COUGH AND COLD MEDICATIONS SHOULD NOT BE USED FOR INFANTS AND CHILDREN UNDER 6 YEARS OF AGE

The Saudi Food and Drug Authority (SFDA) advises healthcare professionals and consumers not to use cough and cold medications for treatment of cough and cold symptoms in infants and children under 6 years of age. This Safety communication was based on a review of all available information on safety and effectiveness of using cough and cold medications in this group of patients. These medications affected by this safety communication contain the following active ingredients:

- **Anti-histamines**: Loratadine, Chlorpheniramine, Diphenhydramine, Triprolidine, Doxylamine, Promethazine, Pheniramine, Cetirizine, Desloratadine, Brompheniramine, Dimethindene, Dexchlorpheniramine.
- **Decongestants**: Pseudoephedrine (d-Isoephedrine), Oxymetazoline, Phenylephrine, Ephedrine.
- **Antitussives**: Dextromethorphan.
- **Expectorants**: Guaifenesin, Carbocysteine, Ammonium chloride.

WITHDRAWAL

SFDA WITHDRAWS BUFEXAMAC CONTAINING PRODUCTS

The Saudi Food and Drug Authority (SFDA) has revoked the marketing authorization of Bufexamac-containing products. This withdrawal was based on the Registration Committee decision dated 13/03/2011 for the following reasons:

1. According to current evidence, the effectiveness of bufexamac has not been shown.
2. The risk of developing a contact allergic reaction to bufexamac is high especially in patients with past medical history of eczema and other skin inflammatory diseases.
3. Bufexamac is considered to be ‘sensitizer’ drug which leading to exacerbate the reactions with repeated exposure.
4. The allergic reactions resulted from bufexamac can cause serious adverse events and might lead to hospitalization.

5. The benefits of bufexamac-containing medicines do not outweigh their risks.

Bufexamac is a non-steroidal anti-inflammatory drug (NSAID). It was used to manage the clinical symptoms of inflammation such as; redness, itching and hot skin associated with inflammatory diseases like eczema and dermatitis. Additionally, it could be used to treat hemorrhoids or anal fissures when combined with other therapeutic substances.

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Table 1 Products containing bufexamac that are withdrawn from the Saudi market.

SAFETY OF PIOGLITAZONE - (Actos®)

Recently, the French Medicine Agency has suspended marketing authorization of anti-diabetic drug Pioglitazone (Actos®). French agency action has been announced after the result of recent retrospective cohort study has become available. This study was carried out in France and suggested an excess increase in bladder cancer among pioglitazone and pioglitazone-containing product users, Adjusted Hazard Ration (HR) was (1.22 [95% CI: 1.05-1.43]).

The Study data were retrieved from French health insurance. All included patients were on anti-diabetic medicaments and were followed-up for four consecutive years (2006-2009).

On the other hand, The European Medicines Agency (EMA) has initiated a safety review of the pioglitazone and pioglitazone-containing product since March 2011. In addition, the Committee for Medicinal Products for Human Use (CHMP) is intended to enclose the recent French study recommendations with respect to pioglitazone safety within their next meeting agenda. Furthermore, the United States Food and Drug Administration (US-FDA) is currently reviewing a ten-year epidemiological study concerning the association between the increased risk of bladder cancer and use of pioglitazone.

At this time, SFDA is currently reviewing all data on this safety concern and will release the results of this review when it finished. SFDA advises all healthcare professionals to continue to follow the recommendations in the drug label. In addition, SFDA advises patients not to stop taking pioglitazone (Actos®) and to talk to their doctors and/or pharmacists if they have any concern or contact the SFDA National Drug and Poison Information Center on the internet at http://www.sfda.gov.sa/Ar/Drug/Topics/toxicinfo_dept/
COMPULSIVE DISORDERS CAUSED BY MADOPAR®

The National Drug and Poison Information Center (NDPIC) were asked to evaluate the relationship between Madopar® and the compulsive disorders.

Background:

Madopar® is dopamine agonist tablets containing Levodopa and Benserazide (as benserazide hydrochloride). Used to treat Parkinson’s.1 Parkinson disease (PD) is primarily treated by drugs that restore or improve brain dopaminergic neurotransmission. Brain dopamine also plays a central role in the behavioral reward system of both humans and animals, reinforcing a myriad of both productive and counterproductive behaviors.2 It has been implicated in mediating the reward of gambling behavior and increased libido (including hypersexuality) and Several recent reports have linked PD dopamine agonist to these pathological conditions3.

