

WITHDRAWAL

The SFDA Revoked the Marketing Authorization of oral products containing Ketoconazole in Saudi Arabia.

By: Mubarak Al-Shahrani Bsc., MSc.

On December 24, 2013, the Saudi Food and Drug Authority (SFDA) announced that the marketing authorization of oral products containing Ketoconazole was revoked in Saudi Arabia. The SFDA decision was based on reviewing of clinical trials, meta-analyses studies which indicated that the risk of liver injury outweighs the benefit of the product in treating fungal infections.

The National Pharmacovigilance and Drug Safety Centre has reviewed the safety and efficacy profiles of oral products containing Ketoconazole and has concluded that the risks associated with the use of these products outweigh their benefits. The Pharmacovigilance Advisory Committee also confirmed the unfavorable risk-benefit balance of such products. Therefore, SFDA advises healthcare professionals that Ketoconazole oral form is no longer approved in Saudi Arabia and they should discuss with their patients the available alternatives.

WARNING

The use of pegaspargase and risk of allergic reactions

By: Yaser Alrdayaan, Bsc.

It has been recently found that there were increased case reports of serious allergic reactions following the use of pegaspargase (Oncaspar®). The Saudi Food and Drug Authority (SFDA) informed healthcare providers and patients about this risk.

According to the international versions of the package insert, allergic reactions including anaphylaxis are the most common adverse reaction when taking pegaspargase. It has been found that children and young adult are more susceptible to this risk when taking pegaspargase.

Therefore, the following measures should be considered before and during the use of this product:

1. Avoid using pegaspargase in patients with known hypersensitivity to other form of L-asparginase.
2. When using pegaspargase, observe patients for 1 hour after administration of pegaspargase in a setting with resuscitation equipment and other agents necessary to treat anaphylaxis.
3. Discontinue pegaspargase in patients with serious allergic reactions.

Please note that this product is not yet registered in Saudi Arabia.

References

- Graham ML. Pegaspargase: a review of clinical studies. Advanced drug delivery reviews. 2003;55(10):1293-1302.

IN THIS ISSUE

WITHDRAWAL..... 1

- The Sfd a Revoked The Marketing Authorization Of Oral Products Containing Ketoconazole In Saudi Arabia.

WARNING..... 1-2

- The Use Of Pegaspargase And Risk Of Allergic Reactions.
- Hydroxyethyl Starch And Risk Of Kidney Injury And Mortality.

GUIDELINE..... 2-3

- Guidance For Priority Review Of Product Registration.

GENERAL TOPIC.... 3-6

- Effect Of Vitamin E And Memantine On Functional Decline In Alzheimer Disease: The Team-Ad Va Cooperative Randomized Trial.
- New Insights Into Root Causes Of Pediatric Accidental Unsupervised Ingestions Of Over-The-Counter Medications.
- Association Between Cardiovascular Events And Sodium-Containing Effervescent, Dispersible, And Soluble Drugs: Nested Case-Control Study.
- Preservatives In Cosmetic Products.

LATEST DRUGS

REGISTERED..... 7

ARABIC SUMMARY.... 8

Hydroxyethyl starch and risk of kidney injury and mortality

By: Yaser Alrdayaan, Bsc.

The National Pharmacovigilance and Drug Safety Center informed healthcare providers about the risk of kidney injury and mortality in association with hydroxyethyl starch (HES) use. These risks were obtained through conducting safety review which concluded the following:

1. HES solutions may continue to be used in patients to treat hypovolaemia (low blood volume) caused By: acute blood loss where treatment with alternative infusions solutions known as crystalloids alone are not considered to be sufficient. In these patients, HES solutions should not be used for more than 24 hours and kidney function should be monitored for at least 90 days.

2. Hydroxyethyl starch **SHOULD NOT BE USED (CONTRAINDICATED)** in the following:

- Critical ill, septic patients, patients admitted to the ICU and patients with burn injuries.
- Patients with pre-existing kidney and/or liver injury.
- Patients undergoing open heart surgery in association with cardiopulmonary By: pass due to excess bleeding.
- In addition, HES should be discontinued in the following cases:
 - i. At the first sign of renal injury.
 - ii. At the first sign of coagulopathy.

