مستشفى الملك فيصل التخصصي ومركز الأبحاث
King Faisal Specialist Hospital & Research Centre
Gen. Org. مؤسسة عامة

Pharmacy Newsletter

King Faisal Specialist Hospital and Research Center - Riyadh

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Prucalopride (Resolor®) Medication Utilization Evaluation Report

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Introduction: Prucalopride (Resolor®) is a serotonin 5-HT_4 receptor agonist, that enhances peristaltic movement, gastric secretions and motility. It was approved by Formulary and Therapeutics Committee (FTC) for the treatment of idiopathic chronic constipation in adult females after failure of at least two laxatives from different classes, at the highest recommended and tolerated doses for at least 6 months. The medication was added to the formulary in January 2014 to be prescribed according to the hospital guideline.

Projected number of patients to be treated as per the requestor: 10 patients per year

Formulary restriction: Surgical oncology physicians for the approved indication

Dosage Form Available at KFSH&RC: 1 mg, 2 mg Oral Tablet

Justification for the MUE: To evaluate the utilization with regards to the approved FTC indications and restrictions. In addition to the high cost of prucalopride compared to other formulary alternatives.

Methodology

Study design: Retrospective MUE study (data collected from electronic chart and paper chart).

Inclusion criteria: Any patient who received one dose or more as an outpatient or inpatient between June 2015–June 2016.

Exclusion criteria: Patients who received it outside the study period.

Sample size: Total of 5 patients, all patients were included.

Summary of MUE Results:

- The actual number of patients who received prucalopride was five patients, while the projected number per year was ten patients at the time of formulary addition
- Total of three patients were male and two were female. The average age of male patients was 73 years, and of females was 65 years
- Only one form B was filled when prucalopride was used for a male patient
- Two of the patients had orders prescribed by surgical oncology consultants, two by intensivists and one by family medicine physicians
- In two cases the approval was obtained from gastroenterology consultants which are not the privileged service to prescribe prucalopride as per the current guidelines and formulary restrictions
- All patients were using other concurrent therapy for treating constipation and some of them were on more than one medication
- One of the patients who received prucalopride had a functional gastrointestinal disorder (achalasia) which is considered one of the contraindications of using this medication
- Three patients received prucalopride for a duration of more than 12 weeks and two patients for less than 4 weeks
- Prucalopride use outcomes were not clearly documented in most patients

Action Plans and Future Recommendations:

- Emphasize on the importance of abiding to prescribing restrictions before dispensing from pharmacy
- Encourage clear documentation

Results Continued on Page 6

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Formulary & Therapeutics Committee Updates

The following are formulary changes by the Formulary & Therapeutics Committee (FTC) from Apr-Jun 2017 meetings. Please refer to the Online Hospital Formulary to check the status of the new medications and details on dosing and uses.

Approved New Formulary Additions

- **Abacavir (Ziagen®) 300 mg tablet and 20 mg/mL oral solution**

  Treatment of HIV infection. Prescribing restricted to adult and pediatric infectious disease consultants and assistant consultants.

- **Aldesleukin (Proleukin®) 22,000,000 IV solution**
- **Sargramostim (Leukine®) 500 mcg injection**
- **Dinutuximab (Unituxin®) 17.5 mg/5 mL IV solution**

  Aldesleukin, dinutuximab, sargramostim combination with isotretinoin indicated for the treatment of pediatric patients with high-risk neuroblastoma stage IV. Prescribing restricted to pediatric hematology/oncology physicians according to approved guidelines and protocol.

- **Dolutegravir (Tivicay®) 50 mg tablet**

  Treatment of HIV infection. Prescribing restricted to adult and pediatric infectious disease consultants and assistant consultants.

- **Elvitegravir, Cobicistat, Tenofovir Alafenamide (Genvoya®) tablet**

  Treatment of HIV infection. Prescribing restricted to adult and pediatric infectious disease consultants and assistant consultants.

- **Emtricitabine, Tenofovir Alafenamide (Descovy®) tablet**

  Treatment of HIV infection. Prescribing restricted to adult and pediatric infectious disease consultants and assistant consultants.

