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## FDA Issues Safety Warning for Sodium Phosphate for Constipation

Phosphate-containing laxatives may not be the safest option for patient with kidney diseases and some other illnesses. A new warning concerning the safety of sodium phosphate products when administered in larger doses than advised, has been published by the Food and Drug Administration (FDA).

Sodium phosphate laxatives are marketed in Egypt as Laxel® sachets containing sodium phosphate, Enema® enema that contains sodium acid phosphate and sodium phosphate, and Enemax® enema which contains sodium phosphate and disodium phosphate.

FDA is warning that more than one dose in 24 hours of sodium phosphate drugs may cause serious harm to the kidneys and heart, and even death. FDA referred the findings to reports of severe dehydration and changes in the levels of serum electrolytes include calcium, sodium, and phosphate. This issue was

brought up in a review of the agency's Adverse Event Reporting System database and the medical literature that showed 54 cases in 25 adults and 29 children with serious adverse effects linked to sodium phosphate products.

The FDA safety communication advises caregivers that

individuals of 55 years and above are at risk. Individuals who are dehydrated or experiencing symptoms of dehydration are not advised to use the drug along with those suffering from kidney disease, bowel obstruction or inflammation.

The warning urges patients to follow up with their physicians if they take drugs that affect the renal function, including diuretics; angiotensin-converting enzyme inhibitors; angiotensin receptor blockers; and non-steroidal anti-inflammatory drugs.



**Sodium phosphate drugs may cause serious harm to the kidneys.**

oral sodium phosphate drugs are not suitable for ages 5 or below without a healthcare professional's approve, and that the use of rectally introduced sodium phosphate drugs should not be used under the age of 2. Also, indi-

*References:*

1. *Medscape Online*
2. *FDA.gov*
3. *The Journal of the American Medical Association Network*
4. *Pharmaceutical Online*

## New Meclizine Restrictions

Meclizine is used to prevent and treat nausea, vomiting, and dizziness caused by motion sickness. It is most effective if taken before symptoms appear. This medication is sometimes prescribed for other uses.

Safety and efficacy of mecliz-



**Navidoxine® (meclizine)**

ine in children younger than

12 years of age have not been established; therefore, the manufacturers state that use of the drug in this age group is not recommended. If the drug is used in this age group (e.g., for the prevention and treatment of nausea, vomiting, and/or vertigo associated with

“Restriction of meclizine use in children under two years of age.”

motion sickness), it should be only under the advice and supervision of a physician.

The Pharmacovigilance Committee (PVC) based on Egyptian Pharmaceutical Vigilance Center (EPCV) assessment decided that:

“Based on EPVC assessment and study; Pharma-

covigilance Committee recommends:

- Restriction of meclizine use in children under two years of age.
- Allow the usage under medical supervision only; in children from 2-12 years of age.
- The product label should state this recommendation clearly, and to be

reviewed by Pharmacological Committee.”

#### References:

1. Lexicomp Online
2. EPVC Newsletter, Volume 5, Issue 5 p.4



Diacerin®

## PRAC Recommends Diacerein to Remain Available with Restrictions

Diacerein belongs to a class of substances called anthraquinones. It is indicated for degenerative joint diseases such as osteoarthritis.

The European Medicines Agency's Pharmacovigilance Risk Assessment Committee (PRAC) has re-examined diacerein-containing medicines and is recommending that they remain available but with restrictions.

Due to the risks associated with severe diarrhoea, diacerein is no longer recommended in patients aged 65

years and above. It is also advised that patients start treatment on half the normal dose (i.e. 50 mg daily instead of 100 mg) and should stop taking diacerein if diarrhoea occurs.

In addition, diacerein-containing medicines must not be used in any patient with liver disease or a history of liver disease, and doctors should be monitoring their patients for early signs of liver problems.

These recommendations are the outcome of a re-examination of the PRAC's November 2013 opinion,



which recommended the suspension of diacerein due to concerns over the risks of severe diarrhoea and liver effects.

#### References:

1. European Medicines Agency
2. EPVC Newsletter

“Diacerein is no longer recommended in patients aged 65 years and above.”

“Fewer than 10% of kids who received just one of the vaccines developed a fever in the first day after being immunized.”

## Study Finds Giving Prevnar® and Flu Vaccine Together Raises Risk of Fever

Fever is a common side effect of many vaccinations, with the Centers for Disease Control and Prevention estimating that one-third of people receiving Pfizer's Prevnar 13® develops a mild case. Flu vaccines also cause



Prevnar® Vaccine

cases, prompting researchers to investigate a question: does giving the shots simultaneously raise the risk of fever?

Writing in JAMA Pediatrics, the researchers reported



Flu Vaccine

asking the parents of 530 children to send a text with their kid's temperature each evening for a week following vaccination in order to assess the likelihood of developing a fever of 38°C or higher after receiving a trivalent flu vaccine or Prevnar 13®. Fewer than 10% of kids who received just one of the vaccines developed a fever in the first day after being immunized,

but the risk rose significantly when both doses were given simultaneously.