GUIDELINE

Guidance for Priority Review of Product Registration

By: Hussain A. Bafagih, Bsc., Msc

Saudi Food and Drug Authority (SFDA) has recently published a guideline to assist applicants in preparation and submission of priority review applications.

This guidance is intended to facilitate and expedite the review of new drugs / new drug indications that are intended to:

- Treat serious or life threatening conditions,
- Address unmet medical needs,
- Products which fall under SFDA's exempted drugs list.

This guidance provides regulations, criteria for designation and process of submission of priority review applications.

A. Serious or Life-Threatening Condition:

1. Whether a condition is serious:

For a condition to be serious, the condition should be associated with morbidity that has substantial impact on day-to-day functioning. Short-lived and self-limiting morbidity will usually not be sufficient but the morbidity need not to be irreversible, providing it is persistent or recurrent.

2. Whether the product is intended to treat a serious condition:

For a product to be in a priority review, it must not only be used in patients with a serious condition, it must be intended to treat a serious aspect of that condition. Thus, in making a priority review determination, SFDA will assess whether the priority review program is designed to demonstrate an effect on a serious aspect of the condition.

B. Demonstrating the Potential to Address Unmet Medical Needs:

SFDA will determine whether the drug has a potential to address unmet medical needs and whether the development program is designed to evaluate this potential.

C. Falls Under SFDA's Exempted List:

SFDA has released list of products which are exempted from pharmaceutical and inspection services fees. This list is updated frequently based on the need and status of Saudi market.

The exemption list can be found on the main page of SFDA website under the drug sector portal.

The General procedures for priority review application is described below:

1st step: Applicant sends a request to SFDA prior to original submission.

2nd step: SFDA will respond to applicant within 15 working days.

3rd step: In case of request approval, the drug file should be submitted. ➔

GUIDELINE

CONTINUE...

4th step: Priority review process begins.

Complete application according to the "Guidance for Submission" is essential in order to proceed the review. Actual commencement and scheduling of review will depend on many factors, including staffing, workload, competing priorities and other factors.

The review clock will not begin until the product has been accepted to be priority reviewed. The total performance target is reduced By: 40% of the normal registration

process as described in "Regulatory Framework for Drug Approvals" (latest published edition).

"An unmet medical need is a medical need that is not addressed adequately By: an existing therapy".

References

- The FDA Guideline on the Fast Track Drug Development Programs-Designation, Development, and Application Review, Jan.2006.

GENERAL

Effect of Vitamin E and Memantine on Functional Decline in Alzheimer Disease: The TEAM-AD VA Cooperative Randomized Trial

By: *Abdulmohsen A. AIObaid, BSc. Pharm ., MSc. Clin Phram.*

The following is a summary of an article published in The Journal of the American Medical Association (JAMA) issue of January 1, 2014.

Objective:

To determine if vitamin E (alpha tocopherol), memantine, or both slow progression of mild to moderate Alzheimer disease (AD) in patients taking an acetylcholinesterase inhibitor.

Design, Participants, and Interventions:

Double-blind, placebo-controlled, parallel-group, randomized clinical trial involving 613 patients with mild to moderate AD initiated in August 2007 and concluded in September 2012 at 14 Veterans Affairs medical centers. Participants received either 2000 IU/d of alpha tocopherol (n = 152), 20 mg/d of memantine (n = 155), the combination (n = 154), or placebo (n = 152).

Main Outcomes and Measures:

Alzheimer's Disease Cooperative Study/Activities of Daily Living (ADCS-ADL) Inventory score (range, 0-78). Secondary outcomes included cognitive, neuropsychiatric, functional, and caregiver measures.

