EGYPTIAN DRUG AUTHORITY

هيئة الدواء المصرية

EPVC

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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DHPC : Risk of Medication Errors with Tranexamic Acid Injection Resulting in Inadvertent Intrathecal (Spinal) Injection

Back ground:

The Egyptian drug authority is alerting health care professionals about the risk of inadvertent intrathecal administration of tranexamic acid injection. Intrathecal administration of tranexamic acid injection may result in serious life-threatening injuries, including seizures, cardiac arrhythmias, paraplegia, permanent neurological injury, and death. In most of the cases reported tranexamic acid injection was erroneously administered instead of the intended intrathecal anesthetic (e.g., bupvicaine injection) for neuraxial anesthesia.

Eda has published a DHPC regarding this issue on EDA official website.

FDA also has the same alert regarding the same risk.

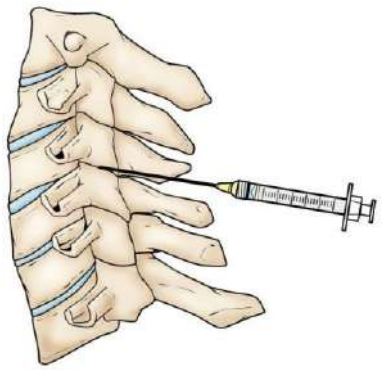
Tranexamic acid injection is an antifibrinolytic indicated in patients with hemophilia for short-term use (2 to 8 days) to reduce or prevent hemorrhage and reduce the need for replacement therapy during and following tooth extraction. Health care professionals should administer tranexamic acid injection by the intravenous route. It is supplied in single-dose ampules and single-dose vials containing 1,000 mg tranexamic acid in 10 mL and is available as a generic drug product and under the proprietary name, Cyklokapron.

Tranexamic acid injection, bupivacaine injection and other products used in the peri operative setting may have a similar appearance, such as similar vial cap color or packaging that may contribute to the mix-ups. Other practice-level and facility-level contributing factors such as storing products with similar appearance in close-proximity may also contribute to these errors.

The FDA is taking action to address tranexamic acid injection medication errors. This includes revising the tranexamic acid injection container labels and carton labeling to highlight there commended intravenous route of administration; and strengthening the warnings in the tranexamic acid prescribing information to include the risk of medication errors due to in correct route of administration.

Careful handling of tranexamic acid injection is important to prevent medication errors that could result in serious injury or death. Health care professionals should consider the following steps:

Store tranexamic acid injection vials separately from other drugs, in a way that makes the labels visible to avoid reliance on identifying drugs by the vial cap color.



Add an auxiliary warning label to note that the vial contains tranexamic acid.

Check the container label to ensure the correct product is selected and administered.

Utilize barcode scanning when stocking medication cabinets and preparing or administering the product.

Current situation

EDA and FDA continues to receive reports of tranexamic acid injection being erroneously administered intrathecally instead of the intended intrathecal (spinal) anesthetic (e.g.,bupivacaine injection) for neuraxial anesthesia.

These medication errors have resulted in severe outcomes, including death, disability, and prolonged hospitalization. FDA is conducting a safety evaluation and is investigating the issue. After the evaluation is complete, FDA will communicate any findings or additional actions that will help mitigate these medication errors.

References:

1. ***FDA:*** ***(Click Here)***
2. ***EDA DHPC:*** ***(Click Here)***

Statin-induced Muscle-Related Adverse Effects

1. Reason for publishing:

The regional center in Cairo received a yellow card concerning a 45-year-old female with a history of hypertension and hyperlipidemia, who was prescribed atorvastatin 40 mg daily to help manage her elevated cholesterol levels. After two weeks of therapy, she began experiencing persistent muscle aches and soreness, particularly in her legs. Her symptoms were mild at first but worsened over time, leading her to seek medical advice, and the need to take muscle relaxants.

The use of statins, including atorvastatin, is widely recognized for its efficacy in reducing cardiovascular risk by lowering LDL cholesterol. However, muscle-related adverse events, such as myopathy and muscle pain, remain a concern for both patients and healthcare professionals.

