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WARNING

Saudi Food and Drug Authority (SFDA) PRESS RELEASE- Use of Gilenya® and Cardiovascular Adverse Events after the First dose.

By: Fawaz Alharbi, B. Pharm, MSc, CPP & Ali Y. Alshahrani, B. Pharm

The Saudi Food and Drug Authority (SFDA) would like to inform health care professionals that SFDA has evaluated the recent safety issue concerning the risk of death and cardiovascular events reported after the first dose of multiple sclerosis drug Gilenya® (fingolimod).

The Saudi Food and Drug Authority (SFDA) would like to inform health care professionals that SFDA has evaluated the recent safety issue concerning the risk of death and cardiovascular events reported after the first dose of multiple sclerosis drug Gilenya® (fingolimod).

Gilenya® is an oral medication for the treatment of relapsing forms of multiple sclerosis (MS) in adults.

The evaluation was included a reported case of patient with multiple sclerosis who died within 24 hours after receiving the first dose of Gilenya®, clinical studies and several cases of bradycardia and atrioventicular block that have been reported after the 1st dose of Gilenya®.

As a result, there was an increase in the cardiovascular events reporting rate in patients who receive the 1st dose of Gilenya®. In addition, two clinical studies showed an increase in the incidence of bradycardia after the 1st dose of Gilenya® administration and in both studies the incidence of bradycardia was higher for patients receiving higher doses of Gilenya®.

Considerations that should be taken by health care professionals:

1. **The use of Gilenya® should be contraindicated in patients with:**
   a. Recent (within the last 6 months) occurrenceof: myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or Class III/IV heart failure.
   b. History or presence of Mobitz Type II 2nd degree or 3rd degree AV block or sick sinus syndrome, unless patient has a pacemaker
   c. Baseline QTc interval ≥500 ms
   d. Treatment with Class Ia or Class III anti-arrhythmic drugs
2. **First dose monitoring should include the followings :**
   a. Observe all patients for signs and symptoms of bradycardia for at least after first dose with hourly pulse and blood pressure measurement.Obtai Electrocardiogram(ECG) prior to dosing and at the end of the observation period
   b. Patients who develop a heart rate <45 bpm, or a new onset 2nd degree orhigher atrioventricular block should be monitored until resolution of the finding. Patientsat lowest post-dose heart rate at the end of the observation period should be monitored until heart rate increases.
   c. In patients experiencing symptomatic bradycardia, begin continuous ECG monitoring until the symptoms have resolved; if pharmacological intervention is required to treat bradycardia, continuous ECG monitoring should continue overnight in a medical facility, and first-dose monitoring procedures should be repeated for the second dose.
   d. Patients at higher risk of symptomatic bradycardia or heart block because of a coexisting medical condition or certain concomitant medications should be observed overnight with continuous ECG monitoring.

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In This Issue

WARNING

Saudi Food and Drug Authority (SFDA) PRESS RELEASE- Use of Dasatinib (Sprycel®) and risk of Pulmonary arterial hypertension (PAH).

By: Ali Y. Alshahrani, B. Pharm

The Saudi Food and Drug Authority (SFDA) would like to provide all health care professionals with important safety information about the potential increase in the risk of pulmonary arterial hypertension (PAH) with use of dasatinib (Sprycel®).

Sprycel® is an oral medication approved in Saudi Arabia for the treatment of adults who newly diagnosed with Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase, adults with chronic, accelerated, or myeloid or lymphoid blast phase Ph+CML whom no longer benefit from or did not tolerate other treatments including imatinib and for the treatment of adults with Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL) whom no longer benefit from or did not tolerate other treatments.1

The evaluation was included published observational study and safety signals detection of WHO adverse drug reaction database [Vigibase®].

An observational study aimed to investigate the risk factors and management and outcome of pleural effusion associated with dasatinib therapy was evaluated. This study included 138 patients, the median time receiving dasatinib therapy was 42 weeks, pleural effusion occurred in 48 patients. In 18 patients with pleural effusion a statistical significant increase in the right ventricular systolic pressure (RVSP) was observed at the onset of pleural effusion when compared to the baseline (P=0.0014). RVSP is considered a noninvasive surrogate marker of pulmonary artery pressure.2

Vigibase® data mining was performed and 46 case reports of pulmonary hypertension (PH) with use of dasatinib were retrieved. Of these 46 cases, 30 cases were reported as pulmonary hypertension and 16 cases as pulmonary arterial hypertension (PAH).