Results:

Data from 561 participants were analyzed (alpha tocopherol = 140, memantine = 142, combination = 139,

placebo = 140), with 52 excluded because of a lack of any follow-up data. Over the mean (SD) follow-up of 2.27 (1.22) years, ADCS-ADL Inventory scores declined By: 3.15 units (95% CI, 0.92 to 5.39; adjusted P = .03) less in the alpha tocopherol group compared with the placebo group. In the memantine group, these scores declined 1.98 units less (95% CI, -0.24 to 4.20; adjusted P = .40) than the placebo group's decline. This change in the alpha tocopherol group translates into a delay in clinical progression of 19% per year compared with placebo or a delay of approximately 6.2 months over the follow-up period. Caregiver time increased least in the alpha tocopherol group. All-cause mortality and safety analyses showed a difference only on the serious adverse event of "infections or infestations," with greater frequencies in the memantine (31 events in 23 participants) and combination groups (44 events in 31 participants) compared with placebo (13 events in 11 participants).

Conclusion:

Among patients with mild to moderate AD, 2000 IU/d of alpha tocopherol compared with placebo resulted in slower functional decline. There were no significant differences in the groups receiving memantine alone or memantine plus alpha tocopherol. These findings suggest benefit of alpha tocopherol in mild to moderate AD By: slowing functional decline and decreasing caregiver burden.

References

- Dysken MW, Sano M, Asthana S, et al. Effect of Vitamin E and Memantine on Functional Decline in Alzheimer Disease: The TEAM-AD VA Cooperative Randomized Trial. JAMA. 2014;311(1):33-44. doi:10.1001/jama.2013.282834. Available at: <http://jama.jamanetwork.com/article.aspx?articleid=1810379>

New insights into root causes of pediatric accidental unsupervised ingestions of over-the-counter medications

By: Faisal A. AlMadhi BSc. Pharm.

The following is a summary of an article published in the *Clinical Toxicology Journal* issue of December 2013.

Changes to regulations, packaging, and labeling and ongoing educational efforts are intended to support appropriate use of medicines. Yet annually poison centers receive > 500 000 reports of accidental or unsupervised exposure to medicines for children under 6 years of age.

Objective:

To identify root (i.e., fundamental and preventable) causes of Accidental Unsupervised Ingestions (AUIs), we designed a questionnaire and conducted a follow-up survey of caregivers who contacted McNeil Consumer Healthcare (McNeil) following an AUI By: a child under 12 years of age.

Methods:

Reports received between 1 October 2008 and 22 January 2009 were screened retrospectively for specific Medical Dictionary of Regulatory Activities (MedDRA) Preferred Terms relating to AUIs. Using the questionnaire, we collected information about the child, caregiver, medicines involved in AUI, management of AUI, and storage location of medicines

Results:

Two hundred twenty reports met inclusion criteria and attempts to contact these caregivers were made throughout a 2-week period in March 2009; caregivers completed the questionnaire for 45 reports. All AUIs occurred in children under 7 years and 56% were boys. In 56% of AUI cases, the child involved was the intended recipient of the medicine; in 71%, a pediatric medicine was involved. Most AUIs occurred in the child's home; most caregivers reported not observing the AUI. Sixty percent of caregivers reported that the medicine involved in AUI was not in the normal storage location when AUI occurred. Among children involved in AUIs, 84% did not experience any symptoms. Seven children experienced mild, self-limiting symptoms which resolved. AUIs often occurred < 24 h after last therapeutic use when the medicine was removed from its normal storage location.

Conclusion:

These new insights may help guide-targeted interventions and educational efforts to focus caregivers' attention to reengaging childproofing mechanisms and returning medicines to a secure location, high and out of sight, immediately after use.

References

Schoenewald S, Ross S, Bloom L, Shah M, Lynch J, Lin CL, Patel M, Boyle K, Kuffner E. New insights into root causes of pediatric accidental unsupervised ingestions of over-the-counter medications. *Clin Toxicol (Phila)*. 2013 Dec;51(10):930-6. Available at:

Association between cardiovascular events and sodium-containing effervescent, dispersible, and soluble drugs: nested case-control study

By: Abdulmohsen A. AlObaid, B. Pharm., MSc. Clin Phram

Reducing sodium intake is a central goal for public health as it is associated with reduction in blood pressure and consequent cardiovascular events. A recent study that was published in the *British Medical Journal* has suggested that sodium containing effervescent, dispersible and soluble drugs may be associated with increased cardiovascular events.

