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P.I.L.L- Pharmacy Information Link Letter

Aga Khan University
Hospital, Nairobi

September 2006

Drug news

- **Withdrawal of Triapin (Ramipril+Felodipine) from Kenyan market**

Sanofi- Aventis are no longer importing the above drug due to problems sourcing it for the Kenyan market. Please change your patients to ramipril and felodipine separately or consider other antihypertensive agents.

- **Glaucoma eye drops**

Recently, a consultant ophthalmologist, Dr. Damji visited the hospital from Canada and donated some eye drops to the hospital. These are available free of charge for all patients. Unfortunately they have a short expiry and we urge you to take this opportunity to assist your patients as soon as possible. The drugs available are :

- 1.Travatan- Travoprost 0.004% eye drops
- 2.Alphagan-Brimonidine 0.15% eye drops
- 3.Lumigan- Bimatoprost 0.03% eye drops

- **NEW**

Sirdalud 2mg and 4mg tablets (tizanidine)

Class

Skeletal Muscle Relaxant, Centrally Acting

Dosage, Adult (usual)

Spasticity, Skeletal: initial, 4 mg/day ORALLY and gradually increase in 2-4 mg increments on an individual basis over 2-4 weeks; maintenance, 8 mg ORALLY every 6-8 hr (max dose 36 mg/day)

Dosage, Pediatric, (usual)

safety and efficacy have not been determined in children

Dose Adjustments:

geriatrics: use with caution in geriatric patients

renal impairment: use with caution in patients with CrCl less than 25 mL/min (clearance may be reduced by 50%)

Monitoring- reduction in pain and muscle spasms, passive limb movement, blood pressure hepatic function (aminotransferase); at baseline, at 1, 3, and 6 months of therapy and periodically thereafter, based on clinical status

Contraindications- hypersensitivity to tizanidine products

Precautions

concomitant use of oral contraceptives (clearance is reduced by approximately 50%)
congestive heart failure or cardiac arrhythmias, hypotension or concurrent antihypertensive medication, liver disease, renal impairment

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Drug News cont.

Adverse Effects

COMMON

Cardiovascular: Hypotension (Mild) (20%)

Gastrointestinal: Constipation (3%), Vomiting (3%), Xerostomia (39%)

Hepatic: Liver function tests abnormal (3%)

Neurologic: Asthenia (25%), Disturbance in speech (3%), Dizziness (12%), Dyskinesia (3%), Somnolence (38%)

Ophthalmic: Amblyopia (3%)

Psychiatric: Nervousness (3%)

Renal: Urinary tract infectious disease (3%)

Respiratory: Pharyngitis (2%)

SERIOUS

Cardiovascular: Angina pectoris (rare), Heart failure (rare), Myocardial infarction (rare), Orthostatic hypotension (infrequent), Phlebitis (rare), Syncope (infrequent)

Dermatologic: Cellulitis (infrequent)

Gastrointestinal: Gastrointestinal hemorrhage (infrequent)

Hematologic: Leukopenia (rare), Thrombocytopenia (rare)

Hepatic: Hepatitis (infrequent)

Respiratory: Pulmonary embolism (rare)

Other: Death (infrequent)

Drug Interactions

Amiodarone (major, theoretical) ,Cimetidine (major, theoretical), Ciprofloxacin (contraindicated, established) ,Ethinyl Estradiol (major, probable) ,Fluvoxamine (contraindicated, established) ,Fosphenytoin (moderate, probable) , Lisinopril (moderate, probable) ,Mestranol (major, probable), Mexiletine (major, theoretical), Norfloxacin (major, theoretical) Phenytoin (moderate, probable) ,Propafenone (major, theoretical) ,Rofecoxib (major, theoretical) ,Ticlopidine (major, theoretical)

Pregnancy Category -C

Breast Feeding- Infant risk cannot be ruled out.

- **NEW**

Terbisil Cream

Contains Terbinafine— generic for Lamisil cream

FDA labeled indications

Onychomycosis

Tinea corporis

Tinea cruris

Tinea pedis

REASON FOR CHANGE	Number of Interventions
1 Change from IV to oral	3
2 Change to formulary drug from non-formulary drug	17
3 Doctor not informed/could not be reached	9
4 Dosage adjustment in liver/renal/weight based	5
5 Dosage high/low	92
6 Drug contraindicated	18
7 Drug missed out on discharge/regimen	8
8 Drug unsafe in pregnancy/breast feeding	13
9 Duration/Frequency/Strength not indicated	43
10 Incorrect frequency	36
11 Other- dose difficult to measure, drug allergy, wrong drug prescribed	58
12 Potential interaction between drugs	3
13 Prescription illegible	1
14 Prescription unclear	6
15 Prescription/dosage illegible	1
16 Therapeutic duplication	42
TOTALS	355

Bowel cleansing oral sodium phosphates

Risk of renal damage

USA. The US FDA has issued an alert that acute phosphate nephropathy, a type of acute renal failure, is a rare but serious adverse event associated with the use of oral sodium phosphates (OSP) for bowel cleansing. According to the Alert, acute phosphate nephropathy has been documented in 21 patients who used an OSP solution and in one patient who used an OSP tablet; older individuals, those with kidney disease or decreased intravascular volume, and those using medicines that affect renal perfusion or function (diuretics, angiotensin converting enzyme (ACE) inhibitors, angiotensin receptor blockers (ARBs), and possibly nonsteroidal anti-inflammatory drugs) are at higher risk of acute phosphate nephropathy.