Muscle pain associated with statins may be due to muscle enzyme changes, as statins interfere with the cholesterol synthesis pathway, which also plays a role in muscle cell function. This side effect can range from mild soreness to severe pain and, in rare cases, muscle breakdown (rhabdomyolysis).

Background

- .Atorvastatin is a potent statin medication commonly prescribed for the management of hypercholesterolemia and prevention of cardiovascular events, including heart attacks and strokes.
- It is a selective, competitive inhibitor of HMG-CoA reductase, the rate-limiting enzyme responsible for the conversion of 3-hydroxy-3-methyl-glutaryl-coenzyme A to mevalonate, a precursor of sterols, including cholesterol. Atorvastatin lowers plasma cholesterol and lipoprotein serum concentrations by inhibiting HMGCoA reductase and subsequently cholesterol biosynthesis in the liver and increases the number of hepatic LDL receptors on the cell surface for enhanced uptake and catabolism of LDL.
- Hyperlipidemia, also known as dyslipidemia or high cholesterol, means you have too many lipids (fats) in your blood. Hyperlipidemia, especially elevated LDL cholesterol levels, is a significant risk factor for cardiovascular diseases. Statins are an integral part of managing this condition, with atorvastatin being one of the most commonly prescribed drugs in its class.

Labeled information:

- **Indications:** Atorvastatin is indicated for the treatment of primary hyperlipidemia, mixed dyslipidemia, familial hypercholesterolemia, and for the prevention of cardiovascular events in patients at high risk.
- **Adverse Effects:** Common side effects include muscle pain, weakness, and fatigue. Serious adverse effects include rhabdomyolysis and liver enzyme abnormalities. According to Atorvastatin's Summary of Product Characteristics (SmPC) it was stated under section (4.4 Special warnings and precautions for use) that: “Atorvastatin, like other HMG-CoA reductase inhibitors, may in rare occasions affect the skeletal muscle and cause myalgia, myositis, and myopathy that may progress to rhabdomyolysis, a potentially life-threatening condition characterized by markedly elevated creatine kinase (CK) levels (> 10 times ULN), myoglobinaemia and myoglobinuria which may lead to renal failure, therefore Atorvastatin should be prescribed with caution in patients with pre-disposing factors for rhabdomyolysis.

Statin-induced Muscle-Related Adverse Effects

- A CK level should be measured before starting statin treatment in the following situations: – Renal impairment. – Hypothyroidism -Personal or familial history of hereditary muscular disorders. – Previous history of muscular toxicity with a statin or fibrate – Previous history of liver disease and/or where substantial quantities of alcohol are consumed.

Recommendations for Healthcare Professionals:

Adjust the Statin Dose: Reducing the statin dosage may alleviate muscle aches, as they sometimes improve or resolve with lower doses. Discuss the benefits and drawbacks of this approach with the patient. If LDL levels remain high despite the reduction, additional lifestyle modifications or another cholesterol-lowering medication may be necessary.

Consider Switching to Another Statin: If muscle aches persist, switching to a different statin might improve symptoms. Should the muscle discomfort continue with a different statin, alternative cholesterol-lowering medications are available. Consider non-statin options such as:

Ezetimibe: Prevents the absorption of LDL cholesterol in the small intestine.

Bile acid sequestrants: Interfere with the reabsorption of cholesterol from the bloodstream.

PCSK9 inhibitors: Help eliminate more LDL cholesterol by inhibiting a specific protein.

Implement a Statin "Vacation": Under the guidance of the healthcare provider, a temporary pause of three to four weeks from statin therapy may help determine if muscle pain is related to the medication. Alternatively, taking the statin every other day may help reduce muscle discomfort while still lowering LDL levels.

Assess Drug Interactions: Ensure that the patient discusses all medications, supplements, and herbs they are taking. Some substances may interact with statins, increasing the likelihood of side effects.

Encourage Physical Activity: While muscle soreness is common post-exercise, research suggests that moderate physical activity can mitigate some muscle-related side effects of statins. Advise patients who are new to exercise to consult with their healthcare provider to ensure they engage in safe activities.