- **Rilpivirine, Emtricitabine, Tenofovir Alafenamide (Odefsey®) tablet**

  Treatment of HIV infection. Prescribing restricted to adult and pediatric infectious disease consultants and assistant consultants.

- **Selexipag (Uptravi®) 200, 400, 600, 800, 1000, 1200, 1400, 1600 mcg tablet**

  Treatment of adult patient with pulmonary arterial hypertension (WHO Group I). Prescribing restricted to Adult Pulmonologists.

Approved New Dosage Form Addition

- **Darunavir (Prezista®) 100 mg/mL oral suspension**

  Treatment of HIV infection. Prescribing restricted to adult and pediatric infectious disease consultants and assistant consultants.

- **Raltegravir (Isentress®) 100 mg granules for oral suspension**

  Treatment of HIV infection. Prescribing restricted to adult and pediatric infectious disease consultants and assistant consultants.

- **Rituximab (MabThera®) 1400 mg subcutaneous injection**

  Treatment of adult patients with Diffuse Large B Cell lymphoma or Follicular Lymphoma as a maintenance therapy.

For more information on the indications, age specifications, doses and guidelines please check the online hospital formulary: http://online.lexi.com/lco/action/home

- **Trastuzumab (Herceptin®) 600 mg subcutaneous injection**

  Treatment of HER2 positive metastatic breast cancer.

New/Updated Guidelines

- **Lenalidomide (Revlimid®) Prescribing Guidelines for the treatment of Multiple Myeloma and Myelodysplastic Syndromes in adult patients**

  New guideline to ensure appropriate use of medication as it is expensive and has a teratogenic risk. The SFDA have mandated a risk management plan (REMS) to be in place.

Approved Indication Deletion

- **Iloprost (Ventavis®) solution for oral inhalation**

  Indication for pulmonary hypertension will be deleted for adult patients and kept for pediatric patients only. Guidelines for adult pulmonary hypertension will be updated accordingly.

Central Policy and Procedures (CPP)

- Parenteral Nutrition and Enteral Feeding in Pediatric Hematopoietic Progenitor Stem Cell (HPC) Transplantation Patients (MCO-CS-PCS-07-032).
- Restricted Formulary Medication (MCO-CS-PCS-07-004)

Approved Drug Sample

- **Granisetron (Sancuso®) transdermal patch**

  Prevention of nausea and vomiting in patients receiving moderately and/or highly emetogenic chemotherapy. Prescribing is restricted to medical oncology consultants. This was approved for a total of 10 patients in KFSHRC Jeddah.

TRAINING AND MENTORSHIP IN PHARMACY PROFESSION

BUILDING AN INTEGRATED MODEL

مستشفى الملك فيصل التخصصي و مركز الأبحاث
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NOVEMBER 1 & 2
2017

KING FAISAL SPECIALIST HOSPITAL AND RESEARCH CENTER RIYADH, SAUDI ARABIA

OBJECTIVES

- Build an integrated and practical model for pharmacy training and mentorship
- Define standards for undergraduate and postgraduate training programs in Saudi Arabia
- Discuss best practice models in pharmacy education and training
- Review local and international practice models in pharmacy training
- Recommend steps on how to build new training programs or refine the existing ones
- Discuss preceptors development programs and staff engagement initiatives

TOPICS

- The impact of structured pharmacy training on overall health care in the kingdom
- Mentorship and pharmacy training
- The key components for successful training programs
- Advancing pharmacy related research
- International and local residency programs
- International and local perspectives on accreditation

WORKSHOPS

- Mentorship
- Pharmacy Residency Programs Local and International Accreditation

TARGET AUDIENCE

- Pharmacists
- Pharmacy trainees and residents
- Academia
- Government personnel
- Pharmacy students
- Pharmacy technicians
- Other healthcare providers

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What is in the News

USFDA Warns Against the Use of Codeine and Tramadol in Children and Breastfeeding Mothers