In August 2005, Netherlands Pharmacovigilance Centre had drawn attention to pathologic compulsive behaviors provoked by drug therapy for Parkinson disease (PD) by article entitled ‘Pergolide and pathologic gambling’. In addition, during the Sifrol (pramipexole) variation procedure in 2005 to add warnings about pathological gambling, France proposed that the need to add pathological gambling as adverse reactions to all dopamine agonists should be considered. Sweden has also communicated this issue on their website in October 2005.1 This Assessment Report considers the need to add pathological gambling and increased libido as adverse reactions to Madopar®.

Regulatory condition of Madopar®:

Madopar® is available in many countries, but not in the United States. The combination of levodopa and benserazide is sold as Prolopa® in Canada. In the U.S., the approved medication of Parkinson’s treatment is called Sinemet, which includes carbidopa rather than benserazide.

By July 2006, the Pathological gambling, increased libido and hypersexuality have been recommended to be add by the European Union’s Pharmacovigilance Working Party for all dopamine agonists, and applies to products containing dopamine agonists for all indications including restless legs syndrome, endocrine disorders, and Parkinson’s disease in Section 4.4 (Special warnings and precautions for use) of the Summary of Product Characteristics (SPCs).1

In DailyMed the Pathological gambling, increased libido and hypersexuality have been added by FDA and applies for the levodopa/ carbidopa tablets in adverse reaction section, but not levodopa/ carbidopa extended release tablets product and some dopamine agonist.

Published literature:

The literature indicates that the risk of pathologic gambling or hypersexuality has been linked to dopamine agonist treatment, but rare cases of pathologic gambling have been associated with carbidopa/levodopa monotherapy as shown below.

Pathologic gambling:

Gschwandtner U et al. report 2 patients with Parkinson’s disease who developed pathological gambling following disease deterioration and a subsequent increase in the dose of dopamine agonist drug treatment. The first patient was taking pergolide and levodopa, and frequently self medicated with additional doses of levodopa. The second patient developed compulsive gambling after taking additional doses of pergolide and levodopa.2

In retrospective database review of 1,884 patients with Parkinson’s disease seen at the Muhammad Ali Parkinson’s disease Centre (Phoenix, AZ, USA) from 1 May 1999 to 30 April 2000, 9 patients with pathological gambling were identified and 8 of the 9 patients were taking levodopa with other dopamine agonist.4

A case report describes the occurrence of pathological gambling in a patient with idiopathic Parkinson’s disease associated with bromocriptine and levodopa treatment.5

Kurlan R. describes 6 patients with Parkinson’s disease who developed severe repetitive behaviour, including 2 patients with pathological gambling after taking levodopa/ carbidopa and dopamine agonist.6

In 2004, article describes 2 cases in which pathological gambling developed after the patients self-initiated increases in dopaminergic drug treatment following an increase in symptoms of Parkinson’s disease. The case was taking levodopa, with other dopamine agonist.7

Dodd et al. encountered 11 patients identified from their Movement Disorder Clinic with idiopathic Parkinson’s disease who had developed pathological gambling. All 11 patients were taking therapeutic doses of a dopamine agonist and 8 patients were also taking levodopa. Pathological gambling developed within 3 months of starting the agonist or after increasing the dose of agonist in 7 patients.8

Bharimal A et al., conclude that dopamine agonist (in combination with levodopa) was associated with a significantly higher prevalence of pathological gambling in Parkinson disease, particularly in patients who were recreational gamblers previously. 9

Increased libido:

Utti et al describe 13 patients identified from their Parkinsonism Clinics who experienced hypersexuality of concern to the patient’s family or a social agency. Of the remaining 11 cases, 8 were considered to have a single ‘presumed causative agent’; levodopa (3 cases), bromocriptine (2 cases), amantidine (1 case), pergolide (1 case) and selegiline (1 case). 3 cases had 2 presumed causative agents; levodopa and bromocriptine (1 case), levodopa and perolide (1 case), and levodopa and amantidine (1 case). The authors state that most patients showed some degree of dose dependency between anti-parkinsonian drugs and hypersexuality. 10

A published article reports psychosexual disorders after long-term treatment with levodopa in 4 patients with Parkinson’s disease, cumulating in psychiatric emergency admission to hospital following an acute episode.11
A case report describes aberrant sexual activity in a patient with Parkinson’s disease while taking carbidopa/levodopa and pergolide. The patient recovered after treatment with clozapine without any change to his antiparkinsonian medication.12

Giovannoni et al describe ‘hedonistic homeostatic dysregulation’ (a neuropsychological behavioural disorder associated with substance misuse and addiction) following dopamine-replacement therapy in patients with Parkinson’s disease. The authors state that these patients take increasing amounts of their dopamine-replacement therapy and may develop a cyclical mood disorder with manic psychosis or hypomania. 2 reports of patients displaying hypersexuality are provided in the article. In both cases, the patients were taking high doses of apomorphine and levodopa.13

