Saudi Drug Bulletin

Drug Sector

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WARNING

Cefepime Use and Risk of Nonconvulsive Status Epilepticus in Patients with Renal Impairment.

By: Ali Y. Alshahrani, B.Pharm, MSC.

The Saudi Food and Drug Authority is reminding health care professionals about the need to adjust the dosage of the antibacterial drug, cefepime in patients with renal (kidney) impairment. There have been cases of a specific type of seizure called nonconvulsive status epilepticus associated with the use of cefepime in patients with renal impairment who did not receive appropriate dosage adjustments of cefepime.

Cefepime is a 4th generation cephalosporin antibacterial drug that used to treat pneumonia, urinary tract, skin, and intra-abdominal infections.

Cases of nonconvulsive status epilepticus associated with cefepime are documented in the medical literature and have been identified in the World Health Organization adverse drug events database.

Most cases occurred in patients with renal impairment who did not receive appropriate dosage adjustment; however, some cases occurred in patients receiving appropriate dosage adjustment for their degree of renal impairment. In the majority of cases, the seizures were reversible and resolved after discontinuing cefepime and/or after hemodialysis.

Considerations for health care professionals:

- The dosage of cefepime should be adjusted in patients with creatinine clearance less than or equal to 60 mL/min.
- Nonconvulsive status epilepticus has been reported with cefepime. Most cases occurred in patients with renal impairment for whom the dosage was not appropriately adjusted.
- In the majority of cases, the seizures were reversible and resolved after discontinuation of cefepime and/or after hemodialysis. If a patient experiences a seizure during cefepime therapy, health care professionals should consider discontinuing cefepime or making appropriate dosage adjustments in patients with renal impairment.

WARNING

Saudi Food and Drug Authority (SFDA) PRESS RELEASE- Safety of Codeine in Children Following Tonsillectomy and/or Adenoidectomy

By: Fawaz F. Alharbi, B.Pharm, MSC & Mohammed A. Alhusain, B.Pharm.

The Saudi Food and Drug Authority (SFDA) would like to share some recent information regarding use of codeine in children as post-operative pain killer. On 2009 and 2012, three pediatric deaths and one life threatening case of respiratory depression were reported in the medical literature after taking

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codeine for relieving pain following tonsillectomy and/or adenoidectomy for obstructive sleep apnea syndrome.1,2 These cases were for children who have genetic ability to convert codeine into fatal amounts of morphine in the body. The age of those children were between two and five years.

Codeine is converted inside the body to morphine in the liver by a cytochrome P450 2D6 enzyme (CYP2D6). Moreover, codeine is converted to morphine faster and more completely in some people who have DNA variations due to the fact that CYP2D6 is more active. Those patients who have this condition are called "ultra-rapid metabolizers" and they usually have higher amounts of morphine than normal in blood after taking codeine (table 1). Subsequently, the high levels of morphine may lead to breathing difficulty that may be considered as a fatal outcome.

Table 1. Prevalence of Ultra-rapid Metabolizers in Different Populations (Adopted from FDA website[3])

Population	UM Genotypes / Phenotypes (↑Activity)	Prevalence % (UM/Total n)
African/Ethiopian	UM (active duplicate genes)	29% (35/122)
African American	UM (three active duplicate genes)	3.4% (3/87) 6.5% (60/919)
Asian	UM (active duplicate genes)	1.2% (5/400) 2%
Caucasian	UM (three active duplicate genes)	3.6% (33/919) 6.5% (18/275)
Greek	CYP2D6*2xN/UM	6.0% (17/283)
Hungarian	UM (active duplicate genes)	1.9%
Northern European	UM (active duplicate genes)	1-2%

UM = ultra-rapid metabolizer; CYP2D6 = cytochrome P450 2D6

In the meantime, SFDA is reviewing all data on this safety concern and will release the results of this review when it finished. SFDA advises all healthcare professionals to prescribe codeine-containing drugs in the lowest effective dose for the shortest period of time and should be used on an as-needed basis. All healthcare professionals should be aware of the risks of using codeine in children, particularly in those who have undergone tonsillectomy and/or adenoidectomy for obstructive sleep apnea syndrome.

