EGYPTIAN DRUG AUTHORITY

هيئة الدواء المصرية

IN THIS ISSUE

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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 2024

Volume 15 Issue 8

Safety Notification Reminder ! Pseudoephedrine-contraindications

The Regulatory Authority in New Zealand has published the following safety notification:

Key messages

- Pseudoephedrine is included in some cold and flu medicines for its nasal decongestant effects.
- Pseudoephedrine must not be used in people with uncontrolled hypertension or severe coronary artery disease, concomitantly with monoamine oxidase inhibitors (MAOIs), or people with hypersensitivity to pseudoephedrine.

What is pseudoephedrine?

Pseudoephedrine is a sympathomimetic used as a nasal decongestant.1, 2 It provides short-term symptomatic relief of runny noses and nasal congestion due to conditions such as colds and flu. Combination products contain pseudoephedrine with either paracetamol or ibuprofen, which relieve other cold and flu symptoms such as headache, body aches and fever. Some combination products also contain a sedating antihistamine to relieve sneezing, itchy or watery eyes and assist rest.

Use of pseudoephedrine

Cold and flu medicines containing pseudoephedrine can be used in adults and children . Advise patients of the following.

- Do not use more than one cold and flu medicine to avoid accidental overdose.
- Follow the recommended dose on the pack and do not exceed this dose.

When should pseudoephedrine be avoided?

.Pseudoephedrine may exacerbate some existing medical conditions or increase the risk of adverse effects. Therefore, there are situations where the use of pseudoephedrine must or should be avoided, as outlined below.

1. Pseudoephedrine is contraindicated and must not be used in patients• with uncontrolled hypertension or severe coronary artery disease
2. Taking monoamine oxidase inhibitors (MAOIs) or who have taken MAOIs within the previous 14 days
3. With known hypersensitivity or idiosyncratic reaction to pseudoephedrine and any other ingredients in the medicine

Use pseudoephedrine with caution in patients with hepatic or renal impairment, severe hepatic or renal dysfunction, controlled hypertension, hyperthyroidism, diabetes mellitus, coronary or ischemic heart disease, glaucoma and enlarged prostate. Note that combination products have additional contraindications and cautions because they contain other active ingredients. Check the data sheets for full information. Additionally, pseudoephedrine is included on the World Anti-Doping Agency (WADA) in competition prohibited list.3 Athletes must stop taking pseudoephedrine at least 24 hours before competition.

Other considerations for use

Other considerations for use of pseudoephedrine include the following.

Effects on sleep: Advise patients of sleeplessness if taken a few hours before going to bed. However, note that combination products containing a sedating antihistamine may cause drowsiness.

Ischemic colitis (reduced blood flow to the colon): Advise patients to discontinue use and seek medical advice if they develop sudden abdominal pain, rectal bleeding or other symptoms of ischaemic colitis.

Skin reactions: Advise patients to discontinue use and seek medical advice if they develop a rash with or without fever or erythema (skin redness).

Posterior reversible encephalopathy (PRES) or reversible cerebral vasoconstriction (RCVS): Advise patients to discontinue use and seek medical advice if they develop sudden onset of severe headache, nausea, vomiting and visual disturbances.

Ischaemic optic neuropathy: Advise patients to discontinue use and seek medical attention if they experience a sudden loss of vision or decreased visual acuity, such as scotoma (a blind spot).

References:

Medsafe : *(Click Here)*

Local Safety Report: Management of irinotecan related diarrhea

Since the beginning of 2024, the Egyptian Pharmaceutical Vigilance Centre has received ten ICSRs of Irinotecan induced diarrhea. Three out of ten ICSRs were serious, life-threatening and caused prolonged hospitalisation. The following is one of those case scenarios:

M.N.A. is an elderly male, 70 years old, suffering from metastatic colon cancer, treated with FOLFIRI Protocol, Irinotecan 260 mg, Calcium folinate 240 mg, 1000 mg 5-Flurouracil as continuous infusion / 46 hours (Every 15 days).

After Irinotecan administration – before calcium folinate infusion- the case experienced muscle spasm, dizziness, dyspnoea, bone pain, diarrhea, anorexia.

The infusion was held temporarily for assessment and presenting the corrective treatments including Hydrocortisone, pantoprazole. ECG and Electrolytes were normal

After the case is controlled, the regimen was resumed, muscle spasm, dizziness, dyspnea, bone pain was resolved except diarrhea. The consultant did not modify Irinotecan dose, three days later the case improved and recovered, although the case was serious, life threatening and needed prolonged hospitalization. Concomitant medications include Calcium folinate and 5-flurouracil.

Background

Diarrhea can be a side effect of chemotherapy, radiation therapy, immunotherapy and targeted therapies and can be intensified when treatment modalities are combined. Treatment-induced diarrhea can lead to malnutrition, weight loss, electrolyte imbalance, renal insufficiency and hospital admission, and can have a significant negative effect on a patient's quality of life causing discomfort and limiting daily activities.