A case report describes hypersexuality in a patient with Parkinson’s disease 5 days after standard levodopa was substituted with controlled-release levodopa together with an increase in dose of bromocriptine. Another case report describes the occurrence of increased penile erections and libido in a patient with Parkinson’s disease after the daily dose of cabergoline plus levodopa was increased.14

Klos et al describe pathological hypersexuality in 13 patients with Parkinson’s disease and 2 patients with multiple atrophy syndrome identified from their clinic database. All patients were male and the majority had developed Parkinson’s disease at a relatively young age. The onset of hypersexuality was within 8 months after starting dopamine-agonist therapy in 14 of the 15 cases.

10 patients were taking an agonist plus levodopa: levodopa plus pramipexole (4 cases), levodopa plus pergolide (3 cases), and levodopa plus ropinirole (3 cases); the remaining patient was taking levodopa monotherapy.15

Spontaneous reports of compulsive disorders received in European Union’s:

Pathologic gambling

Reports of pathological gambling in association with dopamine agonists have been received nine in France, 2 in Netherlands, and 6 cases in the UK. 8 Cases were taking an agonist plus levodopa, 5 cases of them were specifically on Madopar®.1

Increased libido:

Reports of increased libido in association with dopamine agonists have been received 10 in France, 1 in Ireland, 14 in UK and Netherlands received 1 report.8 Cases were taking an agonist plus levodopa, 5 cases of them were specifically on Madopar®.1

Conclusions

In general, these data suggest that both pathological gambling and increased libido, including hypersexuality in the majority of reports and articles were in patients receiving a dopamine agonist in combination with levodopa. Although there were no reports of pathological gambling reported in patients taking levodopa monotherapy, levodopa may have contributed to the development of pathological gambling and increased libido in patients receiving combination therapy.

Reference List:

FINGERPRINT SCANNER MACHINES AND PUBLIC SAFETY

The national Drug and Poison information center (NDPIC) at the Saudi Food and Drug Authority (SFDA) frequently receives questions from some Authorities and the public about safety of fingerprint scanner machines. In this article, The NDPIC had reviewed some research articles related to this issue.

Fingerprint Scanner Machines are biometric terminals intended for access control and time & attendance.

The most common methods today for these equipment are optical scanning (by using light sensor system) and capacitance scanning (by using low voltage current). However, according to a research in the health care websites the light and the low voltage electrical current does not have any risk to the public health due to the use of ordinary light or small electric voltage current which will not effect the public health even in case of chronic exposure.

The only question can be raised about these devices and examined in research is that: Can these devices be one way for disease transmission?

According to the information found in public health references, The procedures of fingerprint reading imply physical contact between the finger and the surface of the devices, and successive applicants are aligning their fingers on the same surface area. Transfer of microorganisms from environmental objects to humans has been described in both the healthcare and the community settings, and hands are known to be the main route of transfer.1-3

In 2008 Jacobs and Van Ranst, did an evidence-based systematic review of these devices, their risk for infection transmission, they found that the hygiene was not an issue for biometrics devices and no more harmful than handling a keyboards of public PC, pens or doorknob. These matter can be avoided by applying Simple hygienic measures.4

Purdue University researchers in the US investigated bacterial recovery transferred from three biometric sensors and the survivability of bacteria on the devices. One of the modalities tested were fingerprint device called HandKey III, which typically require sensor contact with the hand or fingers to collect the biometric. Each sensor was tested separately with Staphylococcus aureus and Escherichia coli. Survivability was investigated by sterilizing the sensor surface, applying a known volume of diluted bacterial culture to the sensor and allowing it to dry. Bacteria were recovered at 5, 20, 40 and 60 minutes after drying by touching the contaminated device with a sterile finger cot. At five minutes past the dry time, the survival of the bacteria on the devices had decreased to 15% for the fingerprint sensor. After 20 minutes, the survival rate had approached zero for all three devices, yet even at 60 minutes a small quantity of bacteria were still recoverable.5

The Researcher advice those people how are still anxious about touching surfaces in public places is that it is best to wash your hands with soap and warm water on a regular basis. This will remove the majority of bacteria from the surface of the hand.5

NDPIC RECOMMENDATIONS:

Most of the accessible studies show that The fingerprints devices used are not really major risk factors for infection transmission and can be avoided by applying simple hygienic procedures. On this basis of the display information, We did not find that the exposure to such devices represent any real danger to public health and it can be used.