References

1. Ciszkowski C, Madadi P, Phillips MS, Lauwers AE, Koren G. Codeine, ultrarapid-metabolism genotype, and postoperative death. N Engl J Med 2009;361:827-8.
2. Kelly LE, Rieder M, van den Anker J, Malkin B, Ross C, Neely MN, et al. More codeine fatalities after tonsillectomy in North American children. Pediatrics 2012;129:e1343-7.
3. U.S. Food and Drug Administration. FDA Drug Safety Communication: Codeine use in certain children after tonsillectomy and/or adenoidectomy may lead to rare, but life-threatening adverse events or death. 2112; http://www.fda.gov/Drugs/DrugSafety/ucm313631.htm#data. Accessed 25 AUG, 2012.

SFDA Statement About the Recent Updates Concerning Safe Use of Azithromycin.

By: Ali Y. Alshahrani, B.Pharm, MSc & Abdullah R. Almatrafi, B.Pharm.

The Saudi food and drug authority would like to inform healthcare professionals and patients that the Saudi Food and Drug Authority (SFDA) is aware of the recent safety issue concerning the risk of cardiovascular death in patient treated with azithromycin that was obtained by a study published in the New England Journal of Medicine, on May 17, 2012, which compared the risk of cardiovascular death in patients treated with azithromycin, amoxicillin, ciprpfloxacin, levofloxacin, and no antibacterial drug. The study concluded that the use of Azithromycin for 5 days sowed small absolute increase in the cardio-vascular adverse events which may result in fatalities among the patients with high baseline risk of cardio-vascular disease.

The study, also, reported a small increase in cardiovascular deaths, and the risk of death due to any cause, in persons treated with amoxicillin, ciprofloxacin, or no antibiotic treatment. The risks of cardiovascular death associated with levofloxacin treatment were similar to those associated with azithromycin treatment.

The SFDA is currently reviewing all available data on this safety concern and will release the results of this review when it finished, Therefore, patients taking azithromycin should not stop taking the medicine without talking to their physicians.

GUIDLINE

Guidelines for Biowaivers

By : Hussain A. Bafagih, B.Pharm, Msc.

Saudi Food and Drug Authority (SFDA) has recently published a guideline for biowaiver based on Biopharmaceutics Classification System (BCS) specially for immediate-release solid oral dosage form. This guidance is intended to facilitate and support the workflow of drug registration. BCS-based biowaiver is meant to reduce the in vivo bioequivalence studies, i.e., it may represent a substitute for in vivo bioequivalence.

The BCS is a scientific framework for classifying drug substances based on their aqueous solubility and intestinal permeability. There are four classes:

Class 1: High Solubility- High Permeability.
Class 2: Low Solubility- High Permeability.
Class 3: High Solubility- Low Permeability.
Class 4: Low Solubility- Low Permeability.

BCS-based biowaivers intended to address the question of bioequivalence between specific test and reference products.

This guidance will be applied to immediate release, solid pharmaceutical products for oral administration and systemic action having the same pharmaceutical form and is restricted to highly soluble drug substances with known human absorption and considered not to have a narrow therapeutic index.

The biowaiver guidelines is not applicable for products designed to be absorbed in the oral cavity (sublingual, buccal, and modified release formulations). While, for orodispersible formulations the BCS-based biowaiver approach may only be applicable when absorption in the oral cavity can be excluded. Moreover, Biowaiver is not applicable when the test product contains a different ester, ether, isomer, mixture of isomers, complex or derivative of an active substance from that of the reference product, since these differences may lead to different bioavailabilities not deducible by means of experiments used in the BCS-based biowaiver concept.

The principle of BCS-based biowaivers is to establish bioequivalence in:

- Generic medicinal products
- Extensions of innovator products
- Variations that require bioequivalence testing.
- Between early clinical trial products.
- It is important to avoid the use of excipients that might affect the bioavailability unless they have been used in the reference product in the same qualitative and quantitative manner.

References:

1. The GCC guidelines for bioequivalence, version 2, 2011.
2. Guidance for Industry: "Waiver of in vivo Bioavailability and Bioequivalence Studies for Immediate-Release Solid Oral Dosage Forms Based on a Biopharmaceutics Classification System". U.S. Food and Drug Administration, Center for Drug Evaluation and Research, 2000.
3. WHO, Annex 8, Proposal to waive in vivo bioequivalence requirements for WHO Model List of Essential Medicines immediate-release, solid oral dosage forms.
4. EMA as described in " Guideline on The Investigation of Bioequivalence", 2010.

