REGULATORY

Potential Signals of Serious Risks/New Safety Information Identified by the Adverse Event Reporting System (AERS) between October - December 2010

The table below lists the names of products and potential signals of serious risks/new safety information that were identified for these products during the period October-December 2010 in the AERS database. The appearance of a drug on this list does not mean that FDA has concluded that the drug has the listed risk. It means that FDA has identified a ***potential safety issue***, but does not mean that FDA has identified a causal relationship between the drug and the listed risk. If after further evaluation the FDA determines that the drug is associated with the risk, it may take a variety of actions including requiring changes to the labeling of the drug, requiring development of a Risk Evaluation and Mitigation Strategy (REMS), or gathering additional data to better characterize risk.

Product Name: Active Ingredient *or* Product Class (uses)	**Potential Signal of a Serious Risk / New Safety Information**	**Additional Information (as of February 15, 2011)**
Asenapine maleate (Schizophrenia/Bipolar Disorder)	Hypersensitivity	FDA is continuing to evaluate this issue to determine the need for any regulatory action.
Dronedarone HCl (cardiac arrhythmias)	Liver failure	FDA Drug Safety Communication. The Warnings and Precautions and Adverse Reactions sections of the labeling for Multaq were updated February 11, 2011, to include liver failure. Dronedarone HCl (Multaq) Labeling approved February 11, 2011 (PDF - 198KB)
Fenofibrate products (Hypolipidemic agent)	Paradoxical decrease in HDL	FDA is continuing to evaluate this issue to determine the need for any regulatory action.
Golimumab (immunosuppressive drug used for RA, etc)	Hypersensitivity reactions and anaphylaxis	FDA is continuing to evaluate these issues to determine the need for any regulatory action.
Ibuprofen lysine (NSAID)	Serious skin reactions (in pediatric patients)	FDA is continuing to evaluate this issue to determine the need for any regulatory action.
Morphine sulfate; Naltrexone HCl (opioid analgesic)	Withdrawal symptoms (not with misuse)	FDA is continuing to evaluate this issue to determine the need for any regulatory action.
Oxycodone HCl ; new controlled-release tablets (opioid)	Choking and gastrointestinal obstruction	FDA is continuing to evaluate these issues to determine the need for any regulatory action.
Regadenoson (pharmacologic stress agent for radionuclide myocardial perfusion imaging)	QT prolongation	FDA is continuing to evaluate this issue to determine the need for any regulatory action.
Sevelamer HCl (to prevent hyperphosphatemia in patients with CRF)	Choking (esophageal obstruction)	FDA is continuing to evaluate this issue to determine the need for any regulatory action.

Reference : Potential Signals of Serious Risks/New Safety Information Identified by the Adverse Event Reporting System (AERS) between October - December 201[Cited 2010 July 15] Available From http://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/surveillance/adversedrugeffects/ucm249657.htm

Examples of sound-alike and/or look-alike drug name pairs in international markets

The existence of confusing drug names is one of the most common causes of medication error and is of concern worldwide. With tens of thousands of drugs currently on the market, the potential for error due to confusing drug names is significant. This includes non-proprietary names and proprietary (brand or trademarked) names. Many drug names look or sound like other drug names. Contributing to this confusion are illegible handwriting, incomplete knowledge of drug names, newly available products, similar packaging or labeling, similar clinical use, similar strengths, dosage forms, frequency of administration, and the failure of manufacturers and regulatory authorities to recognize the potential for error and to conduct rigorous risk assessments, both for non-proprietary and brand names, prior to approving new product names

The following table includes examples of name pairs that have been confused in several countries around the world.