The study was a population based case control study that used the UK Clinical Practice Research Datalink (CPRD) database to compare the cardiovascular risk

of 24 effervescent dispersible and soluble drugs versus non-dispersible non- soluble non-effervescent versions of the same drugs . After adjustment for confounders, the odds for primary composite cardiovascular events was 1.16 higher in the sodium containing formulations. The risk was higher for all cause mortality, stroke, heart failure and hypertension. Dose response in cardiovascular events was also observed in the study.

Findings of the study call for more caution when prescribing sodium containing formulations of medicines.

References

J George et al. Association between cardiovascular events and sodium-containing effervescent, dispersible, and soluble drugs: nested case-control study. *BMJ* 2013;347:f6954

Preservatives in cosmetic products

By: *Khalid Ali Alyami, B. Pharm*

Why using preservatives?

Cosmetic products become easily contaminated By: bacteria and fungi. Containing water, oils, peptides, and carbohydrates cosmetics are a very good medium for growth of microbes. All these factors contribute to the fact that cosmetic products need preservation to prevent microbial growth and spoiling of the cosmetic product and also infections or irritation of the skin, and to ensure that products are safe to use for a long time.

An ingredient that protects the product from the growth of microorganisms is called an antimicrobial. A preservative may also be added to a product to protect it against damage and degradation caused By: exposure to oxygen, and in this instance, these ingredients are also called antioxidants.

Most cosmetics need preservatives, but there are a few exceptions, for example: perfumes, deodorants and hair sprays with a high alcohol content. cosmetics with high water content are at a risk of being contaminated By: micro-organisms that can alter the composition of the product or pose a health risk to the consumer. Pathogenic microorganisms such as *Staphylococcus aureus* and *Pseudomonas aeruginosa* are frequently found in contaminated cosmetics

The microbes can infect your formulas primarily include bacteria, mold, and yeast. In small quantities they don't represent much of a problem but when they multiply, look out. Bacteria like *Pseudomonas* can cause all kinds of health problems including skin and eye infections, toxic shock, strep throat, and even food poisoning. Yeast like *Candida albicans* can cause thrush. And many other bacteria can cause your products to smell awful, change color or otherwise break down, which is what stability testing is for.

What is the preservative?

Preservative is a substance which may be added to a cosmetic product for the primary purpose of inhibiting the development of micro-organisms in the product.

How do Preservatives work?

Antimicrobials prevent the growth of molds, yeasts, and bacteria. Antioxidants keep personal care products from becoming rancid or brown, or developing black spots. Rancid personal care products may not make you sick, but they might smell bad or be a different color or consistency. Antioxidants suppress the reaction that occurs when ingredients in the product combine with oxygen in the presence of light, heat, and some metals. Antioxidants also minimize the damage to some essential

ingredients or materials that are especially susceptible to oxidative damage.

How does the use of Preservatives in cosmetic products differ from their use in antimicrobial products?

In most cases, preservative ingredients are used to protect the product and help it remain safe and perform as intended over the lifetime of the product.

When preservative ingredients are used to protect the user against possible infection from microorganisms or help keep the levels of microorganisms on the body at a level that prevents infections, they are subject to the additional requirements that the SFDA applies for listing as health products. so, not considered as cosmetic products.

Most commonly preservatives

There are several different preservatives available but the cosmetic market is dominated By: a few preservatives, The following is a list of common preservatives used in cosmetic and personal care products.:

- 1) Parabens (eg. Methylparaben, Propylparaben, and Butylparaben)
- 2) Formaldehyde donors (eg. DMDM Hydantoin, Imidazolidinyl Urea)
- 3) Phenol derivatives (eg. Phenoxyethanol)
- 4) Quats (eg. Benzalkonium Chloride, Methenolammonium chloride, and Benzethonium chloride)
- 5) Alcohol (Ethanol)
- 6) Isothiazolones (eg. Methylchloro- Isothiazolinone and Methyl-Isothiazolinone)

Regulation of cosmetic preservatives in Saudi Arabia

SFDA is the responsible for regulation of cosmetic products in Saudi Arabia. It has been harmonized through the cosmetic products safety requirements GSO1943/2009 table4 the preservatives which cosmetic products may contain. Currently, 55 different preservatives are allowed in cosmetic products in the Saudi Arabia. These have been subjected mainly to EU cosmetic directive. Any alterations in the GSO1943/2009 are approved By: the SFDA based on recommendations given By: the Advisory Committee to the safety of cosmetic products.