After reviewing data from observational study and safety signals detection of Vigibase® with respect to the risk of pulmonary arterial hypertension in patients using dasatinib, we concluded that the use of dasatinib have an association with an increased risk of PAH which need some considerations to be taken by healthcare professionals before dasatinib therapy initiation.

Considerations that should be taken by health care professionals:

1. Patients should be evaluated for signs and symptoms of underlying cardiopulmonary disease before starting dasatinib.
2. An echocardiography should be performed at treatment initiation in every patient presenting symptoms of cardiac disease and considered in patients with risk factors for cardiac or pulmonary disease.
3. Patients who develop dyspnea and fatigue after initiation of dasatinib should be evaluated for common etiologies (e.g. pleural effusion, pulmonary edema, anemia, lung infiltration).
4. During the evaluation process, guidelines for non-hematologic adverse reactions should be followed. If the adverse reaction is severe, treatment must be withheld until the event has resolved or improved.
5. If no alternative diagnosis is found, a diagnosis of PAH should be considered. The diagnostic approach for PAH should follow standard practice guidelines.
6. If PAH is confirmed, dasatinib should be permanently discontinued. Follow-up of patients diagnosed with PAH should follow standard practice guidelines.3-6

LABEL UPDATE

Use of Fluconazole during pregnancy and the Risk of birth defects.

By : By: Naser A. Aljaser, B. pharm, MSc

Although there is no strong evidence of the association between birth defects and using fluconazole during pregnancy, many cases were reported in the medical literature. Fluconazole is used to treat serious fungal infections, including yeast infections of the vagina, mouth, throat, esophagus and other organs. Furthermore, it is used to treat specific diseases such as meningitis. using fluconazole during pregnancy is occasionally prescribed as a treatment for vaginal fungal infection. In addition, the US Food and Drug Administration FDA has released a safety communication regarding the risk of using fluconazole during pregnancy. It has been found that fluconazole might be associated with higher risk of birth defect to the fetus.

Literately, birth defects are not associated with lower doses of fluconazole. A cohort study was conducted by Nørgaard et al to investigate the association of using Fluconazole during pregnancy and the risk of congenital malformation. The study recruited 1079 participants, and found that there was no significant risk of congenital malformation associated with using fluconazole.1 Vaginal fungal infections are usually treated with small doses of fluconazole; however, in some cases higher doses may

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be indicated to treat serious infections. This may lead to serious birth defects such as; short broad head features, abnormal looking face and oral cleft. Fluconazole is considered by the US FDA as a category C, so there are important precautions that should be taken into account when prescribing fluconazole to pregnant women. For example, health care providers should avoid using high doses (400-800 mg/day) during pregnancy, unless the benefits outweigh the risk. Furthermore, patients should not take fluconazole unless advised by their physician.

2 In addition, the Saudi Food and Drug Authority has requested a further labeling update to involve the teratogenic effects of using fluconazole during pregnancy.

References:

1. Nørgaard M, Pedersen L, Gislum M, et al. Maternal use of fluconazole and risk of congenital malformations:

   a.Danish population-based cohort study. Journal of antimicrobial chemotherapy. 2008;62(1):172-176.
2. FDA Drug Safety Communication:Use of long-term, high-dose Diflucan (fluconazole) during pregnancy may be associate with birth defects in infants. 2011; http://www.fda.gov/Drugs/DrugSafety/ucm266030.htm#data. Accessed 5/12/2012.

LABEL UPDATE

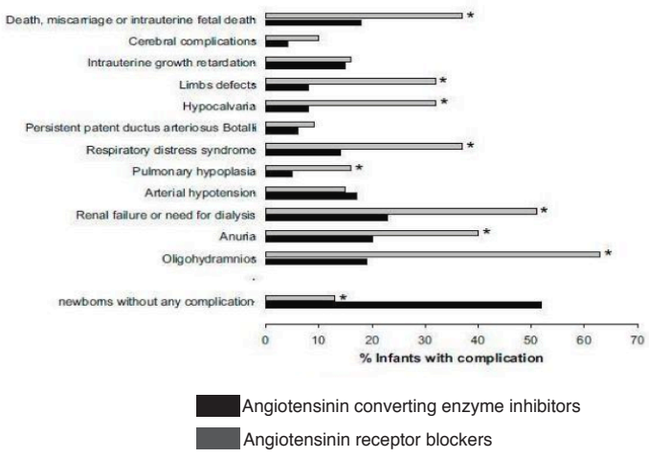
Angiotensin converting enzyme inhibitors (ACEIs) and angiotensin receptor blockers (ARBs) use during pregnancy.

