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

October 2021

Volume 12 **Issue 10**

AstraZeneca & Janssen COVID-19 Vaccine: Warning for Guillain-Barre syndrome

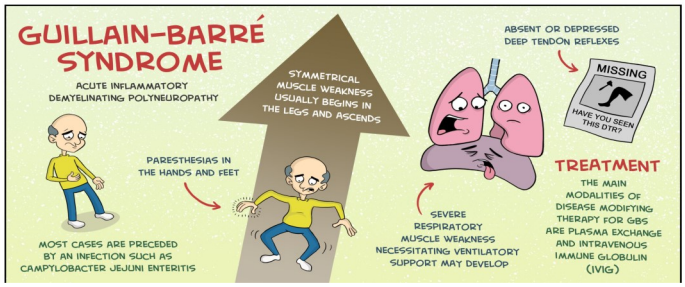
COVID-19 Vaccine is a vaccine for preventing coronavirus disease 2019 (COVID-19) in people aged 18 years and older . It is made up of another virus (of the adenovirus family) that has been modified to contain the gene for making a protein from SARS-CoV-2. As part of the review of COVID-19 available vaccines; cases of Guillain-Barré syndrome (GBS) were reported following vaccination with AstraZeneca and Janssen vaccines leading to updating the product information to include warning to raise awareness among healthcare professionals.

Review of risk

Guillain-Barré syndrome is a rare immune system disorder that causes nerve inflammation and can result in pain, numbness, muscle weakness and difficulty walking. In the most severe cases it can progress to paralysis. Most people fully recover from the disorder. GBS has also been observed at an increased rate associated with certain vaccines, including certain seasonal influenza vaccines and a vaccine to prevent shingles.

In view of the seriousness of this rare condition, it was recommended to add a warning for GBS Summary of product characteristics and patient leaflet of the vaccine to alert healthcare professionals and people taking the vaccine of this potential risk. Healthcare professionals should be alert to signs and symptom of GBS, allowing early diagnosis, supportive care and treatment. People taking the vaccine are advised to seek immediate medical attention if they develop weakness and paralysis in the extremities that can progress to the chest and face. The benefit-risk balance of the vaccine remains unchanged.

Although the available evidence suggests an association between the Janssen vaccine and increased risk of GBS, it is insufficient to establish a causal relationship.



These side effects are very rare, and the benefit-risk balance of the vaccine remains unchanged.

In reference to EMA; General Advice about Guillain-Barré syndrome :

* Healthcare professionals should be alert of GBS signs and symptoms
* People taking the vaccine are advised to seek immediate medical attention if they develop weakness and paralysis in the extremities that can progress to the chest and face.
* Talk to your doctor, pharmacist or nurse before you are given the vaccine if you previously had Guillain-Barré syndrome (temporary loss of feeling and movement)

References:

1. *EMA (Click here)*
2. *Smpc EMA (Click here)*
3. *FDA (Click here)*

Topical corticosteroids: Information on the risk of topical steroid withdrawal reactions

Topical corticosteroids are safe and highly effective treatments for skin conditions such as eczema, psoriasis, and atopic dermatitis when used correctly. Rarely, severe adverse effects can occur on stopping treatment with topical corticosteroids, often after long-term continuous or inappropriate use of moderate to high potency products. To reduce the risks of these events, prescribe the topical corticosteroid of lowest potency needed and ensure patients know how to use it safely and effectively.

Risk of risk

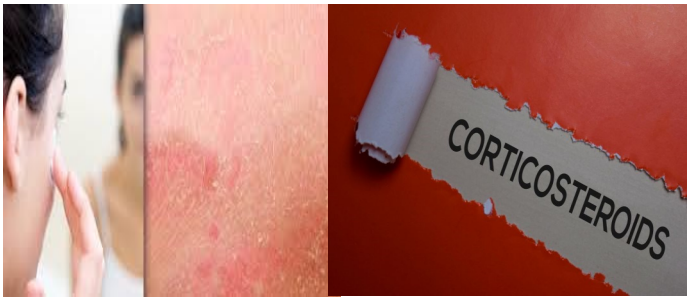
Topical corticosteroids are safe and highly effective treatments for skin conditions such as eczema, psoriasis, and atopic dermatitis when used correctly. They are available in different potencies; mildly potent , moderately potent, potent and very potent.

Topical steroid withdrawal reactions have been reported in some long-term users of topical corticosteroids after they stop use.

This is a mixed group of symptoms or conditions, often also referred to by patients as 'red skin syndrome' or 'topical steroid addiction'.