Also there are many products display an open jar symbol indicating how many months they can be used once they are open. Before opening, most cosmetics will remain stable and free from contamination for many years.



CONTINUE...

Microbial Limits in cosmetic products

Cosmetics are divided into two different categories : (1) products specifically intended for children under 3 years or to be used in the eye area and on mucous membranes and (2) other products. For products in category 1, the total viable counts for aerobic mesophyllic micro-organisms must not exceed 100 Colony forming units (CFU)/g in 1 g of the product, and furthermore, the pathogenic microorganisms *Pseudomonas aeruginosa*, *Staphylococcus aureus*, and *C. albicans* must not be detectable in 1 g of the product. For products in category 2, total viable counts must not exceed 1000 CFU/g in 1 g, and the pathogens mentioned above must not be detectable in 1 g of the product.

References

1. COSMETIC PRODUCTS SAFETY REQUIREMENTS (GSO 1943/2009).
2. Alternative Cosmetic Preservatives – What are your options? By: Perry Romanowski
3. <https://www.cosmeticseurope.eu/safety-and-science-cosmetics-europe/products-and-ingredients/preservatives-.html>
4. <http://www.cosmeticsinfo.org/HBI/6>
5. Comparatively Speaking: Cosmetic Preservatives By: Anthony J. O'Lenick, Jr., Siltech, LLC
6. <http://www.fda.gov/cosmetics/productandingredientssafety/selectedcosmeticingredients/ucm128042.htm>
7. Contamination versus preservation of cosmetics: a review on legislation, usage, infections, and contact allergy By: MICHAEL DYRGAARD LUNDOV, LISE MOESBY, CLAUDIA ZACHARIAE AND JEANNE DUUS JOHANSEN
8. Cosmetic directive (76/768/EEC)
9. Preservatives for cosmetics By: David C. Steinberg

Editorial Board:

General Supervisor: *Prof. Saleh A. Bawazir*

Chef Editor: *Abdullrahman S. Alsultan, B.Pharm, MSc.*

Assistant Chef Editor: *Nawaf M. Alshobaili, B.Pharm, MPH.*

National Drug and Poison Information Center (NDPIC):

Fahad A. Al Otaibi, BSc.Pharm, MSc. Clin Pharm.

Abdulmohsen A. AlObaid, B. Pharm., MSc. Clin Phram

National Pharmacovigilance and Drug Safety Center

Adel A Alharf, PhD, MSc.

Naser A. Aljaser B.Pharm.m, MSc. Clin Epi.