By : Mubarak S. Alshahrani, B. Pharm, MSc

Despite warnings related to the use of angiotensin converting enzyme inhibitors (ACEIs) and angiotensin receptor blockers (ARBs) during pregnancy, a number of case report series and recent meta-analysis have highlighted the issue of using them in childbearing mothers. In addition, the European Medicines Agency (EMA) has considered ACEIs and ARBs use during second and third trimesters of pregnancy as a contraindication.1,2 Furthermore, the issue of prescribing ACEIs and ARBs to childbearing women, though small but apparently present, raises issues of awareness among medical practitioners in relation to the related harmful consequences of such prescribing.

In a recent meta-analysis published in 2012, a total of 186 well-documented cases of prenatal exposure to ACEIs and ARBs were registered in childbearing mothers.

The adverse events, which were 118 well-documented cases reported in the ACEI class, ranged from death or renal failure to pulmonary distress syndrome (figure-1) 3. Also, ARB-related adverse events during pregnancy (e.g. oligohydramnios to limb defects in born children), were well-documented in 68 cases (figure-1). Moreover, the rennin-angiotensin system (RAS) is an important factor in the development of the prenatal renal system and blockade of such system with either ARBs or ACEIs may result in a number of serious adverse events.3 Therefore, the Saudi Food and Drug authority is, indeed, updating the patient's information leaflets (PIL) for a number of ARB medications in the Saudi market with regard to the changes related to the use of these medications in each trimester of pregnancy.



The complications observed following exposure during pregancy to drugs that inhibit the renin-angiotensin system (expressed as percentages).The black bar indicated angiotensin-coverting enzyme inhibitors: gray bar, angiotensin receptor blockers. Denotes a singnificnt difference between the 2 groups *(p<0.05)*.

References:

1. EMA. European Medicines Agency http://www.ema.europa.eu/docs/en_GB/document_library/Referrals_document/Lisonorm_29/WC500007804.pdf. Accessed 17/12/2012, 2012.
2. EMA. European Medicines Agency. http://www.ema.europa.eu/docs/en_GB/document_library/Referrals_document/Cozaar_Comp_30/WC500008584.pdf. Accessed 17/12/2012, 2012.
3. Bullo M, Tschumi S, Bucher BS, Bianchetti MG, Simonetti GD. Pregnancy Outcome Following Exposure to Angiotensin-Converting Enzyme Inhibitors or Angiotensin Receptor AntagonistsNovelty and Significance A Systematic Review. Hypertension. 2012;60(2):444-450.

LABEL UPDATE

The risk of Transmission of Creutzfeldt-Jakob Disease and Blood products.

By: Fawaz Alharbi, B. Pharm, MSc, CPP and Abdullah R. Almatrafi, B.Pharm

The Saudi Food and Drug Authority SFDA has requested manufacturers to add new safety information to precautions and warnings section of the summary of product characteristics (SPC) of blood products. The new precautions highlights the theoretical risk of transmission of Creutzfeldt-Jakob Disease (CJD) by blood products.

Creutzfeldt-Jakob Disease is a disease that could lead to progressive neurodegenerative damage of the brain, which are accompanied with various central nervous system symptoms. There are four types of CJD: sporadic

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(sCJD), variant (vCJD), genetic (gCJD) and iatrogenic (iCJD).

Sporadic CJD is considered the most common form of CJD that characterized by neurological symptoms, followed by rapid progressive course . While patients who have vCJD usually presented with psychiatric or behavioural symptoms that may not be clearly identified.

CJD can be transmitted through exposure to contaminated blood products. The possibility for transmission of infection by vaccines is remained theoretical and there is no evidence for transmission of CJD by these products.3

References:

1. Sikorska B, Knight R, Ironside JW, Liberski PP. Creutzfeldt-Jakob disease. Neurodegenerative Diseases. 2012:76-90.
2. NCJDRSU. THE DIFFERENT TYPES OF HUMAN PRION DISEASE. 2012; http://www.cjd.ed.ac.uk/documents/cjdtype.pdf. Accessed 15/12/2012.
3. Erstad BL. Implications of prion-induced diseases for animal-derived pharmaceutical products. American journal of health-system pharmacy. 2002;59(3):254-260.

GUIDLINE

Guidance for the Registration Requirements for Energy Drinks.

