Benefits still considered to outweigh risks when given short-term and in low doses to treat nausea or vomiting

News about Domperidone in 7/3/2014:

The European Medicines Agency's Pharmacovigilance Risk Assessment Committee(PRAC) has completed a review of domperidone-containing medicines and has recommended changes to their use throughout the European Union (EU), including using these medicines only to relieve symptoms of nausea and vomiting, restricting the dose and adjusting doses carefully by weight where it is licensed in children. Reducing the recommended dose and duration of treatment was considered key to minimising its risks.

Domperidone should no longer be authorised to treat other conditions such as bloating or heartburn. It must not be given to patients with moderate or severe impairment of liver function, or in those who have existing abnormalities of electrical activity in the heart or heart rhythm, or who are at increased risk of such effects. In addition, it must not be used with other medicines that have similar effects on the heart or reduce the breakdown of domperidone in the body (thus increasing the risk of side effects). The product information should be amended appropriately. Products supplying a dose of 20 mg by mouth, and suppositories of 10 or 60 mg are no longer recommended for use and should be withdrawn, as should combination products with cinnarizine (an antihistamine) where available.

The Committee's recommendations follow a careful assessment of all the available evidence on the effectiveness and safety of domperidone, including published studies and reviews, experimental data, reports of side effects, post-marketing studies and other external information and comment. Domperidone was clearly associated with a small increased risk of potentially life-threatening effects on the heart. This was seen particularly in patients older than 60 years, those taking daily doses of more than 30 mg and those taking other medicines that have similar effects on the heart or reduce the breakdown of domperidone in the body. PRACconsidered that reducing the recommended dose and duration of treatment was a particular key to minimising the risks with domperidone.

What MOTILIUM (Domperidone) is used for?

MOTILIUM is used to treat the following conditions in adults:

1- nausea and vomiting
2- Discomfort caused by a slow moving stomach known as gastroparesis.

You have to know: domperidone should no longer be authorized to treat other conditions such as bloating or heartburn.

MOTILIUM is an antiemetic and a prokinetic medicine. It works by blocking the action of a chemical messenger in the brain which causes the feeling of nausea and vomiting, as well as increasing the movement or contractions of the stomach and intestines, allowing food to move more easily through the stomach.

Before you prescribe MOTILIUM

Do not give MOTILIUM if:

1- Your patient has an allergy to MOTILIUM, or any of the ingredients.
2- The patient has a tumor of the pituitary gland called prolactinoma.
3- Patient has severe belly cramps or persistent black stools
4- The patient has or has had liver disease, bleeding, obstruction or perforation in the stomach and intestines.
5- The patient is taking another medicine containing the active ingredient ketoconazole, fluconazole or voriconazole which is used to treat fungal infections. Or taking an antibiotic containing the active ingredient erythromycin, clarithromycin or telithromycin , or taking another medicine containing the active ingredient amiodarone, which is used to treat fast heart rate.

Important Note:

A risk of unusual heart beat or sudden heart failure has been associated with MOTILIUM use. The risk is higher in patients older than 60 years or taking more than three tablets daily. MOTILIUM should be used with caution and should be taken at the lowest effective dose, particularly in older patients. Treatment with MOTILIUM should be stopped if signs or symptoms occur that may be associated with unusual heartbeat.

Before you start to give it

You must ask your patient if:

- She is pregnant or planning to become pregnant
- She if breast feeding or wish to breastfeed
- She/he has a pre-existing heart condition
- She/he has or has ever had liver or kidney disease
- She has or has ever had breast cancer
- He/she is not able to digest lactose which is a sugar found in milk and milk products.

Check if your patient is taking other medicines:

- Medicines for treating fungal infections, such as ketoconazole, fluconazole, itraconazole and voriconazole.
- Medicines that neutralise or reduce the amount of stomach acid (such as antacids, ranitidine, cimetidine, omeprazole)
- Anticholinergic drugs (used to prevent travel sickness, treat Parkinson's Disease or relieve stomach cramps or spasms)
- An antibiotic, such as clarithromycin, telithromycin and erythromycin
- Medicines used to treat HIV infections, such as amprenavir, atazanavir, fosamprenavir, indinavir, nelfinavir, ritonavir and saquinavir
- Medicines used to treat high blood pressure or chest pain, such as diltiazem and verapamil
- Amiodarone used to treat fast heart rate
- Aprepitant used to treat nausea and vomiting
- An antidepressant called nefazodone.

These medicines may be affected by MOTILIUM or may affect how well MOTILIUM works.

The Dosage: (according to the New JFDA's Recommendation and restriction in 7/3/2014)

The recommended dose should be reduced to 10 mg up to three times daily by mouth for adults and adolescents weighing 35 kg or more.

In children and adolescents weighing less than 35 kg, it should be given by mouth at a dose of 0.25 mg/kg of bodyweight up to three times daily.

The medicine shouldn't normally be used for longer than one week.

How to take it:

MOTILIUM is best taken 15 to 30 minutes before meals or food.

Do not take medicines that neutralise stomach acid or medicines that reduce the production of stomach acid within 2 hours of taking MOTILIUM. This is because sufficient stomach acid is required to ensure that MOTILIUM is properly absorbed by the body.

References:

1- Domperidone-containing medicines . European Medicines Agency. 7/3/2014. http://www.ema.europa.eu/docs/en_GB/document_library/Referrals_document/Domperidone_31/Recommendation_provided_by_Pharmacovigilance_Risk_Assessment_Committee/WC500162559.pdf.
2- Motilium . 1/2014. http://www.news-medical.net/drugs/Motilium.aspx
3- JFDA .

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16/4/2014