PharmWatch

For Current Pharmacovigilance News

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PHARMACOVIGILANCE

Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug related problems (*WHO definition*).

The Ministry of Health is actively involved in ensuring the efficacy and safety of all pharmaceuticals. Physicians, pharmacists, patients and other stakeholders are encouraged to report any efficacy and safety issues identified with all pharmaceuticals.

MINISTRY OF HEALTH STANDARDS AND REGULATION DIVISION /UNIVERSITY OF THE WEST INDIES PHARMACOLOGY SECTION NEWS

Therapeutic Equivalence

The FDA criteria for Therapeutic Equivalence:

The Generic drug substitute must:

- Be chemically equivalent
- Be bioequivalent
- Be proven to have the same safety profile
- Meet the same batch-to-batch requirements for strength, purity and quality
- Be manufactured under the same strict good manufacturing practice regulations as the branded pharmaceutical.

For more information, go to: http://www.fda.gov/cder/orange/obannual.pdf

Ensuring Quality of Generic Drugs

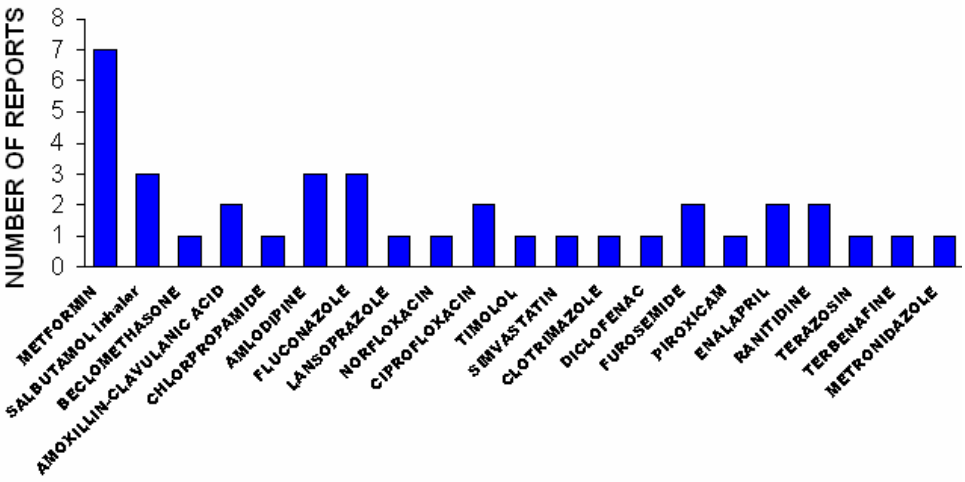

Figure 1. Survey of physicians completed in December 2005. Physicians were asked to indicate any clinical complications with generics that occurred in the past year that they believe would not have occurred if they had used the corresponding innovator drug. The graph shows the drugs that were reported by responders verses number of reports.

Dr. M. Gossell-Williams

Generics have made a significant impact in the provision of better healthcare. A 2002 survey conducted in USA reported that nearly a quarter (24 percent) of the survey respondents said they have not been able to afford a prescription medication when there was no generic available.

Jamaica's drug policy allows generic substitution except in instances such as where patient control may be lost, where the therapeutic index of the drug is narrow or where the physician specifically indicates no substitution.

In a recent survey of 60 physicians island-wide it was found that although physicians were willing to prescribe generic drugs, 20 were able to list generics that were associated with clinical complications, including failure of therapy, hospitalization and requiring a change of prescription (Figure 1).

It is the aim of the MOH to ensure that all drugs available satisfy therapeutic standards. Physicians, pharmacists, patients and all other stakeholders therefore must play an active role in drug monitoring programmes. Pharmacovigilance is everyone's responsibility.

REPORT ALL ADVERSE DRUG REACTION TO THE MINISTRY OF HEALTH, STANDARDS AND REGULATIONS DIVISION, 2-4 KING STREET, KINGSTON

SPECIAL REPORT

Fuzeon®

Active Ingredient: Enfuvirtide
Other Names:T 20
Manufacturer: Hoffmann La-Roche Limited
Therapeutic indication: Antiviral agent indicated for treatment of HIV-1 infection in combination with other anti-retroviral agents.
Mechanism of Action: First member of the therapeutic class called *fusion inhibitors*. It is an inhibitor of the structural rearrangement of HIV-1 gp41 that functions by specifically binding to this virus protein extracellularly and thereby blocking the virus from entering the cell.
Protein Binding: 92% protein bound to plasma proteins in HIV infected plasma over a concentration range of 2 to 10mcg/ml.
Vd: 5.5 ± 1.1 L.
Tmax: Not available.
Serum T ½: - 3.8 hours
Metabolism: Catabolism to constituent amino acids.
Excretion: Not available
Dosing-Adults: 90 mg (1ml) twice daily injected subcutaneously into the upper arm, anterior thigh or abdomen.
Dosing – Paediatric: No data are available to establish dose recommendation in children below the age of six. Paediatric 6 – 16 years old the recommended dose is 2 mg/kg twice daily up to a maximum dose of 90 mg bid.
Dosing – Special Population: No dosage adjustment is required for patient with renal impairment with creatinine clearance above 35 ml/min. No data is available for patients with renal impairment with creatinine clearance below 35 ml/min. No data available to establish dosage for patients with hepatic impairment.
Side Effects: Diarrhoea, nausea, fatigue, eosinophilia
Local injection site reaction (98%): pain, erythema, induration, cysts and nodules, pruritis, ecchymosis
Increased rate of bacterial pneumonia.
Hypersensivity reaction,immune mediated reactions
Overdose: No specific antidote -
Treatment of overdose should be consistent with general supportive measures.
Pregnancy and Lactation: No human studies in pregnancy, therefore not recommended.
Drug Interactions: Unlikely to have significant drug interactions with concomitantly administered CYP450 substrates.
Baseline Assessment: CBC/diff, LFTs, CK, electrolytes, glucose, fasting cholesterol profile.
Routine Labs: CBC/diff monthly, CK/LFTs, electrolytes, glucose q3 months.
Dosage Form: Single-use vial: enfuvirtide 108 mg. Reconstitute with 1.1 ml of sterile water for injection. Final concentration 90 mg/ml.
Storage: Store powder for solution at room temperature. The reconstituted solution is stable for 24 hours in the fridge.
Special Instructions: Sterile technique should be employed in the preparation of the solution. It may take up to 45 minutes for the powder to solubilize. It should be brought to room temperature before using. Injection sites should be rotated. Massage area after injection to reduce pain. Monitor carefully for local infection or cellulites.