More than one-third of children who were given both vaccines developed a fever by the night after being immunized. This translates into around 20 extra cases of fever per 100 vaccinations compared to just receiving either the flu shot or Prevnar 13®. The finding corroborates warnings on the CDC website, which advise parents of children who have previously had seizures to talk to their doctor before giving Prevnar 13® and flu vaccine together. The resulting fever can cause febrile seizures. While fevers and febrile seizures are distressing for children

and their parents, the risk of long-term harm is minimal. The benefits of being protected against influenza and pneumococcus outweigh the risks. The study also has several weaknesses. No randomization occurred, the study took place over a single flu season and the participants were mainly urban Latinos. It is unclear whether the findings would be the same for other populations and different flu seasons.

“The findings advise parents of children who have had seizures to talk to their doctor before giving Prevnar 13® and flu vaccine together.”

#### References:

1. *Fierce Vaccines.com*

## Ebola Virus Continues to Spread in West Africa

Early last year, Ebola virus infections characterized by fever, severe diarrhea, vomiting, and a high case-fatality rate in West Africa and France were reported. The virus continues to spread in West Africa. Less severe outbreaks took place in West Africa before; but never of this spread.

Global efforts have been sparked by the United Nations, the WHO and the Centers of Disease Control (CDC), in a new attempt to limit the spread of Ebola.

Ebola incubates in humans for 2-21 days, with most patients becoming symptomatic after 8-9 days. Patients could experience severe symptoms within 1-2 days of infection.

Patients who develop a fulminant course often die within 8-9 days. Those who survive beyond 2 weeks have a better prognosis.

Identifying Ebola is difficult, as in the early days of the disease; symptoms may be similar to other infections. Only after 3-5 days might the hallmark of the illness become evident.

Patients with Ebola are not infectious until symptoms have developed. Ebola is not an airborne disease. It is not spread by casual contact. It is acquired by direct contact with infected secretions. Studies indicate that Ebola is in higher concentration in vomit, blood, and diarrhea, making disinfection of public areas such as restrooms imperative to contain the virus.

Effective decontamination methods include steam sterilization, chemical sterilization, incineration, and gaseous methods.

At this time, only supportive care is available. Yet upcoming human vaccine trials may be promising. Previous attempts at a human vaccine in the early 2000s were not successful.

Kent Bradely, a US doctor survived using an experimental treatment ‘Zmapp’. Reports say other doctors treated with ZMapp have improved. However, a 75-year-old priest died despite having ZMapp.

Another approach involves transfusing blood from recently recovered patients, on the premise that it contains antibodies.

The results have not been formally reported.

Ebola infection hasn't been reported in Egypt till now.

#### References:

1. *Medscape.com*
2. *Webmd.com*



A woman died of Ebola Virus.



## Sovaldi® Now Available in Egypt with One Percent of its Price

After 6 months of negotiation, Gilead Sciences has agreed to supply Egypt; the country with the highest prevalence of hepatitis C virus (HCV) in the world, with its new HCV medicine "Sovaldi®" (sofosbuvir) with a 99% price cut of its actual market price.

The total number of Egyptians suffering from HCV is about 14 percent of the population (11.8 million patients), according to the World Health Organization. Every year, there are 170,000 - 200,000 new cases in Egypt. Sovaldi® was approved by Food and Drug Agency (FDA) in December 2013. It became available in the Egyptian market on the sixteenth of October, 2014. Sovaldi® was agreed to be sold in medical centers affiliated to Ministry of Health and was agreed to be available for sale in pharmacies. This agreement with the US pharmaceutical company is considered very important in the medical field in Egypt, as the Egyptians are in great need to have affordable HCV medications. The original price in the USA for the drug course treatment of 12 weeks is \$84,000, but in Egypt it costs \$300 (L.E. 2,200) for the same course. This offer is much lower than the initial offer to Egypt in March, which was \$900 per treatment course.

According to a declaration from the Ministry of Health, the US pharmaceutical company has a production plan to supply Egypt with Sovaldi® every six months. 8 out of 26 medical centers are expected to receive 50,000-60,000 patients who will be treated with Sovaldi®. Up till now only three centers offer the drug. Pharmacies will sell it at around L.E.14,940 per box. Other patients will receive it for free as part of the governmental health program.



Sovaldi®

### References:

1. *Drugs.com*
2. *English.ahram.org.eg*
3. *Hepmag.com*
4. *Dailynewsegypt.com*
5. *Pharmaceuticalsinsight.com*

## Faculty of Pharmacy Gains Ground in Pharmacy Practice in Egypt

Misr International University (MIU), Faculty of Pharmacy prides itself on having successfully held five Drug Information workshops and trained, thereby, 107 pharmacists from all over Egypt throughout the year 2014. This is in response to the high demand from various hospitals, and as per the mission of the Faculty of Pharmacy to advance the pharmacy practice in Egypt.

The Drug Information course is intended to provide pharmacists with the required professional and clinical skills to be able to fulfill their role as the source for scientifically valid and up-to-date medication related information. The hands-on training provided by the course enhances the clinical competences of retrieving and interpreting drug related information as well as critical evaluation of medical information for quality and applicability.



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