AWARENESS

Inhaled Corticosteroids use in Children and the Effects on Adult Height.

By : Mohammed A. Barasain, RPh

Diminished height as a result of a decrease in growth velocity with the use of Inhaled corticosteroids (ICS) in children has long been recognized. However, this effect on early growth velocity and final adult height is unknown.

The New England Journal of Medicine NEJM published a long term analysis of The Childhood Asthma Management Program (CAMP) trial in the September 6, 2012 issue. The CAMP trial is a double blind placebo controlled trial began in 1993. Patients were randomized to receive the inhaled corticosteroid budesonide (Pulmicort), the mast cell stabilizer nedocromil (Tilade), or placebo. In addition, albuterol was used for asthma symptoms in all three groups. After approximately 12 years of follow up, a mean decrease in adult height of 1.2 cm was detected with the budesonide group compared to placebo. In comparison, a mean decrease of 0.2 cm was detected in the nedocromil group compared to placebo.

The registered inhaled corticosteroids available in Saudi Arabia are:

Generic Name	Trade Name (s)
Beclomethasone	Beclazone, Clenil
Budesonide	Budiair, Pulmicort
Fluticasone	Flexotide

Nedocromil is not registered in the kingdom.

In conclusion, ICS remain the standard therapy for asthma control in children and perhaps the risk of a diminished height has to be accepted for severely asthmatic children. The common medical practice of prescribing ICS to children during sand storms or dust seasons in the Kingdom is not supported by evidence of a benefit for patients. Such practice has to be avoided as most cases are not asthmatic and they might only be allergic to sand and dust. Prescribing ICS to children should be limited to asthma control to avoid the risk of diminished height in non asthmatic children.

Reference:

Kelly HM, Sterngberg AL, Lescher R, et al. Effect of Inhaled Glucocorticoids in Childhood on Adult Height. N Engl J Med 2012; 367:904-912

1. Available on: http://www.nejm.org/doi/full/10.1056/NEJMoa1203229

Implementation of new technologies in the National Drug and Cosmetics Control Laboratories.

By : Abdullah F. Almeshal, B.Pharm, MSc.

Since the National Drug and Cosmetics Control Laboratories (NDCCL) became under the SFDA umbrella, the drug sector administration was working hardly to provide NDCCL with the newest technologies in the analysis field to ensure accuracy of the results. Their aim was to fully automate NDCCL, thus they purchased many instruments with high quality and new technology. The automation plan was not concentrated only on the analysis part but also the handling process of the samples and obtaining the result. However they bought the Laboratory Information management system (LIMS).

LIMS is used by many big companies all over the world. ARAMCO, SABIC and many other are the companies using LIMS in Saudi Arabia1. This system consists of 400 modules, at the mean time SFDA uses 6 modules which are:

1. Sample management module: This module deals with the samples handling process, starting from logging the samples by the requestors and determining the purpose of analysis, then receiving the requests by the receiving unit and directing them to the appropriate analytical department to be analyzed, then assigning the samples to the laboratory analyst by the heads of the department, after that laboratory analyst will perform the tests needed and enter the results in LIMS, which then approved by the head of the department to be then sent to the executive director for authorization. Finally, the final report issued with the executive director signature to be available for the requestors to view and print.
2. Instrument management module: this module consist of two parts, the first part is for the laboratory analyst to make a request for maintenance that sent through LIMS to the maintenance engineer to take care of. Second part is designed for maintenance engineer as a reminder for the preventive maintenance of instruments.
3. Inventory management module: this module designed to keep track of each category of inventory “chemicals, standers, glassware, spare parts, and animals” and then alert the Logistic department when there are only 20% of the that inventory.
4. Document manager module: this module is for electronic archiving of all NDCCL documents. Some of these documents pass through four steps “Create, Review, Approve, and release” before they are stored in LIMS database. The NDCCL staff also can search for any archived document within LIMS.
5. Non-conformity module: Laboratory analyst can use this module to notify the Quality Assurance (QA) staff about any test’s result that is out of specification so the QA staff can investigate and find the root that causes of this result.
6. Laboratory Station module: this module is to link the analysis instrument with LIMS so the results are transfered and stored automatically from the instrument to LIMS.