By : Khalid E. Alanazi, BSc., MSc

Energy drinks are those with high caffeine levels which are claimed by manufacturers to give the consumer more 'energy' than a typical soft drink. The Saudi Food and Drug Authority (SFDA) has published a guidance for energy drinks registration. Energy drinks are defined as "carbonated or non carbonated drinks prepared essentially from water, natural carbohydrates, caffeine and other elements such as vitamins, minerals, amino acids and other permitted additive materials. Juices, fruit pulp and plant extract can be added". Energy drinks registration file can be submitted to SFDA by applicants in both hard-copy and soft-copy versions to get marketing approval in Saudi Arabia.

Requirements for labeling information of Energy Drinks:

The following information should appear prominently on product labeling (in Arabic and English) and company websites in which the product is featured.

-Drinking more than two bottles per day may be harmful to your health.

- Energy drinks should not be consumed by pregnant and breastfeeding women.
- Energy drinks should not be consumed by heart hypertensive or diabetic patients.
- Energy drinks should not be consumed by children under 16 years old.
- Energy drinks should not be consumed by athletes during sport activities.
- Not suitable for persons sensitive to caffeine.
- Medical claims and any phrases (e.g. energy drink, power drink, etc) that may support energy drinks consumed are prohibited.
- Maximum daily allowance of energy drinks.

General considerations:

- Producing and importing energy drinks to Saudi Arabia is prohibited, unless approved by SFDA.
- Energy drinks may contain other ingredients, such as glucuronolactone and taurine, and sometimes vitamins, minerals and herbal substances. Such ingredients should be in compliance with the requirements of handling energy drinks (GSO 1926/2009):

Not more than 32 mg of Caffeine, 20 mg of Inositol, 240 mg of Glucuronolactone and 400 mg of Taurine for each 100 ml of energy drinks.

Not more than 0.1ppm of arsenic, 0.2 ppm of Lead, 2.0 ppm of Copper, 2.0 ppm of Zinc, 0.5 ppm of Iron and 250 ppm of Tin for each energy drink.

Energy drinks should be presented with detailed information about their contents.

-Energy drink should be free from doping drugs and other hormones.

References:

1. Health Canada (2010),report by the expert panel on caffeinated energy drinks (online). Available at: http://www.hc-sc.gc.ca/dhp-mps/prodnatur/activit/groupe-expert-panel/report_rapport-eng.php (Accessed 11 December 2012).
2. Saudi food and drug authority (2012),Data Requirements for Energy Drinks Submission ,version 1,2011. Available at: http://www.sfda. gov.sa/Ar/Drug/Topics/Guides/ (Accessed 11 December 2012).
3. Saudi standards, metrology and quality organization, GCC Standardization Organization: The requirements of handling energy drinks - GSO 1926/2009, 2009.

AWARENESS

Health Concerns of Antibacterial / Antimicrobial Soaps.

By : Mobark Aldossari, B.Pharm., MSc.

Over the last ten years antibacterial soaps have been widely used. An antibacterial soap is any cleansing product which contains an active antibacterial ingredient in its formulation. Antibacterial agents have a broad-spectrum properties in killing bacteria, microbes and germs. Therefore, such products are marked as antibacterial, antimicrobial, antiseptic, or germicidal agents.

Triclosan (TCS) and Triclocarban (TCC) are commonly used as antibacterial agents in antibacterial soaps. However, there are some health concerns regarding the overuse of antibacterial soaps.

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One concern is that both TCS amd TCC have almost similar mechanism of action (MOA). Thus, long term use of antibacterial soaps may lead into an increase in bacterial resistance. The other concern is because of TCS can be contaminated by dioxin compounds either due to the ability of TCS to convert to dioxins in the presence of free chlorine ,in tap water and UV light or production of dioxins during TCS syntheses. Dioxins ,especially as 2,3,7,8-tetrachlorodibenzo-p-dioxin (2,3,7,8-TCDD) are considered carcinogenic substances and hormonal disruptors.

Various regulatory authorities worldwide have released information regarding the use of antibacterial soaps. The US Food and Drug Administration FDA has announced that the use of TCS in soaps and body washes has no additional benefits to health over the use of regular soaps.

In addition, the ministry of environment in Germany in 2002 advised consumers against using cleaning agents containing antibacterial ingredients and manufacturers to stop marketing and advertising their antibacterial soaps. Moreover, in 2012 health Canada recalled contaminated foaming hand soaps (0.3% TCS) with (Pseudomonas aeruginosa).

