There is no specific treatment, although methylprednisolone has been reported to be effective in some cases.

References:

1. ***Cytarabine SPCs:*** *(Click Here)*
2. ***BC cancer Drug monograph- :*** *(Click Here)*
3. ***Clinical Key drug monograph:*** *(Click Here)*
4. ***NHS AML protocols: - :*** *(Click Here)*
5. ***Eviq protocols: - :*** *(Click Here)*
6. ***VigiLyze, qualitative view***

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

The Egyptian Pharmaceutical Vigilance Center (EPVC) is happy to announce that it provided high level vigiflow expansion training in cooperation with "Central Administration for Pharmaceutical Affairs - MoHP" to focal points from different Health Affairs Directorates.

In addition to advancing the information on the national database that explains the framework and expresses gratitude for those organizations' principal goals, the trainings aim to raise knowledge of the significance of completeness scores. Apart from conducting preparation sessions, EPVC also handles case intake procedures, audits, gives planning organizations input, and determines if further preparation is required to ensure that the quality of cases added to the national database is kept at the highest level.

Meanwhile, EPVC is effectively obtaining examples from the national database, implementing the required adjustments, and offering the planning organizations helpful feedback. This all-encompassing methodology is anticipated to yield a more robust and dependable means of overseeing and monitoring dangers to pharmaceutical safety.

Appreciation would be extended by the Egyptian Pharmaceutical Vigilance Center (EPVC) to some SMC organisations "Damnhour Oncology, Qena Onology Center, Nasser Institute" for their high entering rate of ICSRs on vigiflow.

Thank you for submitting cases to the national database reporting system. EPVC would also like to thank all the organizations that worked with us to expand the Vigiflow system. We appreciate their commitment and progress in improving the monthly section cases and progressively higher case quality stages in the national database, and we wish them continued success in their endeavors.

"Together for Safe Medicine" Initiative News:

EDA is extremely thankful for 4th wave participants for their valuable sharing and activities used in spreading the science of pharmacovigilance all over Egypt governments by using most recent social media tools as YouTube channels, Podcast and on line competitions related science of Pharmacovigilance and ADRs reporting between HCPs and public. Special thanking for the following participants from governmental hospitals and community pharmacies :

- Mansora international hospital team (Dr Fatma Elzahraa, Dr Nesma Elsayed and dr Shrouk Ahmed)for using Podcast as a recent Social media tool used for spreading pharmacovigilance science.
- Kafar Elshikh university Hospitals (Dr Norhan Mahrous) for spreading Pharmacovigilance science between school children in a simple way.
- El Quisia hospital Assiut Governorate (Dr Esraa Ahmed) for making interesting Online competition between HCPs to educate pharmacovigilance science with interesting way.
- Damietta Specialized Hospital (Dr Nesma Ahmed) For making AI vedio Discussion Pharmacovigilance science.
- Dr Weal zitone for using his YouTube channel to spread pharmacovigilance science
- Dr Samir Aziz for using new social media tools as TikTok to spread pharmacovigilance science.

EPVC Tips

On Pharmacovigilance

Active Listening for Improved Patient-Provider Communication

Active listening: is a powerful tool for fostering trust, understanding, and effective communication between healthcare providers and patients. Here's how to practice active listening:

1. Give your full attention: Maintain eye contact, avoid distractions, and show that you are genuinely interested in what the patient is saying.
2. Paraphrase and summarize: Repeat back what the patient has said in your own words to ensure understanding and confirm that you've captured the key points.
3. Ask open-ended questions: Encourage the patient to elaborate on their thoughts and feelings by asking open-ended questions that begin with "how," "what," or "why."
4. Validate their emotions: Acknowledge the patient's feelings and let them know that their emotions are valid and understood.
5. Avoid interrupting: Allow the patient to finish speaking without interruption. This shows respect and helps build trust.

By practicing active listening, you can create a more empathetic and supportive environment for your patients, leading to improved health outcomes and overall satisfaction.

Visit EDA website to find all medicine- related news, updates and alerts Click here

You will find all EPVC Newsletters and DHPCs here

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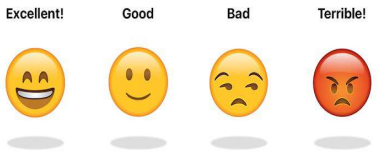
One report counts

A call for reporting

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

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

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

Communication information

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