USFDA has issued new actions limiting the use of tramadol and codeine. Tramadol should not be used to treat pain, and codeine should not be used to treat pain or cough in children younger than 12 years. The mandated changes include a new warning for tramadol against its use in children younger than 18 years to treat pain after tonsillectomy and/or adenoidectomy. Additionally, FDA recommend against codeine and tramadol use in adolescents between 12 and 18 years who are obese or have conditions such as obstructive sleep apnea or compromised respiratory function, that may increase the risk of serious breathing problems. The FDA also warned breastfeeding mothers to avoid using both drugs due to the risk of serious adverse reactions in breastfed infants, such as excess sedation and respiratory depression that could result in death.

Rare Cases of Hypothyroidism Following Iodinated Contrast Media Administration

Health Canada has evaluated the possible association between exposure to iodinated contrast media (ICM) products and development of hypothyroidism in adult and pediatric patients. Ten international cases of hypothyroidism were identified following ICM exposure. However, the majority of the patients were infants. Based on Health Canada review, the potential risk of hypothyroidism following exposure to ICM is rare.

Healthcare professionals are encouraged to monitor the thyroid function in infants exposed to ICM.

Severe Skin Adverse Effects Including Stevens-Johnson Syndrome (SJS) and Toxic Epidermal Necrolysis (TEN) with Darbepoetin Alpha

Health Canada have reported that in some patients Darbepoetin alpha has been associated with severe skin reactions, including life-threatening reactions Stevens-Johnson Syndrome (SJS) and Toxic Epidermal Necrolysis (TEN) which is could be a serious life-threatening condition.

To date, there have been eleven cases of SJS and four cases of TEN reported internationally in patients treated with dabepoetin alpha in the post-marketing setting.

It is recommended for healthcare professionals to:

- Discontinue therapy immediately if a severe skin reaction occurs or SJS/TEN is suspected
- Permanently discontinue if SJS/TEN is confirmed
- Remind patients to discuss any skin reactions and to seek immediate medical attention if they experience any of the SJS/TEN symptoms

All drug safety alerts are communicated to the end-users of concern, as per the IPP MCO-CS-PCS-07-075: Dissemination and Action Related to Drug Safety Alerts at KFSHRC. For more info access IPP via Unified KFSH&RC Portal.

SFDA Reports Cases of Accidental Overdose due to Medication Errors with Levetiracetam (Keppra®) Oral Solution Dosing

The current available formulary product is Keppra® 300 mL (100 mg/mL) bottle that is supplied by the manufacturer with a 10 mL oral syringe; graduated every 0.25 mL, corresponding to 25 mg.

Accidental overdose can occur when inappropriate graduated syringes are supplied with the oral solution, resulting in dosing errors. Additionally, medication errors can also occur due to the misunderstanding of parents and/or caregivers on how to properly measure the dose using an oral syringe.

Levetiracetam overdose often has no symptoms, but may cause somnolence, agitation, depressed level of consciousness, respiratory depression or coma.

Pharmacists should be aware of the recommended size of oral syringes to

supply patients on dispensing:

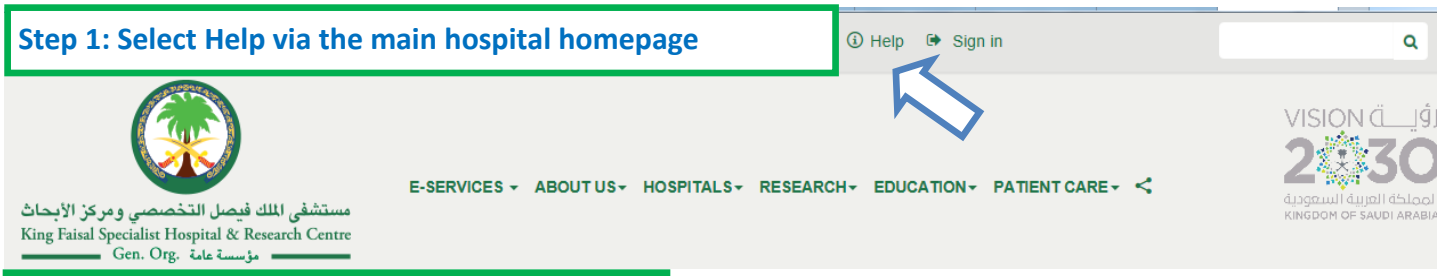
- Infants <6 months: 1 mL syringe
- Infants and Children > 6 months to < 4 years: 3 mL syringe
- Children ≥ 4 years: 10 mL syringe

Physicians and pharmacists are advised to educate patients and/or caregivers on how to measure the prescribed dose and to use the appropriately graduated oral syringe.