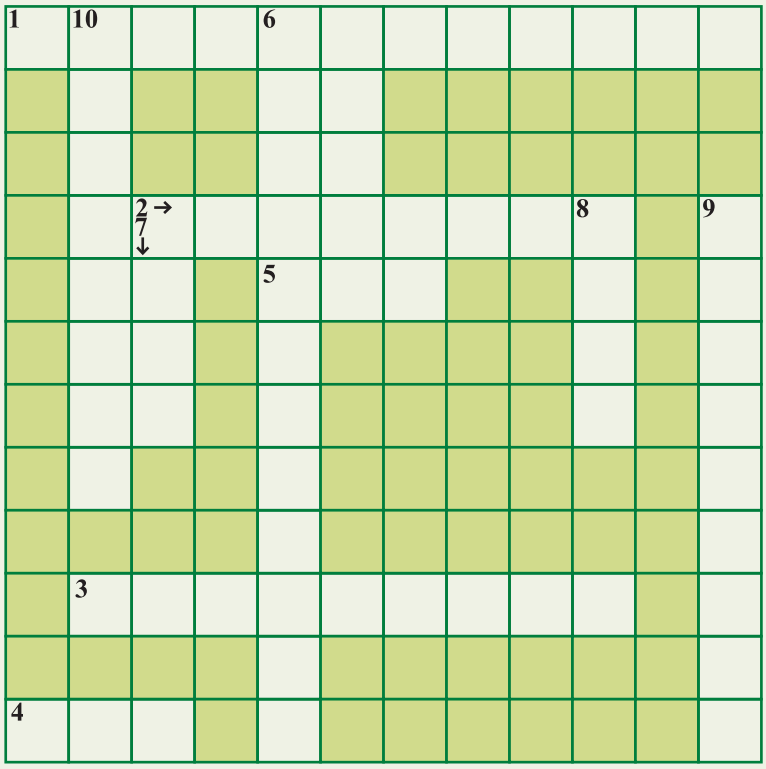
Brand name **(Non-proprietary name)**	***Brand name*** **(Non-proprietary name)**
Avanza **(mirtazapine)**	*Avandia* **(rosiglitazone)**
Losec **(omeprazole)**	*Lasix* **(frusemide)**
Quelicin **(succinilcolina)**	*Keflin* **(cefalotina)**
Celebrex **(celecoxib)**	*Cerebyx* **(fosphenytoin)**
fluoxétine	*Fluvoxamine*
Reminyl **(galantamine hydrobromide)**	*Amarel* **(glimepiride)**
morphine	**hydromorphone**
Diamox **(acetazolamide)**	*Zimox* **(amoxicillin)**
Flomax **(morniflumato)**	*Volmax* **(salbutamol sulphate)**
Almarl **(arotinolol)**	*Amaryl* **(glimepiride)**
Taxotere **(docetaxel)**	*Taxol* **(paclitaxel)**
Dianben **(metformin)**	*Diovan* **(valsartan)**
Ecazide **(captopril/hydrochlorothiazide)**	*Eskazine* **(trifluoperazine)**
Avastin **(bevacizumab)**	*Avaxim* **(hepatitis A vaccine)**
Lantus **(insulin glargine)**	*Lanvis* **(toguanine)**

Reference :

Look alike, sound alike Medications Names [Cited 2011 July 15]. Available from http://www.ccforpatientsafety.org/common/pdfs/fpdf/Presskit/PS-Solution1.pdf

Crosswords 1

Dr Sharmada Nerlekar (Assoc Prof, Dept of Pharmacology)



ACROSS

1. This oral antifungal is known to produce photodermatitis (12)
2. Heparin is known to cause this dermatological toxicity (8)
3. Phenylbutazone commonly causes this adverse effect on the skin (9)
4. An AKT drug causing lichenoid skin eruptions (3)
5. Barbiturates have a propensity to produce this syndrome (3)

DOWN

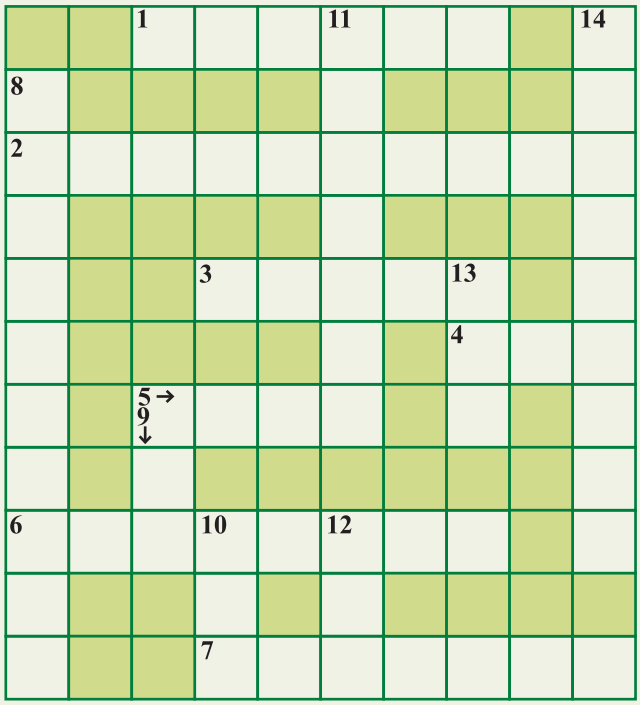
6. Apart from Phenytoin this antiepileptic can also cause Stevens-Johnson syndrome (12)
7. Iodides can produce this dermatological adverse reaction (4)
8. Hyperpigmentation is often due to this hormone (4)
9. Fixed drug eruptions are due to this ACE inhibitor in particular (9)
10. This AKT drug can skin rashes, orange sweat and cloth staining (8)