A particularly severe type of topical steroid withdrawal reaction, with skin redness and burning worse than the original condition, is currently an under-recognised side effect of topical corticosteroid treatment. Patients report encountering difficulties with diagnosis, leading many to self-treat. However, topical steroid withdrawal reactions are now being recognised by experts in the field and there are treatment options, in addition to alternative treatment approaches for the underlying condition.

Topical steroid withdrawal reactions are thought to occur after prolonged, frequent, or inappropriate use of moderate to high potency topical corticosteroids. Topical steroid withdrawal reactions can develop after application of a topical corticosteroid at least daily for longer than a year. In children they can occur



within as little as 2 months of daily use. People with atopic dermatitis are thought to be most at risk of developing topical steroid withdrawal reactions.

It has been reported that the signs and symptoms occur within days to weeks after discontinuation of long-term topical corticosteroid treatment. They are most commonly seen after treatment of sensitive areas such as the face or genitals.

The lowest potency topical corticosteroid for effective treatment should always be used and this may mean using different products for different areas to be treated.

Characteristic signs of topical steroid withdrawal reactions

The most common reaction is a rebound (or flare) of the underlying skin disorder such as atopic dermatitis. However, patients have described a specific type of topical steroid withdrawal reaction in which skin redness extends beyond the initial area of treatment with burning or stinging and that is worse than the original condition. It can be difficult to distinguish a flare up of the skin disorder, which would benefit from further topical steroid treatment, and a topical steroid withdrawal reaction.

A topical steroid withdrawal reaction should be considered if:

* Burning rather than itch is the main symptom
* Redness is confluent rather than patchy (which may not be so obvious in people with darker skin)

Topical corticosteroids: Information on the risk of topical steroid withdrawal reactions Continued

* Rash resembles atopic dermatitis but involves unusual sites and is 'different' to the skin condition that the patient has experienced before
* There has been a history of continuous prolonged use of a moderate or high potency topical corticosteroid.

Skin biopsy is generally unhelpful to distinguish topical steroid withdrawal reactions from a flare of the underlying skin disorder because the histopathology overlaps.
If the patient's skin condition fails to improve, before prescribing a more potent corticosteroid, consider possible diagnoses such as rosacea, peri-oral dermatitis, infection and allergy to the topical corticosteroid or other topical medications, including moisturizers or cosmetics. Patch testing may identify some cases of contact allergy.

In reference to MHRA; Advice for Healthcare Professionals:

* Long-term continuous or inappropriate use of topical corticosteroids, particularly those of moderate to high potency, can result in the development of rebound flares after stopping treatment – there are reports of such flares taking the form of a dermatitis with intense redness, stinging, and burning that can spread beyond the initial treatment area
* When prescribing a topical corticosteroid, consider the lowest potency needed
* Advise patients on the amount of product to be applied; underuse can prolong treatment duration
* Inform patients how long they should use a topical corticosteroid, especially on sensitive areas such as the face and genitals
* Inform patients to return for medical advice if their skin condition worsens while using topical corticosteroid, and advise them when it would be appropriate to re-treat without a consultation
* For patients currently on long-term topical corticosteroid treatment, consider reducing potency or frequency of application (or both)
* Be vigilant for the signs and symptoms of topical steroid withdrawal reactions

In reference to MHRA; Advice for Patients:

* Topical corticosteroids are used on the skin to reduce inflammation; when used correctly, they are safe and effective treatments for skin disorders
* Always apply topical corticosteroids as instructed
* Seek medical advice before using a topical corticosteroid on a new body area as some areas of the body are more prone to side effects
* Very infrequent cases of severe skin reactions have been reported in long-term users of topical corticosteroids after they stop using them
* If your skin worsens within 2 weeks of stopping a topical corticosteroid, do not start treatment again without consulting your doctor, unless they have previously advised you should do so
* As well as the known side effects associated with using too much of a topical corticosteroid or with using it for too long, remember that using too little can prolong treatment time and increase the risk of certain adverse effects
* Ask your prescriber or pharmacist if you have any questions about your medicines or are concerned about side effects

References:

MHRA (Click here)

Egyptian Pharmaceutical Vigilance Center Announces Activation of EDA's Hotline that Allows Patients to Report ADRs

In efforts of the Egyptian Pharmaceutical Vigilance Center to ensure safe use of drugs and medical devices and for the sake of optimizing the protection of public health; EPVC announces activation of EDA Hotline which allows public to report any adverse events occurring from use of medications and medical devices.

Now you can tell your patients to report on 15301 if they experience any side effect after taking any medication.

15301

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
مركـــز اليـــقظة الصـــيدلية المـــصري

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https://sites.google.com/view/epvc-reporting/healthcare-professional-public-adverse-drug-event-reporting/reporting-other-adverse-drug-event-cases

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