Since all the events are stored within LIMS database NDCCL administration can request for any report to be issued using this database. Moreover, confidentiality in LIMS is very high thus each user of LIMS can see his / her samples or requests only and each head of department can see the samples within his department only and the NDCCL executive director can see the samples information for all NDCCL departments. After the system implementation, the first impression and feedback of users was very positive, they said ” the work became much organized and much easier”.

Reference:

www.naizak.com/Automation/Automation_LIMS.html

Assessing the risk of venous thromboembolic events in women taking progestin-only contraception: a meta-analysis.

By: Mohammed A. Barasain, RPh

The following is a summary of an open access article published in a recent issue of the British Medical Journal BMJ (BMJ 2012;345:e4944).

The objectives of this study were to evaluate the risk of venous thromboembolic events associated with the use of progestin-only contraception and whether that risk differs with the mode of drug delivery (oral, intrauterine, or depot injection). This study was designed as systematic review and meta-analysis of randomized controlled trials and observational studies. Data were collected from PubMed, Embase, Cochrane Library, and reference lists of relevant reviews.

The studies selected and included in the meta-analysis were randomized controlled trials and case-control, cohort, and cross sectional studies with venous thromboembolic outcome for progestin-only contraception reported relative to a non-hormone comparator group. Data were extracted by two independent investigators, and consensus for inclusion was reached after assessment by additional investigators.

Among the 2022 unique references identified by all searches, eight observational studies fulfilled inclusion criteria. A total of 147 women across all studies were diagnosed with a venous thromboembolic event while

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taking progestin-only contraception, and the summary measure for the adjusted relative risk of a venous thromboembolic episode for users versus non-users of a progestin-only contraceptive was, based on the random effects model, 1.03 (95% CI 0.76 to 1.39). Subgroup analysis confirmed there was no association between venous thromboembolic risk and progestin-only pills (relative risk 0.90 (0.57 to 1.45)) or a progestin intrauterine device (0.61 (0.24 to 1.53)). The relative risk of a venous thromboembolic event for users of an injectable progestin versus non-users was 2.67 (1.29 to 5.53).

Conclusions:

Published data assessing the risk of venous thromboembolism in women prescribed progestin-only contraception are limited. In this meta-analysis of eight observational studies, the use of progestin-only contraception was not associated with an increased risk of venous thromboembolism compared with non-users of hormonal contraception. The potential association between injectable progestins and thrombosis requires further study.

Reference:

BMJ 2012; 345 doi: 10.1136/bmj.e4944 (Published 7 August 2012)

Conflict of Interest Reporting by Authors Involved in Promotion of Off-Label Drug Use: An Analysis of Journal Disclosures.

By : Fahad A. Al Otaibi, B.Pharm, MSc. Clin Pharm

The following is a summary of an article published in the Public Library Of Science open access journal PLOS Medicine (Issue: August,2012) by Kesselheim etal.

Background:

Litigation documents reveal that pharmaceutical companies have paid physicians to promote off-label uses of their products through a number of different avenues. It is unknown whether physicians and scientists who have such conflicts of interest adequately disclose such relationships in the scientific publications they author.

Methods and Findings:

Authors collected whistleblower complaints alleging illegal off-label marketing from the US Department of Justice and other publicly available sources (date range: 1996–2010). Authors identified physicians and scientists described in the complaints as having financial relationships with defendant manufacturers, then searched Medline for articles they authored in the subsequent three years. Authors assessed disclosures made in articles related to the off-label use in question, determined the frequency of adequate disclosure statements, and analyzed characteristics of the authors (specialty, author position) and articles (type, connection to off-label use, journal impact factor, citation count/year). 39 conflicted individuals in whistleblower complaints were identified. They published 404 articles related to the drugs at issue in the whistleblower complaints, only 62 (15%) of which contained an adequate disclosure statement. Most articles had no disclosure (43%) or did not mention the pharmaceutical company (40%). Adequate disclosure rates varied significantly by article type, with commentaries less likely to have adequate disclosure compared to articles reporting original studies or trials (adjusted odds ratio [OR] = 0.10, 95%CI = 0.02–0.67, p = 0.02). Over half of the authors (22/39, 56%) made no adequate disclosures in their articles. However, four of six authors with ≥25 articles disclosed in about one-third of articles (range: 10/36–8/25 [28%–32%]).