References:

1. Canadian Partnership for Children's Health & Environment, "Should I use antibacterial soaps?", Personal Care Products < http://www.healthyenvironmentforkids.ca/qa/should-i-use-antibacterial-soaps> , (Accessed 2012-12-15).
2. L. McMurry, M. Oethinger, S. Levy. 1998, "Triclosan targets lipid synthesis". Nature. 394:531-532.
3. H. Pitot III, Y. Dragan. Chemical carcinogenesis. "In Casarett & Doull›s Toxicology" (ed. C.D. Klaassen), 6th ed., pp. 201-267, McGraw-Hill, New York, 2001.
4. K. Rule , V. Ebbett , P. Vikesland. 2005," Formation of Chloroform and Chlorinated Organics by Free-Chlorine-Mediated Oxidation of Triclosan". Environ. Sci. Technol.39 : 3176–3185.
5. A. Aiello, E. Larson, E. Levy. 2007 "Consumer Antibacterial Soaps: Effective or Just Risky? ". Clinical infectuse disease . 45: 137-147.
6. Health Canada. "Contaminated Foaming Hand Soap Recalled Due to Dangerous Bacteria".<http://www.hc-sc.gc.ca/ahc-asc/media/advisories-avis/_2012 /2012_151-eng.php > (Accessed 2012-12-15).

GENERAL

Low-Dose Aspirin for Preventing Recurrent Venous Thromboembolism.

By: Mohammed A. Barasain, RPh

The following is a summary of an article published in the New England Journal of Medicine (NEJM) issue of November 22nd of 2012.

Background:

Patients who have had a first episode of unprovoked venous thromboembolism have a high risk of recurrence after anticoagulants are discontinued. Aspirin may be effective in preventing a recurrence of venous thromboembolism.

Methods:

Researchers randomly assigned 822 patients who had completed initial anticoagulant therapy after a first episode of unprovoked venous thromboembolism to receive aspirin, at a dose of 100 mg daily, or placebo for up to 4 years. The primary outcome was a recurrence of venous thromboembolism.

Results:

During a median follow-up period of 37.2 months, venous thromboembolism recurred in 73 of 411 patients assigned to placebo and in 57 of 411 assigned to aspirin (a rate of 6.5% per year vs. 4.8% per year; hazard ratio with aspirin, 0.74; 95% confidence interval [CI], 0.52 to 1.05; P=0.09). Aspirin reduced the rate of the two pre-specified secondary composite outcomes: the rate of venous thromboembolism, myocardial infarction, stroke, or cardiovascular death was reduced by 34% (a rate of 8.0% per year with placebo vs. 5.2% per year with aspirin; hazard ratio with aspirin, 0.66; 95% CI, 0.48 to 0.92; P=0.01), and the rate of venous thromboembolism, myocardial infarction, stroke, major bleeding, or death from any cause was reduced by 33% (hazard ratio, 0.67; 95% CI, 0.49 to 0.91; P=0.01). There was no significant between-group difference in the rates of major or clinically relevant non-major bleeding episodes (rate of 0.6% per year with placebo vs. 1.1% per year with aspirin, P=0.22) or serious adverse events.

Conclusion:

In this study, aspirin, as compared with placebo, did not significantly reduce the rate of recurrence of venous thromboembolism but resulted in a significant reduction in the rate of major vascular events, with improved net clinical benefit. These results substantiate earlier evidence of a therapeutic benefit of aspirin when it is given to patients after initial anticoagulant therapy for a first episode of unprovoked venous thromboembolism.

References:

1. Brighton Ta Fau - Eikelboom JW, Eikelboom Jw Fau - Mann K, Mann K Fau - Mister R, Mister R Fau - Gallus A, Gallus A Fau - Ockelford P, Ockelford P Fau - Gibbs H, et al. Low-dose aspirin for preventing recurrent venous thromboembolism. 20121122 DCOM- 20121205(1533-4406 (Electronic)).

Multivitamins in the Prevention of Cancer in Men (The Physicians' Health Study II) Randomized Controlled Trial.

By: Mohammed A. Barasain, RPh

The following is a summary of an article published in the Journal of American Medical Association (JAMA) issue of November 14th of 2012.

Background:

Multivitamin preparations are the most common dietary supplement, taken by at least one-third of all US adults. Observational studies have not provided evidence regarding associations of multivitamin use with total and site-specific cancer incidence or mortality.

Objectives and Design:

The objective of this trial was to determine whether long-term multivitamin supplementation decreases the risk of total and site-specific cancer events among men. The trial was a large-scale, randomized, double-blind, placebo-controlled trial (Physicians' Health Study II) of 14 641 male US physicians initially aged 50 years or older (mean [SD] age, 64.3 [9.2] years), including 1312 men with a history of cancer at randomization, enrolled in a common multivitamin study that began in 1997 with treatment and follow-up through June 1, 2011.