Promote Lifestyle Modifications: Recommend a heart-healthy diet rich in fiber and low in saturated and trans fats to lower LDL cholesterol. Encourage regular physical activity—150 minutes of moderate exercise per week— to improve HDL levels. Advise smoking cessation, as these lifestyle changes may reduce the need for higher statin doses.

References

1. ***Atorvastatin SmPC (Summary of Product Characteristics):*** (click here)
2. ***Atorvastatin efficacy in the primary and secondary prevention of cardiovascular events.*** (click here)
3. ***Statin Use and Musculoskeletal Pain Among Adults with and without Arthritis.*** (click here)
4. ***Effect of statin therapy on muscle symptoms: an individual participant data meta-analysis of large-scale, randomised, double-blind trials.*** (click here)
5. ***Hyperlipidemia.*** (click here)
6. ***NHS-Statins: Side effects*** (click here)

Egyptian Pharmaceutical Vigilance Center (EPVC) Vigiflow expansion project:

The The Egyptian Health Care Authority (EHA) organizations have made outstanding efforts in promoting pharmacovigilance within their institutions. The Egyptian Pharmaceutical Vigilance Center (EPVC) would like to express its gratitude for the high quality of Individual Case Safety Reports (ICSRs) they have submitted to VigiFlow.

EPVC greatly commend your exceptional commitment to advancing pharmacovigilance within your organizations. Your diligence plays a crucial role in ensuring safety and efficacy in our practices.

Also, EPVC expresses its gratitude to the Ministry of Health and Population (MoHP) for enhancing pharmacovigilance practices among its organizations and for their high input rate of Individual Case Safety Reports (ICSR) on Vigiflow.

Giza Health Directorate, Cairo Health Directorate, Menofia Health Directorate, Gharbia Health Directorate, Beheira Health Directorate, Al Sharkia Health Directorate, Dakahlia Health Directorate, Assiut Health Directorate, and Al Mamoura Chest Hospital are among the MoHP organizations that EPVC acknowledge their high ICSR entry rate on Vigiflow.

EPVC also acknowledges the Qena Oncology Center, Minya Oncology Center, Nasser Institute, Damanhour Oncology Center, and Mansoura International Hospital for their high rate of ICSR submissions on Vigiflow, maintaining good quality.

We really value your participation in the national database reporting system. Additionally, EPVC would like to express its gratitude to all of the organizations that collaborated with us to expand the Vigiflow system. We wish them ongoing success in their work and commend their dedication to improving the monthly section cases and the increasingly better case quality stages in the national database.

"Together for Safe Medicine" Initiative News:

Following the success of the first six waves of the "Innovative Together for Safe Medicine" initiative, the Egyptian Pharmacovigilance Center (EPVC) is pleased to announce the opening of registration for the 7th wave.

EPVC aims to continue its successful journey in promoting Pharmacovigilance science among both governmental and community pharmacists across all governorates of Egypt. Below are some photos showcasing the activities of the 5th and 6th waves.

The Egyptian Pharmaceutical Vigilance center
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EPVC Tips

On Pharmacovigilance

Pharmacovigilance Tip: Medication Errors

Medication errors can occur at various stages of treatment, leading to overdoses, underdoses, or ineffective treatments. Key types of errors include:

1. Incorrect Strength: Misuse of the wrong dosage strength, often due to similar packaging.
2. Incorrect Dosage Form: Mistaking the medication's form (e.g., immediate vs. extended release).
3. Incorrect Rate: Giving medication at the wrong intervals, either too often or too infrequently.
4. Incorrect Dose: Administering too much or too little of the drug.
5. Incorrect Duration: Incorrectly timing the length of treatment, causing ineffectiveness or side effects.

6. Incorrect Preparation/Action: Errors in preparing or using medication (e.g., mixing, splitting).
7. Incorrect Timing: Taking medication at the wrong time, such as with or without food.
8. Allergy/Contraindication: Prescribing drugs that conflict with a patient's allergies or health conditions.
9. Expired Product: Using medication that has lost effectiveness or is unsafe due to expiration.

These errors highlight the need for accurate prescribing, proper administration, and patient education.

References:

Picture: ***(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

You will also find all alerts regarding counterfeited and falsified products released by Central Administration of Operations 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:

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

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

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