Conclusion:

One in seven authors identified in whistleblower complaints as involved in off-label marketing activities adequately disclosed their conflict of interest in subsequent journal publications. This is a much lower rate of adequate disclosure than has been identified in previous studies. The non-disclosure patterns suggest shortcomings with authors and the rigor of journal practices.

Reference:

http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.1001280

National Drug and Poison Information Center (NDPIC) Possible Risks of Accelerated Drug Approvals!

By : Fahad A. Al Otaibi, B.Pharm, MSc. Clin Pharm

A recent view point by Moore and Furberg published in the journal of American Medical Association JAMA (Vol 30, No 9) highlighted the US FDA's new expedited drug development pathway which is used to speed up the approval of new promising drugs.

Even though allowing new drugs with favorable benefit to risk ratios to become available to patients more rapidly is a positive intention, a main public health concern is that important safety questions remains unanswered for the widespread use of rapidly approved drugs.

In 2011, the US FDA classified every new molecular entity as "innovative" and reported using one or more expedited approval programs for 16 of the 35 new drugs (46%). All 16 of these drugs received priority reviews, which provide shortened review times for drugs that may offer a therapeutic advance; 13 drugs were also designated for the Fast Track program, which allows reviews to begin before clinical studies are complete for drugs that may fill serious unmet medical needs; and 3 drugs received Accelerated Approval, a program that relies on preliminary but not definitive evidence of benefit.

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A question raised by these examples of whether it was a good policy to approve new drugs with significant safety questions unanswered and with optimal doses not determined.

Although Fast Track drug approval might present benefits. However, a substantial safety concern still remains due to lack of completed clinical trials to prove the safety and efficacy of these drugs.

Reference:

http://jama.jamanetwork.com/article.aspx?articleid=1356361

Overview on good storage and distribution practice

By : Abdulmajeed M. Altamimi , B.Pharm.

Good distribution practices (GDP) is That part of quality assurance that ensures that the quality of a pharmaceutical product is maintained by means of adequate control of the numerous activities which occur during the distribution process as well as providing a tool to secure the distribution system from counterfeits, unapproved, illegally imported, stolen, counterfeit, substandard, adulterated, and/or misbranded pharmaceutical products.

Good storage practices (GSP) are applicable in all circumstances where pharmaceutical products are stored and throughout the distribution process.

Storage areas:

Storage areas should be designed or adapted to ensure appropriate and good storage conditions. In particular, they should be clean and dry and maintained within acceptable temperature limits. Pharmaceutical products should be stored off the floor and suitably spaced to permit cleaning and inspection. Pallets should be kept in a good state of cleanliness and repair. There should be a written programme for pest control and the agents used should be safe and there should be no risk of contamination of pharmaceutical products. Records of monitoring data should be made available for inspection by the food and drug authority (SFDA).

Transportation system:

Vehicles is used to distribute, store or handle pharmaceutical products should be suitable for their purpose and appropriately equipped to prevent exposure of the products to conditions that could affect their stability and packaging integrity, and to prevent contamination of any kind. Where special storage conditions (e.g. temperature and/or relative humidity) the expected environmental conditions, are required during transportation, these should be provided, checked, monitored and recorded.

Reference:

WHO expert committee on specification for pharmaceutical preparation.