Intervention:

Daily multivitamin or placebo.

Main Outcome Measures:

Total cancer (excluding non-melanoma skin cancer), with prostate, colorectal, and other site-specific cancers among the secondary end points.

Results:

During a median (interquartile range) follow-up of 11.2 (10.7-13.3) years, there were 2669 men with confirmed cancer, including 1373 cases of prostate cancer and 210 cases of colorectal cancer. Compared with placebo, men taking a daily multivitamin had a statistically significant reduction in the incidence of total cancer (multivitamin and placebo groups, 17.0 and 18.3 events, respectively, per 1000 person-years; hazard ratio [HR], 0.92; 95% CI, 0.86-0.998; P = .04). There was no significant effect of a daily multivitamin on prostate cancer (multivitamin and placebo groups, 9.1 and 9.2 events, respectively, per 1000 person-years; HR, 0.98; 95% CI, 0.88-1.09; P = .76), colorectal cancer (multivitamin and placebo groups, 1.2 and 1.4 events, respectively, per 1000 person-years; HR, 0.89; 95% CI, 0.68-1.17; P = .39), or other site-specific cancers. There was no significant difference in the risk of cancer mortality (multivitamin and placebo groups, 4.9 and 5.6 events, respectively, per 1000 person-years; HR, 0.88; 95% CI, 0.77-1.01; P = .07). Daily multivitamin use was associated with a reduction in total cancer among 1312 men with a baseline history of cancer (HR, 0.73; 95% CI, 0.56-0.96; P = .02), but this did not differ significantly from that among 13 329 men initially without cancer (HR, 0.94; 95% CI, 0.87-1.02; P = .15; P for interaction = .07).

Conclusion:

In this large prevention trial of male physicians, daily multivitamin supplementation modestly but significantly reduced the risk of total cancer.

References:

Gaziano Jm Fau - Sesso HD, Sesso Hd Fau - Christen WG, Christen Wg Fau - Bubes V, Bubes V Fau - Smith JP, Smith Jp Fau - MacFadyen J, MacFadyen J Fau - Schvartz M, et al. Multivitamins in the prevention of cancer in men: the Physicians' Health Study II randomized controlled trial. 20121116 DCOM-20121120(1538-3598 (Electronic)).