Reference: FDA Alert. United States Food and Drug Administration, May 2006 <http://www.fda.gov>.

Glucosamine products

86 reports to date in Sweden

Sweden. The Swedish Adverse Drug Reactions Database contains 86 reports of suspected adverse reactions associated with glucosamine products from 2001 until February 2006, according to the Swedish Medical Products Agency. The Agency says that the majority of these cases were reported after 2002. According to the Agency, previously unknown adverse reactions of particular interest included the following: angioedema (n = 2), urticaria (1), colitis (2), gastric/duodenal ulcer (3), oedema/lower limb oedema (3), dizziness (4), arthralgia (2), bronchial asthma/bronchial asthma aggravated (3), diabetes aggravated (2) and hypercholesterolaemia (2). There were also three cases of an increased effect of Vfarfarin during concomitant treatment with glucosamine products. (Reports in WHO database: All reactions - 645).

Reference:

Three year adverse reaction follow-up of glucosamine products as drugs. Swedish Medical Products Agency, 21 April 2006 (<http://www.moa.se>).

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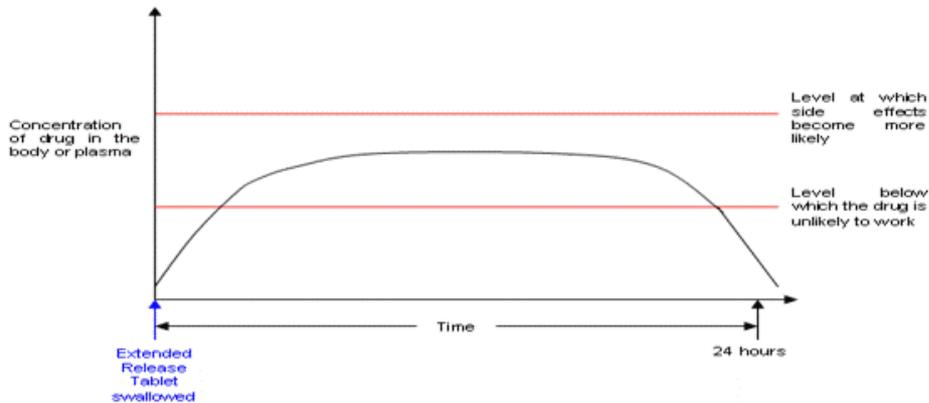
Modified Release formulations

These are frequently identifiable by two letters, such as *m/r*, *LA*, *SA*, *CR*, *XL* or *SR*, or the words 'Retard' or 'Slow' at the end of the name. They are designed to be released gradually over a prolonged period of time, reducing the risk of patients suffering side effects. They are taken just once or twice a day.

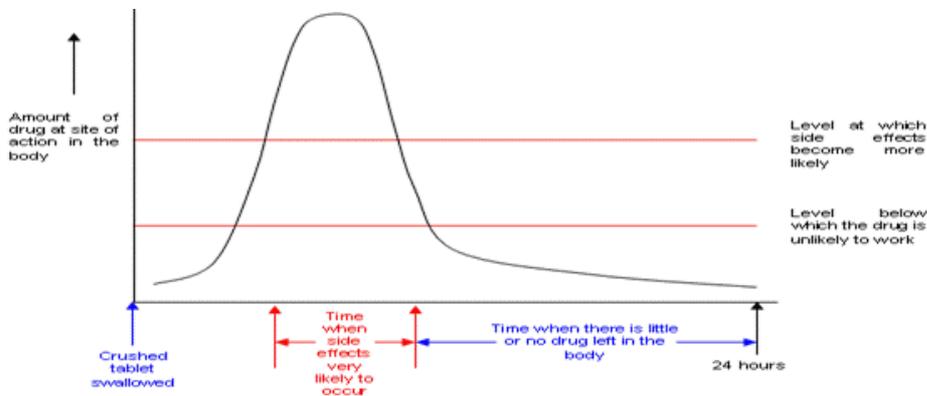
Crushing or opening an extended release formulation may damage the mechanism for slow absorption causing the patient to experience dangerous peaks and subtherapeutic troughs in drug-plasma concentration.

The graphs below show how the concentration of drug in the body or plasma varies for both an extended release preparation taken once daily that is swallowed whole and for one that is crushed or opened.

The first graph relates to an extended release preparation that has not been crushed or opened. It does not sharply peak but gradually increases and plateaus before gradually decreasing without reaching the point at which the patient is likely to suffer side effects.



However, if the medicine is crushed or opened before you swallow it, the graph will look like the one below. You can see that there is a very sharp, high peak soon after taking the medicine, and this is when you are extremely likely to suffer what could be severe side effects. The amount of drug in the body then tails off and there will not be enough in the body for it to work properly.



Enteric Coated and Film coated medicines

These usually have the letters *EN* or *EC* at the end of the name. They are designed to pass from the stomach into the intestine before releasing the active drug. Crushing or opening the medicine will destroy the enteric coating, which could increase the risk of stomach irritation, releasing the drug in the wrong place or reducing its effectiveness.

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