Lastest Drugs Registered

Generic Name	Trade name	Strength	Price SR	Manufacturer
ACYCLOVIR (ACICLOVIR)	VIROL	5%	58.15	RIYADH PHARMA
ALLOPURINOL	ZYLORIC TABLET	100 MG	14.2	GLAXO SAUDI ARABIA
AZATHIOPRINE HYDROCHLORIDE	IMURAN VIAL	50MG	54.85	GLAXOSMITHKLINE (GSK)
BETAHISTINE DIHYDROCHLORIDE	BERTIGO TABLET	16 MG	28.4	Jazeera Pharmaceutical Industries (JPI)
BETAHISTINE DIHYDROCHLORIDE	BERTIGO TABLET	24 MG	30.05	Jazeera Pharmaceutical Industries (JPI)
BETAHISTINE DIHYDROCHLORIDE	BERTIGO TABLET	8 MG	16.8	Jazeera Pharmaceutical Industries (JPI)
BISACODYL	DULCOLAX ENTERIC COATED TABLET	5MG	6.45	DELPHARM REIMS S.A.S
CARBOXYMETHYLCELLULOSE	UNI FRESH UNIT DOSE EYE DROPS	0.50%	12.85	JAMJOOM PHARMACEUTICALS COMPANY
CEFIXIME	CEFIM 100 POWDER FOR ORAL SUSPENTION	20 MG/ML	36.3	OMAN PHARMACEUTICAL PRODUCTS
CEFUROXIME AXETIL	CEFOVEX TABLET	500MG	49.3	OMAN PHARMACEUTICAL PRODUCTS
DIGOXIN	LANOXIN INJ	0.25MG/ML	13.2	GLAXOSMITHKLINE (GSK)
DIGOXIN	LANOXIN PG TABLET	0.0625MG	6.4	GLAXOSMITHKLINE (GSK)
ESTRADIOL VALERATE, NORGESTRIL	PROGYLUTON TAB	0.5, 2 MG	7.95	SCHERING GmbH AND CO. PRODUKTIONS KG.
FLUCONAZOLE	FLUKAS 100 VIAL	2 MG /ML	21.05	MEDIS
FLUCONAZOLE	FLUKAS 200 VIAL	2 MG/ML	29.4	MEDIS
GLIBENCLAMIDE, METFORMIN	GLUCOVANCE	2.5/500	16.5	MERCK SANTE
GLIBENCLAMIDE, METFORMIN	GLUCOVANCE	5/500	23.45	MERCK SANTE
GLIMEPIRIDE	PIRAMYL 6MG TABLETS	6 ML	44.45	TABUK PHARMACEUTICAL MANUFACTURING CO.
GLIMEPIRIDE	GLYPRIDE TABLET	3 MG	21.25	Gulf Pharmaceutical Industries (Julphar)
LATANOPROST	LATAPROST EYE DROPS	50 µg/m	47.9	RIYADH PHARMA
LEVOCETIRIZINE DIHYDROCHLORIDE	LEVOZAL FILM COATED TABLET	5 MG	21.95	JAMJOOM PHARMACEUTICALS COMPANY
LEVOFLOXACIN	LEVOFLOX F.C. TABLET	500MG	49.9	NATIONAL PHARMACEUTICAL INDUSTRIES CO
METRONIDAZOLE	METRONIDAZOLE INJECTION USP	5 MG / ML	8.15	QATAR PHARMA
PAZOPANIB HYDROCHLORIDE	VOTRIENT	200 MG	3511.45	GLAXO
PAZOPANIB HYDROCHLORIDE	VOTRIENT	400 MG	7022	GLAXO
PROCYCLIDINE	KEMADRIN TABLET	5MG	27	GLAXOWELLCOME
RECOMBINANT ANTIHEMOPHILIC FACTOR VIII FORMULATED WITH SUCROSE	KOGENATE FS	250 IU	689.55	BAYER HEALTHCARE
RECOMBINANT ANTIHEMOPHILIC FACTOR VIII FORMULATED WITH SUCROSE	KOGENATE FS	500 IU	1370.3	BAYER HEALTHCARE
RECOMBINANT ANTIHEMOPHILIC FACTOR VIII FORMULATED WITH SUCROSE	KOGENATE FS	1000 IU	2711.75	BAYER HEALTHCARE
SODIUM CHLORIDE	SODIUM CHLORIDE INTRAVENOUS INFUSION	23.40%	10.95	QATAR PHARMA

الملخص العربي:

ARABIC SUMMARY:

■ نصائح بخصوص مستحضر Cefepime:

قامت الهيئة العامة للغذاء والدواء ممثلة في الإدارة التنفيذية للتيقظ وإدارة الأزمات بإصدار نصائح للمختصين الصحيين حول خطر إمكانية حدوث نوبات صرع لدى مرضى الكلى بالتزامن مع استخدام مستحضر Cefepime وهي كالتالي :

ان هناك زيادة في فرصة حدوث نوبات الصرع غير التشنجية لدى المرضى الذين يعانون أمراض الكلى عند استخدامهم لمستحضر Cefepime دون أن يتم تعديل جرعته لتتناسب مع حالة الكلى لديهم.