Latest Drugs Registered

Generic Name	Trade name	Strength	Price SR	Manufacturer
ACETYLCYSTEINE	FLUIMUCIL GRANULES FOR ORAL SOLUTION	100MG/1GM	4.65	ZAMBON SWITZERLAND LTD
ACETYLCYSTEINE	FLUIMUCIL GRANULES FOR ORAL SOLUTION	200MG/1GM	9.35	ZAMBON SWITZERLAND LTD
AMOXICILLIN, CLAVULANIC ACID	AMOXIPLUS POWDER FOR INJECTION	1.2GM	299.7	ANTIBIOTIC S.E
AMPICILLIN SODIUM	AMPICILLIN POWDER FOR IV AND IM INJECTION	1GM	198.85	ANTIBIOTIC S.E
AMPICILLIN SODIUM	AMPICILLIN POWDER FOR IV AND IM INJECTION	500MG	147.4	ANTIBIOTIC S.E
AMPICILLIN, SALBACTAM	AMPIPLUS POWDER FOR INGECTION	1.5GM	752.5	ANTIBIOTIC S.E
AZITHROMYCIN	ZITHROMAX POWDER FOR IV INFUSION	500 MG	60.25	AMGEN TECHNOLOGY
BISOPROLOL FUMARATE	CARDIOPROL TABLETS	10MG	23.05	The Jordanian Pharmaceutical Manufacturing Medical Equipment Co. Ltd. (JPM)
BISOPROLOL FUMARATE	CARDIOPROL TABLETS	5MG	16.25	The Jordanian Pharmaceutical Manufacturing Medical Equipment Co. Ltd. (JPM)
BRIMONIDINE TARTRATE	BRIMO-P OPHTHALMIC SOLUTION	0.10%	20.65	JAMJOOM PHARMACEUTICALS COMPANY
BUDESONIDE	ENEMACORT TABLET FOR ENEMA	0.02MG/ML	20.95	MEDICAL UNION PHARMACETICALS CO
ESCITALOPRAM OXALATE	ZELAX FILM COATED CAPLET	10MG	79.3	Jordan Sweden Medical and Sterilization Co.
ESCITALOPRAM OXALATE	ZELAX FILM COATED CAPLET	20MG	117.1	Jordan Sweden Medical and Sterilization Co.
MEMANTINE HYDROCHLORIDE	EBIXA FILM COATED TABLETS	20MG	315.45	H. LUNDBECK
MONTELUKAST SODIUM	AIRFAST FILM COATED TABLET	10MG	105.7	TABUK PHARMACEUTICAL MANUFACTURING CO.
MYCOPHENOLATE MOFETIL	MOFETAB FILM COATED TABLET	500 MG	1296.15	TABUK PHARMACEUTICAL MANUFACTURING CO.
PAROXETINE HYDROCHLORIDE	SEROXAT CR TABLETS	12.5MG	72.8	GLAXOSMITHKLINE (GSK)
PAROXETINE HYDROCHLORIDE	SEROXAT CR TABLETS	25MG	96.85	GLAXOSMITHKLINE (GSK)
PYRAZINAMIDE	PYRAZINAMIDE ANTIBIOTICE	500MG	59.85	ANTIBIOTIC S.E
RAMIPRIL	RAMIPRIL SANDOZ FILM COATED TABLETS	10MG	45.5	HEXAL
RAMIPRIL	RAMIPRIL SANDOZ FILM COATED TABLETS	2.5MG	25.5	HEXAL
RAMIPRIL	RAMIPRIL SANDOZ FILM COATED TABLETS	5MG	35.5	HEXAL
RISPERIDONE	SAXID TABLET	2MG	57.8	The Jordanian Pharmaceutical Manufacturing Medical Equipment Co. Ltd. (JPM)
RISPERIDONE	SAXID TABLET	4MG	94.8	The Jordanian Pharmaceutical Manufacturing Medical Equipment Co. Ltd. (JPM)
RIVAROXABAN	XARELTO FILM COATED TABLET	10MG	137.5	BAYER SCHERING PHARMA AG
SAXAGLIPTIN	ONGLYZA TABLET	5 MG	140.35	BRISTOL-MYERS SQUIBB
SECNIDAZOLE	SECNEZOLE TABLETS	500MG	11.7	The Jordanian Pharmaceutical Manufacturing Medical Equipment Co. Ltd. (JPM)
TERBINAFINE HCL	TERBIN CREAM	1%	5.4	GLOBAL NABI
TIZANIDINE	TILAX TABLET	2 MG	16.4	RIYADH PHARMA
TIZANIDINE	TILAX TABLET	4 MG	26.9	RIYADH PHARMA

الملخص العربي:

■ بيان الأعراض الجانبية المتعلقة بالجهاز القلبي بعد الجرعة الأولى من إستخدام مستحضر (Gilenya®).

قامت الهيئة العامة للغذاء والدواء ممثلة في الإدارة التنفيذية للتيقظ وإدارة الأزمات بإصدار نصائح للمختصين الصحيين حول خطر إمكانية حدوث أعراض جانبية على القلب مثل انخفاض عدد نبضات القلب (Bradycardia) و الانسداد الأذيني البطيني (Atrioventricular Block) بعد استخدام الجرعة الأولى من مستحضر (Gilenya®) وهي كالتالي:

١. متابعة ضغط الدم و معدل نبضات القلب للمريض كل ساعة، ولمدة ٦ ساعات بعد تناول الجرعة الأولى من مستحضر (Gilenya®).

٢. متابعة تخطيط القلب (ECG Electrocardiogram) قبل تناول الجرعة الأولى وحتى نهاية فترة المتابعة.

٣. في حال ظهور أعراض جانبية على القلب مثل انخفاض عدد نبضات القلب (Bradycardia) أو الانسداد الأذيني البطيني (Atrioventricular block) يجب متابعة مراقبة هذه الأعراض بشكل مستمر حتى زوالها.

٤. يجب زيادة فترة متابعة مراقبة الأعراض القلبية لدى المرضى الذين لديهم قابلية الإصابة بهذه الأعراض (مثل المرضى الذين لديهم تاريخ مرضي قد يؤدي إلى عدم مقدرتهم على تحمل انخفاض عدد نبضات القلب، أو من لديهم تاريخ مرضي بمرض (QT prolongation) أو المرضى الذين يستخدمون مستحضرات أخرى لتقليل نبضات القلب (Bradycardia) أو لتأخير عملية (Atrioventricular conduction) أو المستحضرات التي قد تسبب (QT prolongation) ، بالإضافة إلى متابعة تخطيط القلب (ECG) بشكل مستمر لمدة ٢٤ ساعة من تناول المستحضر.