Tip of the Issue

How to Access Form A and Form B Through the New KFSH&RC Portal

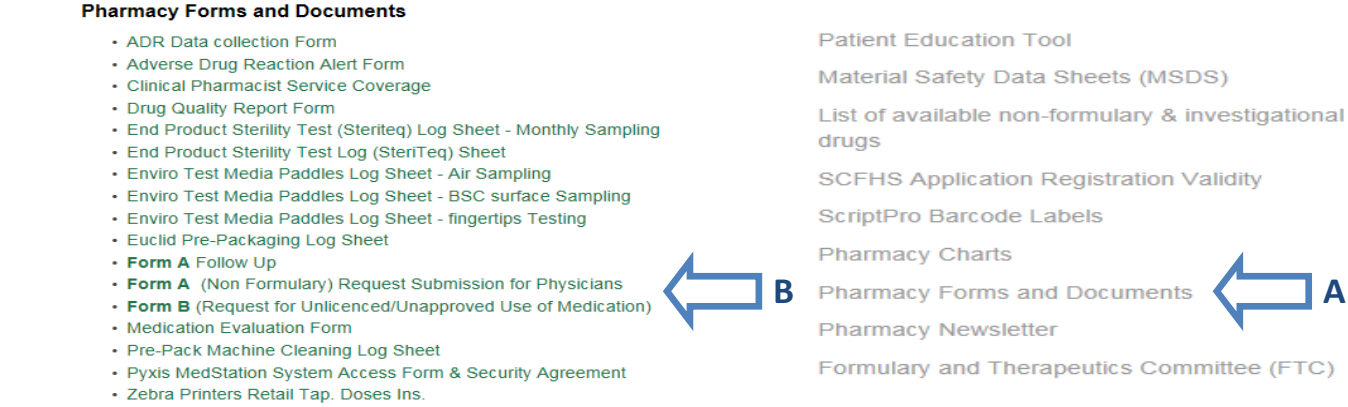
Step 1: Select Help via the main hospital homepage



Step 2: Select Knowledge Base

Step 3: Select Pharmacy—Riyadh

Step 4: Select Pharmacy Forms and Documents



Pharmacy Newsletter

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Continued...

Results

Table 1: Patients Demographics

Demographic		Result (N=5)	%
Male		3	60
Female		2	40
Average age	Male	73	-
	Female	65	-

Table 2: Privileged Service Approval

	Result (N=5)	%
Prescribed by surgical oncology	2	40
Obtained surgical oncology approval		
No:	*3	60
Family medicine	1	-
Critical care medicine	2	-

* 2 approved by gastroenterology consultant (not privileged prescriber)

Table 3: Utilization Stratified by Prescriber Degree

	Result (N=5)	%
Consultant /Associate consultant	5	100

Table 4: Utilization Stratified by Indication

	Result	%
Complies with KFSH&RC indication	2	40
Doesn't comply with KFSH&RC indication (Used for constipation in Males)	3	60

Table 5: Utilization as per Form B Policy

	Result (N=5)	%
Form B filled and approved	1	20

Table 6: Contraindication of using Prucalopride

	Result (N=5)	%
No	4	80
Yes	*1	20

* Patient had structural or functional GIT disorder

Table 7: Treatment Duration

	Result (N=5)	%
<4 weeks	2	40
>12 weeks	3	60

Table 8: Therapy Outcomes

Improvement	Result (N=5)	%
Yes	1	20
No clear documentation	4	80