١. إمكانية حدوث نوبات الصرع غير التشنجية لدى مرضى الكلى حتى عند إعطائهم الجرعات المناسبة لحالة الكلى لديهم.

أن نوبات الصرع غير التشنجية والتي قد تظهر نتيجة لاستخدام مستحضر Cefepime قابلة للشفاء وغالبا ما تختفي بعد وقف استخدام هذا المستحضر.

٢. عند مراجعة قاعدة بيانات رصد الاعراض الجانبية لمنظمة الصحة العالمية تم رصد ٣٤ حالة نوبة صرع غير تشنجي بالتزامن مع استخدام هذا المستحضر.

■ ممارسات التخزين و التوزيع الجيدة.

ممارسات التخزين و التوزيع الجيدة هي ذلك الجزء من ضمان الجودة الذي يضمن المحافظة على جودة المنتجات الصيدلانية أثناء تخزينها و توزيعها و نقلها.

منطقة التخزين يجب أن تصمم بالشكل الذي يضمن توفر ظروف التخزين الجيدة ، على وجه الخصوص ، ينبغي أن تكون نظيفة وجافة و أن تحافظ على درجة الحرارة في حدود مقبولة لضمان سلامة المستحضرات الصيدلانية.

وسائل النقل المستخدمة لتوزيع و تخزين المستحضرات الصيدلانية يجب أن تكون مناسبة ومجهزة بشكل كامل لتمنع تعرض المستحضرات الصيدلانية لأي ظرف قد يؤثر على ثباتيتها أو سلامة أغلفتها، و أيضا لتمنع التلوث من أي نوع .

■ نشر متطلبات الأستثناء من دراسة التكافؤ الحيوي:

"قامت الهيئة العامة للغذاء والدواء مؤخرا بنشر دليل "متطلبات الاستثناء من دراسة التكافؤ الحيوي" بالاعتماد على نظام تصنيف الصيدلة الحيوية (Biopharmaceutics Classification System). وهذا الدليل موجه للشركات ومراكز الأبحاث والمهتمين في تسجيل الأدوية الجنيسة حتى تسهل عملية التسجيل للمستحضرات التي يمكن استثناؤها من دراسات التكافؤ الحيوي. يطبق الدليل للمستحضرات الصلبة فورية التحلل والتي تتمتع بذوبانية عالية".

■ نتائج الدراسات الحديثة التي تناقش سلامة استخدام مستحضر أزيثرومايسين (Azithromycin):

قامت مؤخراً بعض الهيئات الرقابية العالمية باستعراض نتائج الدراسة الحديثة التي تناقش سلامة استخدام مستحضر أزيثرومايسين (Azithromycin) التي تم نشرها مؤخرا في مجلة New England Journal of Medicine. وهي دراسة تبحث احتمالية حدوث وفيات نتيجة حدوث أعراض قلبية وعائية لمستخدمي المضاد الحيوي أزيثرومايسين (Azithromycin) وبعض المضادات الحيوية الأخرى مقارنة بالأشخاص الذين لم تتم معالجتهم بالمضادات الحيوية، وقد أشارت نتائج هذه الدراسة إلى أن استخدام مستحضر (Azithromycin) لمدة خمسة أيام قد يسبب زيادة بسيطة في فرصة حدوث أعراض جانبية قلبية وعائية قد تؤدي إلى الوفاة مقارنة بالمضادات الحيوية الأخرى لدى المرضى الذين لديهم أسباب قابلية الإصابة بالأمراض القلبية الوعائية.

وتود الهيئة العامة للغذاء والدواء أن تطمئن كلا من الممارسين الصحيين والمرضى بأن هذا الموضوع قيد الدراسة، و تقوم حالياً بعمل المراجعات اللازمة للدراسات ذات العلاقة للتحقق من صحة علاقة استخدام مستحضر أزيثرومايسين (Azithromycin) بحدوث أي أعراض جانبية قلبية وعائية.

وبناءً على ما سبق، فإن الهيئة تنصح المرضى بالاستمرار على استخدام مستحضر أزيثرومايسين (Azithromycin) وعدم التوقف عن استخدامه من تلقاء أنفسهم دون الرجوع للطبيب المعالج.

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