■ استعمال الفيتامينات للوقاية من السرطان لدى الرجال

كشفت دراسة علمية نشرت في مجلة الجمعية الطبية الأمريكية (JAMA) بأن الاستعمال المطول لجاميع الفيتامينات (Multivitamins) قد يساعد في الوقاية من بعض أنواع السرطان لدى الرجال وبالأخص سرطان البروستاتا وسرطان القولون.

وقد أجريت الدراسة على 14641 طبيب أمريكي تراوحت أعمارهم بين ٥٠ عاماً وأكثر. وقد وزع المشاركون في الدراسة على مجموعتين، أحدها أعطي عقار وهمي والأخرى قرص يحتوي على مجموعة من الفيتامينات. وقد أثبتت الدراسة في نتائجها بأن الاستخدام اليومي للفيتامينات يقلل من نسبة خطورة حدوث السرطان.

ARABIC SUMMARY:

■ تحذير حول خطر حدوث ارتفاع الضغط الشرياني الرئوي عند استخدام مستحضر داساتينيب، Dasatinib (Sprycel®).

قامت الهيئة العامة للغذاء والدواء ممثلة في الإدارة التنفيذية للتيقظ وإدارة الأزمات بإصدار تعليمات للمختصين الصحيين حول خطر إمكانية حدوث إرتفاع الضغط الشرياني الرئوي (Pulmonary Arterial Hypertension) عند أستخدم مستحضر داسا تينيب Dasatinib المسوق بالاسم التجاري سبرايسل (Sprycel®)ومنها:

١. مراقبة الأعراض والعلامات لمرض إرتفاع الضغط الشرياني الرئوي في المرضى قبل إعطائهم مستحضر داسا تينيب Dasatinib.

٢. يجرى تخطيط القلب (Echocardiography) عند البدء بالمعالجة بمستحضر داسا تينيب Dasatinib لدى المرضى الذين لديهم أمراض قلبية أو لديهم عوامل خطورة لأمراض قلبية أو رئوية.

٣. تقييم الحالات ومعرفة الأسباب للمرضى الذين يعانون من صعوبة التنفس أو الإجهاد بعد البدء باستخدام مستحضر داسا تينيب Dasatinib.

٤. إيقاف مستحضر داسا تينيب Dasatinib عن المرضى في حالة ثبات وجود مرض إرتفاع الضغط الشرياني الرئوي لديهم.

■ تحذير بخصوص منتجات الصابون التي تحوي على مضادات البكتيريا

انتشر استخدام منتجات الصابون المحتوية على مضادات البكتيريا خلال العشر سنوات الماضية. وقد حذرت بعض الأبحاث العلمية من خطورة هذه المنتجات على الصحة العامة. حيث تعتبر مادة التريكلوسان(Triclosan) و التريكلوكاربان(Triclocarban) من أكثر المواد المستخدمة في هذا النوع من المنتجات كمواد مضادة للبكتيريا.

هنالك مخاطر صحية تتعلق باستخدام الصابون المحتوي على المواد المضاده للبكتيريا. فمادة التريكلوسان (Triclosan) و التريكلوكاربان (Triclocarban) قد تزيد من المقاومة البكتيرية لمضادات البكتيريا الموجودة في منتجات الصابون وكذلك بعض المضادات الحيوية بعد مده من الاستخدام المفرط والمتواصل. وهذا التأثير يعزى إلى التشابه في طريقة و مكان العمل في الخلية البكتيرية بين المواد المستخدمة في الصابون المضاد للبكتيريا و المضادات الحيوية. كما توجد أيضاً مخاطر من احتمالية تكون مواد الديوكسين المسرطنة والتي أيضاً تخل بعمل الهرمونات. مواد الديوكسين قد تنتج خلال عملية التصنيع أو من خلال تفاعل التريكلوسان مع الكلورين الحر الموجود في مياه الصنبور في جود الضوء.

كما أصدرت العديد من الهيئات الرقابية بعض النصائح والتحذيرات بخصوص هذه المنتجات. حيث أعلنت إدارة الغذاء والدواء الأمريكية بأنه لا يوجد أي دليل علمي قاطع على أن منتجات الصابون المضادة للبكتيريا ذات قدرة عالية على القضاء على البكتيريا مقارنة بمنتجات الصابون العادية.

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