References:


NO RISK OF CANCER WITH ANGIOTENSSIN-RECEPTOR BLOCKERS (ARBs)

The U.S Food and Drug Administration (FDA), the counterpart for Saudi Food and Drug Authority (SFDA), has reviewed thoroughly the recent literature reports that discuss the risk of cancer associated with use of angiotensin receptor blockers (ARBs). The US-FDA concluded that there was no association between using ARBs and developing cancer.

The US-FDA decision was based on reviewing of meta-analysis of 31 randomized clinical trials which involved 156,000 patients on average who were followed-up for 39 months. This meta-analysis was initiated by US-FDA in order to evaluate the link between patients who had taken ARBs and the risk of cancer compared to patients who had not taken ARBs. The relative risk (RR) of cancer incidents in patients who had taken ARBs was 0.99 (95% confidence interval 0.92 -1.06). In addition to FDA meta-analysis, there were three recent published studies (two meta-analyses and one cohort study) have yielded similar conclusion which indicate that there is no association between using ARBs and cancer development. ARBs is used to control blood pressure and to treat diabetic nephropathy and congestive heart failure.
SAUDI VIGILANCE: THE SUCCESS STORY

The National Pharmacovigilance and Drug Safety Centre (NPC) was officially started in March 2009. The main objectives of NPC are:
1- Early detection of adverse drug reactions.
2- Detection if there is increasing in frequency of (known) adverse reaction.
3- Identification of risk factors and possible mechanisms underlying adverse reactions.
4- Estimation of quantitative aspects of benefit/risk analysis and dissemination of information needed to improve drug prescribing and regulation.
5- Prevention of adverse drug reactions.
6- Drug quality surveillance.
7- Encouraging rational and safe use of drugs.
8- Communication with international institutions working in pharmacovigilance.

Nowadays, there are many medications with multiple indications and consequently multiple risks. Prevention and treatment of diseases are priorities in providing good healthcare system, but a new challenge had emerged which is preventing and treatment of drug related diseases i.e. Adverse Drug Reactions (ADRs)

ADRs are a serious problem and ranked fourth to sixth leading cause of death in the United States of America (USA).1 The percentage of hospital admissions due to ADRs in some countries is about or more than 10%.1 Moreover, treating ADRs imposes a financial burden on healthcare system, as the expenditure for management of drug related harms may represent up to 10-20% of total hospital budget.2 Fortunately, most of these unintended harms are preventable by effective pharmacovigilance system.

The NPC has received around 1500 reports between Oct 2009 to May 2011, and the majority of these were ADRs (no=1267, 85%) (table 1). NPC receives reports from different sources such as public, healthcare professionals and Marketing Authorization Holders (MHAs). Most of reports received by NPC were submitted by MHAs (figure 1). The percentage of serious cases of ADRs was 39 % (figure 2). Anti-infective agents were accounted in the vast majority of cases (figure 3). Skin and subcutaneous tissue disorders system organ class was the most affected system by ADRs in Saudi Pharmcovigilance System Database (figure 4).

As part of NPC strategy to disseminate information about medication safety and enhancing the reporting culture in Saudi health setting, NPC has conducted several workshops in more than 45 healthcare facilities in different regions of Saudi Arabia (figure 5). Furthermore, to facilitate reporting and communication between hospitals and NPC, more than 60 coordinators have recruited.

References:
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المخصر العربي:

لا يتم استخدام نظام الصيد العضوي في الأجهزة المحتوية على بوفيكاماك (Budesonide) أو دروكساك (Droloxacin) للأشخاص الذين يعانون من التحسس الجلدي الشديد أو مرضى الأورام المعدة. يجب على الأطباء核查 جميع الأدوية المعدة المحتوية على بوفيكاماك قبل استخدامها. 

أي شكل من أشكال التحسس المطرد يمكن أن يتسبب في إلغاء استخدام الأدوية المعدة المحتوية على بوفيكاماك.

阿拉伯语摘要:

使用Budesonide & Droloxacin

本研究旨在评估Budesonide和Droloxacin在未经过皮肤检查的患者中的使用情况，并识别可能出现的皮肤问题。研究发现，某些患者在使用这两种药物后出现了皮肤反应，包括皮疹和皮肤刺激。

本研究强调了在使用这两种药物前，必须进行皮肤试验，以确保患者对其没有过敏反应。如果患者对这两种药物中有任何一种出现过敏反应，应立即停止使用，并寻求医生的帮助。

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Visit the Saudi Food & Drug Authority's website: www.sfd.gov.sa/drug

To contact the Saudi Drug Bulletin: assultan@sfd.gov.sa

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