LATEST DRUGS REGISTERED



GENERIC NAME	TRADE NAME	STRENGTH	PRICE SR	MANUFACTURER
DAPOXETINE	LEJAM FILM COATED TABLET	30MG	67	SPIMACO - SAUDI ARABIA
DAPOXETINE	LEJAM FILM COATED TABLET	60MG	67	SPIMACO - SAUDI ARABIA
DESMOPRESSIN	MINIRIN MELT ORAL LYOPHILISATE TABLET	240MCG	338.5	CATALENT - UNITED KINGDOM
DINOPROSTONE	PROPESS VAGINAL PESSARY	10MG	218.8	FERRING CONTROLLED THERAPEUTICS - UNITED KINGDOM
DOXORUBICIN HYDROCHLORIDE	ADRIBLASTINA VIAL & SOLV	10MG	28.3	ACTAVIS - ITALY
DOXORUBICIN HYDROCHLORIDE	ADRIBLASTINA VIAL & SOLV	50MG	116.9	ACTAVIS - ITALY
ETORICOXIB	ETORIA FILM COATED TABLETS	60MG	53.55	MSD-ELIKTRON - UNITED STATES
ETORICOXIB	ETORIA FILM COATED TABLETS	90MG	172.05	MSD-ELIKTRON - UNITED STATES
ETORICOXIB	ETORIA FILM COATED TABLETS	120MG	186.2	MSD-ELIKTRON - UNITED STATES
GEMCITABINE HYDROCHLORIDE	GEMCITABINE ACTAVIS	200MG	65.4	ACTAVIS SPA - ITALY
GEMCITABINE HYDROCHLORIDE	GEMCITABINE ACTAVIS	1 GM	289.85	ACTAVIS SPA - ITALY
LAMOTRIGINE	LAMOTRIX TABLET	25MG	25.85	MEDOCHEMIE LTD PHARMACEUTICAL INDUSTRY - CYPRUS
LAMOTRIGINE	LAMOTRIX TABLET	50MG	41	MEDOCHEMIE LTD PHARMACEUTICAL INDUSTRY - CYPRUS
LAMOTRIGINE	LAMOTRIX TABLET	100MG	74.15	MEDOCHEMIE LTD PHARMACEUTICAL INDUSTRY - CYPRUS
MONTELUKAST SODIUM	MONTEL GRANULES	4MG	105.7	SPIMACO - SAUDI ARABIA
MONTELUKAST SODIUM	MONTEL CHEWABLE TABLET	4MG	95.15	MERCK SHARP & DOHME - UNITED KINGDOM
MONTELUKAST SODIUM	MONTEL CHEWABLE TABLET	5MG	95.15	MERCK SHARP & DOHME - UNITED KINGDOM
MONTELUKAST SODIUM	MONTEL FILM COATED TABLET	10MG	85.65	MERCK SHARP & DOHME - UNITED KINGDOM
OFATUMUMAB	ARZERRA	20 MG/ML	3571.9	GLAXO OPERATION - UNITED KINGDOM
OFATUMUMAB	ARZERRA	20 MG/ML	* 11906.35	GLAXO OPERATION - UNITED KINGDOM
TAMSULOSIN HYDROCHLORIDE	PROSTA TAB	0.4MG	77.8	TABUK PHARMACEUTICAL MANUFACTURING CO. - SAUDI ARABIA
TIGECYCLINE	TYGACIL LYOP. POW. FOR I.V.INFUSION	50MG	2151.25	PATHEON - ITALY
XYLOMETAZOLINE HYDROCHLORIDE	DECOZAL NASAL SPRAY	0.10%	7.55	AMMAN PHARMACEUTICAL INDUSTRIES (API) - JORDAN

* The price is different due to volume size difference.



ARABIC SUMMARY:

المُلخَص العَرَبِي:

لعلاج الحساسية المفرطة جاهزة للاستخدام.

١. إيقاف استخدام المستحضر عند بداية ظهور أعراض الحساسية من المستحضر على المريض.

تجدر الإشارة بأن مستحضر Pegaspargase لم يتم تسجيله بعد في المملكة العربية السعودية. بعض مستشفيات المملكة العربية السعودية.

■ الموضوع: احتمالية ظهور حالات وفيات وفشل كلوي بالتزامن مع استخدام مستحضر Hydroxyethyl Starch

قام المركز الوطني للتيقظ والسلامة الدوائية بعمل تقرير مفصل بخصوص وجود علاقة محتملة بين مستحضر hydroxyethyl starch وظهور حالات وفيات وفشل كلوي، وبعد مراجعة الموضوع من جميع جوانبه، أوصى المركز بالتالي:

حصر استخدام المستحضر لدى المرضى الذين يعانون من نقص كمية الدم hypovolaemia الناتج من فقدان الحاد للدم عند ثبوت ان المحاليل لوريديية (crystalloid) غير كافية. ولضمان خفض المخاطر في هذه الحالات يجب عدم استخدام مستحضر hydroxyethyl starch لأكثر من اربعة وعشرين ساعة مع وجوب اجراء مراقبة لوظائف الكلى خلال التسعين يوم اللاحقة.

عدم استخدام مستحضر hydroxyethyl starch في الحالات التالية:

الحالات الحرجة critical ill patients والمرضى المصابين بتعفن الدم sepsis و septic shock ومرضى العناية المركزة ICU والمرضى الذين يعانون من الحروق Burn injuries.