Products Registered by the Pharmaceutical & Regulatory Affairs Dept. for January – March 2006

Apotex Inc., Canada
Apo-Cefadroxil 500mg Capsules
Bristol Myers Squibb, USA
Baraclude Oral Solution 0.05 mg/ml (entecavir)
Baraclude 0.5 mg Tablets
Baraclude 1 mg Tablets
Cardinal Health, Argentina
Phillips Gel Capsules 100 mg (sodium docusate)
Carlisle Lab. Ltd., Barbados
Micospec BV Cream
Cipla Ltd., India
Trycip Injection (diminazene, phenazone) (veterinary med.)
RepeZe Oral Paste (clenbuterol Hcl) (veterinary med.)
Cosme Pharm, India
Metoclopramide 5 mg/ml; 10 ml vial
Etamsylate 250 mg/2ml injection
Country Life, USA
L-Arginine/ L-Ornithine 1000 mg Capsules
Dabur India Ltd., India
Cytabarine Injection 100 mg/ml
Cytabarine Injection 500 mg/5ml
Cytabarine Injection 1G/10ml
Irinotel Injection 40 mg (irinotecan HCl)
Irinotel Injection 100 mg
Anthracin Injection 10 mg (epirubicin HCl)
Anthracin Injection 50 mg
FDC Ltd., India
Zocon Eye Drops 0.3% w/v(fluconazole)
Federated Pharmaceuticals, Jamaica
Children's Cetamol Liquid SAF (paracetamol)
Children's Cetamol Drops SAF
Children's Cetamol Chewable Tablets
Extra Strength Cetamol Caplets
Children's Cetamol Cold Nightime Liquid (paracetamol, psuedoephedrine, dextromethorphan, diphenhydramine)
Children's Cetamol Cold Daytime Liquid (paracetamo l, pseudoepherine, dextromethorphan)
Hospira Inc. USA for Scios Inc.
Natrecor 1.5 mg vial for injection (nesiritide)
Jamieson Labs Ltd., Canada
Mega Cal Calcium Soft Chews – French Caramel Cream Flavour
Mega Cal Calcium Soft Chews – Swiss Chocolate Flavour

Laboratory Poen, Argentina
Poen Caina Ophthalmic Soln. 0.5 % w/v
(proparacaine Hcl)
Litaka Pharmaceuticals, India
Albendex 100 (albendazole) (veterinary med.)
Litagyl Suspension 125 mg/5ml (metronidazole)
McNeil Consumer and Specialty, USA
Children's Motrin Ibuprofen Oral Suspension 100 mg/5ml Grape Flavour
Meditab Specialties, India
Health 2000 Cefotaxime 1 G Injection
Health 2000 Azithromycin 250 mg Tablets
Merial Inc., USA
Re combitek Canine Parvo + Corona – MLV Vaccine (veterinary med.)
Merk SA de IV
Eutirox 125 mcg Tablets (levothyroxine)
Eutirox 150 mcg Tablets
Eutirox 175 mcg Tablets
Eutirox 200 mcg Tablets
Neon Antibiotics PVT Ltd., India
Altrex 25 mg/ml Injection (methotrexate)
Cyclophosphamide 500 mg vial for Injection
Carbotinol 150 mg/15ml vial for injection (carboplatin)
Carbotinal 450 mg vial for Injection
Cytosar 100 mg/ml Injection
Cyclophosphamide 200 mg vial for Injection
Cyclophosphamide 1 G vial for Injection
Fluonco 250 mg/5ml (fluorouracil)
Bleonco 15 Units vial for Injection (bleomycin sulphate)
Novartis Biociencias, Brazil
Voltaren Aerosol
Novartis Farmaceutica, Mexico
Sandoz Calcium 400 + D
Vifor SA, Switzerland
Ferrum Hausmann Chewable 100mg Tablets (Iron III hydroxide polymaltose complex)
Ferrum Hausmann Chewable Tablets (Iron III hydroxide polymaltose complex 100 mg, folic acid 350 mcg per tablet)

*"**PharmWatch"** is a collaborative effort between the Ministry of Health and Pharmacology Section of the University of the West Indies. **Feedback:** Dr. M. Gossell-Williams927-2216; Mrs. Cynthia Lewis Graham 922-3851; Mrs. Princess Thomas Osbourne: 948-4106*