It may be severe enough to require a dose reduction, a dose delay or discontinuation of treatment, or changes to the patient's radiation therapy treatment plan. In severe cases, if left untreated, it can be life threatening, especially in a patient who is also neutropenic.

Irinotecan-Induced Diarrhea (IID): Two types of diarrheas were observed after administration of irinotecan, namely acute diarrhea and delayed diarrhea. Immediate onset acute diarrhea is defined as diarrhea occurring within 24 h after receiving irinotecan and is usually caused by acute cholinergic properties and is often accompanied by other symptoms of cholinergic excess, such as abdominal cramping, rhinitis, lacrimation, and salivation; acute diarrhea can be successfully prevented with the prophylactic use of atropine. Delayed-type diarrhea is defined as diarrhea occurring more than 24 h after the initial administration of irinotecan. The delayed form usually peaks after about 11 days treatment.

Management of irinotecan-induced diarrhea:

Acute diarrhea:

- Acute diarrhea can be controlled using a dose of 0.25 mg subcutaneous or IV atropine and can be prevented with future courses of chemotherapy by the administration of the atropine prior to the dose of irinotecan. A further 0.25mg dose can be repeated if needed within the 24-hour period post irinotecan.

- Monitor blood pressure and heart rate regularly.

Delayed diarrhea:

- Atropine has no role in delayed diarrhea.
- At the first loose stool, loperamide should be commenced: 4mg (2 tablets), then 2mg every 2 hours until 12 hours after the last loose stool (up to a maximum of 48 hours).
    - ⇒ Exceeding the daily limit of 16 mg/day is accepted for treatment of irinotecan-associated diarrhea in adults.
    - ⇒ Change to as-needed dosing after 12-hour bowel movement-free period.

Local Safety Report: Management of irinotecan related diarrhea

If diarrhea lasts more than 24 hours, ciprofloxacin 500mg twice daily should be started, in addition to loperamide.

Supportive management:

Fluids and electrolytes

Drink 3 or more liters of clear liquids/day, which should consist of electrolyte-containing fluids (sport drinks, broth, decaffeinated tea)

Nutrition

- Avoid dairy, caffeine, alcohol and concentrated fruit juices
- "BRAT" diet (bananas, rice, applesauce, and toast)
- Bulk-forming agents
- Severe diarrhea may require bowel rest with parenteral nutrition

If diarrhea lasts > 48 hours, or if the patient reports symptoms of dehydration or fever, they should be admitted immediately to hospital for rehydration and further management, including an infection screen.

The occurrence of severe diarrhea concomitantly with severe neutropenia is life-threatening, requiring immediate admission to hospital and the institution of supportive measures.

Irinotecan Dose Adjustment for Diarrhea:

Regarding irinotecan induced diarrhoea and dose modifications, it depends on several parameters such as:

- Is irinotecan administered in a single agent or combination schedule?
- What is the diarrhoea grade?
- Is the patient having other comorbidities?
- Disease stage and the general treatment plan

Toxicity grade (value)	During a cycle of therapy	At start of subsequent cycles of therapy (after adequate recovery), compared to starting dose in previous cycle[a]	
	Weekly	Weekly	Once every 3 weeks
Patients with diarrhea should be carefully monitored and treated promptly; may require fluid and electrolyte therapy. Avoid diuretics and laxatives in patients experiencing diarrhea. Advise patients to have loperamide readily available for the treatment of late diarrhea. Delay weekly irinotecan until bowel function has returned to baseline for at least 24 hours (without antidiarrheals).			
Grade 1 (2 to 3 stools/day > pretreatment)	Maintain dose level	Maintain dose level	Maintain dose level
Grade 2 (4 to 6 stools/day > pretreatment)	↓ 25 mg/m^2	Maintain dose level	Maintain dose level
Grade 3 (7 to 9 stools/day > pretreatment)	Omit dose until resolved to ≤ grade 2, then ↓ 25 mg/m^2	↓ 25 mg/m^2	↓ 50 mg/m^2
Grade 4 (≥10 stools/day > pretreatment)	Omit dose until resolved to ≤ grade 2, then ↓ 50 mg/m^2	↓ 50 mg/m^2	↓ 50 mg/m^2

The following table include ' Colorectal Cancer: Single-Agent Schedule: Recommended Dosage Modifications'

Incidence is more than 10 %	Abdominal pain (68%), anorexia (44%), constipation (32%), diarrhea (84%, grades 3/4: 22%; late: 83%, grades 3/4: 31%; early: 43%, grades 3/4: 7%), nausea (70% to 82%; grades 3/4: 11% to 16%), stomatitis (30%; grades 3/4: 2%), vomiting (62% to 63%; grades 3/4: 12% to 14%) Increased serum bilirubin (84%)
Post-marketing reports	Increased pancreatic enzymes, intestinal perforation, non-Hirschsprung megacolon, pancreatitis

References:

Management of diarrhea *(Click Here)*

Irinotecan induced diarrhea- : *(Click Here)*

Irinotecan Information- : *(Click Here)*

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

The Egyptian Pharmaceutical Vigilance Center (EPVC) is delighted to provide Vigiflow expansion training (advanced level) in coordination with Supreme Council of University Hospitals. 65 attendees of focal points from University Hospitals received additional two training sessions titled: "Vigiflow and ICSRs common pitfalls, completeness score and Case quality" These training sessions will help to improve the quality of cases being entered into the national database. By providing training to the focal points of various organizations, the hope is that data entry on the national database reporting system will be strengthened on an advanced level. This will ultimately lead to better case's data quality and more accurate reporting. In the midst of these training sessions, EPVC is actively retrieving cases from the national database, revising them, and giving the coordinating organizations constructive criticism. It is anticipated that this approach will lead to a more strong and dependable way of monitoring and controlling pharmaceutical safety threats. EPVC would like to express its appreciation to to Giza Health Directorate and Cairo Health directorate for their high entering rate of ICSRs on vigiflow To all the organizations who Cooperated with EPVC to expand the Vigiflow system, EPVC would like to thank you for submitting cases to the national database reporting system. We hope they continue to succeed in their endeavors and appreciate their dedication and maturity in moving forward with more advanced stages for case quality as well as their monthly entry cases, which are substantial, in the national database.

"Together for Safe Medicine" Initiative News:

Egyptian Drug Authority (EDA) Extended the registration for the fifth wave of the Central Administration of Pharmaceutical Care pharmacovigilance Initiative "Together for Safe Medicine" till August 30, 2024. Where pharmacists who are owners or employees of a community pharmacy in Egypt; or outpatient pharmacies of any governmental hospital; or any private institution can register for the fifth wave of the initiative.

هيئة الدواء المصرية تعلن عن **مد فترة** التسجيل للدفعة **الخامسة** من مبادرة الرعاية الصيدلية لليقظة الدوائية بالصيدليات "معاً نحو دواء آمن"

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بناء علي رغبة العديد من الصيادلة للمشاركة في مبادرة "معاً نحو دواء آمن" تعلن هيئة الدواء المصرية عن **مد فترة التسجيل** للدفعة **الخامسة** من مبادرة الرعاية الصيدلية لليقظة الدوائية بالصيدليات "معاً نحو دواء آمن"
والتي تستهدف الصيدليات العامة والصيدليات الخارجية بالمستشفيات، حيث تهدف إلى تعزيز تطبيق أنشطة اليقظة الصيدلية بالصيدليات العامة من أجل توفير دواء آمن وفعال مما يضمن سلامة المرضى المصري، كما تقدم الهيئة متابعة مستمرة للصيدليات المشاركة مع فريق اليقظة الدوائية بهيئة الدواء المصرية
إذا كانت صيدلي تمتلك أو تعمل بإحدى الصيدليات العامة بجمهورية مصر العربية،أو اذا كنت تعمل بالصيدليات الخارجية لاى مستشفى، يمكنك التسجيل بمبادرة هيئة الدواء المصرية المجانية
"معاً نحو دواء آمن"
الدفعة **الخامسة**
لمزيد من التفاصيل،
يمكنك مشاهدة الفيديو التعريفي عبر الرابط التالي:-
https://tinyurl.com/56kww6t6
يمكنك تحميل الكتيب التعريفي الخاص بالمبادرة يرجى الضغط على الرابط التالي :-
https://tinyurl.com/3bw372nk
للتسجيل برجاء الضغط على الرابط التالي
https://docs.google.com/forms/d/e/1FAIpQLSfha6orsFg9fJUMliCgoiBZpDm7AJ2EuSf2ZyCpRttJzZ0LBw/viewform?usp=sf_link

علما بأنة تم مد اخر موعد للتسجيل الي يوم الجمعة الموافق30 اغسطس 2024
معاً نحو دواء آمن#
المركز الإعلامي لهيئة الدواء المصرية#

The Egyptian Pharmaceutical Vigilance center
مركز اليقظة الصيدلية المصري

EPVC Tips

On Pharmacovigilance

Patient should carry a list of his medications in case of emergencies

Health care provider should guide the patient to:

- Create an updated list of all medications he is taking, don't forget vitamins, over-the-counter medicines and herbal supplements.
- The list should include the name of the medication, the dose and the number of times a day he has to take it.
- Include information about how to take the medication (with or without food, as a pill, as a shot).
- Include information about any allergies.
- Share the list with close friends, family and caregivers.

Keep the list handy in case of an emergency.

Picture : *(Click Here)*

References:

Tip reference *(Click Here)*

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

You will find all EPVC Newsletters and DHPCs here

The Egyptian Pharmaceutical Vigilance center
مركز اليقظة الصيدلية المصري

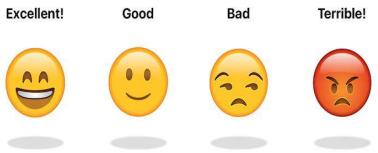
One report counts

A call for reporting

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

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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