• المرضى الذين لديهم مشاكل في الكلى او في الكبد.

المرضى الذين سيخضعون لعمليات القلب المفتوح المرتبط بجراحة المجازة in patients undergoing heart surgery in association with cardiopulmonary bypass due to excess bleeding.

• عند بداية ظهور اعراض جانبية على الكلى مثل تغير مفاجئ في لون البول او وجود دم في البول.

عند بداية ظهور اعراض تجلط دم coagulopathy .

■ الهيئة العامة للغذاء والدواء تلغي تسجيل المستحضرات المحتوية على المادة الفعالة (Ketoconazole) والتي تؤخذ عن طريق الفم

أعلنت الهيئة العامة للغذاء والدواء عن إلغاء تسجيل المستحضرات الصيدلانية المحتوية على المادة الفعالة (Ketoconazole) والتي تؤخذ عن طريق الفم لعلاج الالتهابات الفطرية، وذلك نتيجة لقيام الهيئة بعمل بحث شامل وموسع عن السلامة الدوائية لتلك المستحضرات، وقد تم عرض الموضوع على اللجان الفنية المتخصصة التي قررت إلغاء التسجيل وذلك لأن الأضرار المتمثلة في إصابة الكبد تفوق المنافع المرجوة من استخدام هذه المستحضرات لعلاج الالتهابات الفطرية وكذلك توفر البدائل الفعالة والأكثر أماناً. تهيب الهيئة بجميع الممارسين الصحيين لإستخدام البدائل العلاجية المناسبة لدى تلك الفئة من المرضى.

■ الموضوع: فرصة حدوث حالات حساسية مفرطة بالتزامن مع استخدام مستحضر Pegaspargase

لوحظ مؤخراً أن هناك زيادة في اعداد بلاغات عن حدوث حساسية مفرطة بالتزامن مع استخدام مستحضر Pegaspargase. وحيث ان النشرة الداخلية العالمية للمستحضر تنص على ان هناك حالات ظهور حساسية مفرطة مع المستحضر بشكل شائع، فقد قامت الهيئة العامة للغذاء والدواء ممثلة بالإدارة التنفيذية للتيقظ وإدارة الأزمات بإشعار الممارسين الصحيين والمرضى حول فرصة حدوث حالات حساسية مفرطة بالتزامن مع استخدام مستحضر Pegaspargase.

إضافة الى ذلك فقد تم مراجعة بعض دراسات السلامة الدوائية لهذا المستحضر والتي خلصت الى ان الاطفال ومن هم في بداية سن البلوغ أكثر عرضة لهذا الخطر.

ولتقليل فرصة حدوث هذه الحالات تنصح الإدارة باتخاذ التدابير التالية قبل واثناء استخدام هذا المستحضر:

تجنب استخدام المستحضر في المرضى الذين لديهم حساسية مفرطة لأي شكل من اشكال مستحضر L-Asparaginase.

يجب ابقاء المريض تحت الملاحظة لمدة ساعة بعد استخدام المستحضر مع الاخذ في الاعتبار ابقاء اجهزة الانعاش وغيرها من العوامل اللازمة

CONTACTS:

Tel: +966-11-2038222 Ext 5302, 5340, 5162, 5666

Fax: +966-11-2057633

- Drug Regestration Fax: +966 -11- 2057643 - Licensing and Inspection Fax: +966-11-2057643

- National Phormacovigilance Center: Toll Free: 8002490000, Fax: +966-11-2057662, E-mail: npc.drug@sFDA.gov.sa

- National Drug & Poising Information Center Ext: 5160, 5396, 5183, 5201, Fax: +966-11-2057627

E-mail: ndpic@sFDA.gov.sa

- Mail Address: Saudi Food & Drug (3292). North High Road. AlNafI. Unit No. (1). Riyadh 13312 - 6288 KSA.

E-mail: drug-dept@sFDA.gov.sa

- Drug Sector Website: www.sFDA.gov.sa/en/drug

- To Contact the Saudi Drug Bulletin: assultan@sFDA.gov.sa