ANSWERS

1.Griseofulvin 2.Alopecia 3.Urticaria 4.PAS 5.SLE 6.Ethosuximide 7.Acne 8.ACTH 9.Captopril 10.Rifampin

Crosswords 2

Dr Abhilasha Rashmi (Assist Prof)*, Dr Girish Joshi (Assoc Prof)* ; *Dept. of Pharmacology



ACROSS

1. Deficiency of this vitamin manifests as Diarrhoea Dermatitis and Dementia. (6)
2. Livedo reticularis is the characteristic side effect of this anti-parkinsonian drug (10)
3. Drugs involved in acute phototoxic reactions caused by UV Rays are …….cyclines (5)
4. Severe form of Stevens Johnson syndrome with >30% involvement of body surface area, also called Lyell's syndrome (3).
5. Highest incidence of photosensitivity among quinolones is seen with ……floxacin (4)
6. Repeated large amount of topical application of steroids can lead to …….. syndrome (8)
7. ……. eruptions are the characteristic feature of acute barbiturate poisoning (7)

DOWN

8. Rapid IV injection of this antibacterial agent causes intense flushing due to histamine release known as "Red man syndrome" (10)
9. Hypersensitivity reactions to sulfa drugs can lead to this life threatening skin conditions in which epidermis separates from dermis (3)
10. Redness, warmth and swelling are common side effects with this vaccine against Haemophilus *influenzae* type B (3)
11. This crude preparation, indicated for treatment of Psoriasis, exerts a phototoxic reaction on skin when exposed to UV-A rays (7)
12. Alopecia and dermatitis are the major dermatological ADRs seen with CHOP regimen used for treatment of this cancer (3)
13. Allergic reactions are common with this equine antiserum against Tetanus (3)
14. This Vitamin A derivative, used for treatment of acne, should not be applied together with Benzoyl peroxide (9)

ANSWERS

Across : 1. Niacin 2.Amantadine 3.Tetra 4.TEN (Toxic Epidermal Necrolysis) 5.Spar 6.Cushing's 7.Bullous

Down : 8. Vancomycin 9. SJS (Stevens Johnson Syndrome) 10. HIB (Hemophilus Influenzae B) 11. Coaltar 12. NHL (Non Hodgkin's Lymphoma) 13. ATS (Anti Tetanus Serum) 14. Tretinoin

The bulletin was inaugurated by Dr Y K Gupta, National Coordinator, Pharmacovigilance Programme Of India at the 17th Annual Meeting of SRS. Other dignitaries present on the dais (from left to right) were Dr Rahul Mayekar (AP, Obs and Gynae), Dr Sudhir Pawar (HOD, Pharmacology), Dr Y K Gupta, Dr Sandhya Kamat (Dean, LTMMC & LTMGH), Dr N S Laud (renowned Senior Orthopedician) and Dr Mohan Joshi (In-Charge - Gastroenterology Surgical Services).

Dr Sudhir Pawar presenting a memento to Dr Y K Gupta as a token of our appreciation

We would like to request all the departments to contribute in ADR reporting.
Please feel free to contact us for the same.

Names	Extension No.	Email
Dr Sudhir Pawar	3162	dr.sudhirpawar@gmail.com
Dr Neha Kadhe	3206	nehakadhe@yahoo.com
Dr Manjari Advani	3205	manjari.advani@gmail.com
Dr Jaisen Lokhande	3164	dr_jaisen@yahoo.co.in
Dr Akshata Khanvilkar	3204	akshatakhanvilkar@gmail.com
Dr Pooja Joshi	3204	pooja.zoshi@gmail.com
Dr Sachin Ambirwar	3024	ambirwarsachin@gmail.com

Address for correspondence :
Department of Pharmacology, College Building, LTMMC & LTMGH, Sion, Mumbai - 400022.