Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Maxolon Tablets 10mg

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains metoclopramide hydrochloride equivalent to 10 mg of the anhydrous substance.

Excipient: Lactose monohydrate
For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet.
Product imported from the UK:
White to off-white, round, convex tablets, with a breakline on one side and engraved 'Maxolon' on the other.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Adult population:

1) Disorders of the gastrointestinal tract associated with delayed gastric emptying e.g. reflux oesophagitis, hiatus hernia, post-vagotomy syndrome.

2) Nausea and vomiting associated with administration of some cytotoxic drugs and radiotherapy.

3) Diagnostic procedures e.g. barium studies and duodenal intubations.

4) To counteract gastric stasis associated with attacks of migraine and assist absorption of orally administered analgesics for that condition.

4.2 Posology and method of administration

Route: Oral

Dosage and Administration:

The dosage recommendations given below should be strictly adhered to if side-effects of the dystonic type are to be avoided.

In patients with clinically significant degrees of renal or hepatic impairment, therapy should be at reduced dosage. Metoclopramide is metabolised in the liver and the predominant route of elimination of metoclopramide and its metabolites is via the kidney.

Medical Indications:

Adults 20 years and over: 10 mg three times daily.

Elderly Patients: As for adults. To avoid adverse reactions adhere strictly to dosage recommendations and where prolonged therapy is considered necessary, patients should be regularly reviewed.

Diagnostic Indications: A single dose of Maxolon may be given 5-10 minutes before the examination. Subject to body weight considerations (see above) the following dosages are recommended:

Adults:
20 years and over
10-20 mg

(Paediatric population including adolescents:
Use in the paediatric population is not recommended.)

4.3 Contraindications

Use in patients with phaeochromocytoma, as an acute hypertensive response may be induced.

Use in patients suffering from epilepsy, since the frequency and severity of seizures may be increased.

Use in presence of gastrointestinal haemorrhage, mechanical obstruction or perforation.

Use in patients with a previous history of hypersensitivity to metoclopramide or excipients.

Metoclopramide is contraindicated in neonates.

4.4 Special warnings and precautions for use

If vomiting persists the patient should be reassessed to exclude the possibility of an underlying disorder, e.g. cerebral irritation.

Care should be exercised in patients being treated with other centrally active drugs.

Risk-benefit should be carefully considered in patients with significant hepatic or renal impairment (loss of conjugation and increased risk of extra-pyramidal effects) or with Parkinson's disease (symptoms may be exacerbated).

Metoclopramide should not be used in the immediate post-operative period (up to 3-4 days) following pyloroplasty or gut anastomosis, as vigorous gastrointestinal contractions may adversely affect healing.

The neuroleptic malignant syndrome has been reported with metoclopramide in combination with neuroleptics as well as metoclopramide monotherapy (see adverse reactions).

Maxolon should be used with care in combination with other serotonergic drugs including SSRIs.

Extra-pyramidal disorder may occur, particularly in children and young adults and/or when high doses are used (see 4.8 undesirable effects).

Patients receiving this drug for the disorders associated with delayed gastric emptying should be reviewed at an early stage for response to treatment.

Metoclopramide may cause elevation of serum prolactin levels.

Patients with rare hereditary problems of galactose intolerance, the Lapp lactose deficiency or glucose-galactose malabsorption should not take this medicine.

Care should be exercised when using Maxolon in patients with a history of atopy (including asthma) or porphyria.

Special care should be taken when administering to patients with “sick sinus syndrome” or other cardiac conduction disturbances.

There have been very rare reports of abnormalities of cardiac conduction with intravenous metoclopramide. Maxolon should be used with care with other drugs affecting cardiac conduction.

4.5 Interaction with other medicinal products and other forms of interaction

The action of metoclopramide on the gastrointestinal tract is antagonized by anticholinergics and opioid analgesics. The absorption of any concurrently administered oral medication may be modified by the effect of metoclopramide on gastric mobility. Drugs known to be affected in this way include aspirin and paracetamol.

Metoclopramide should be used with care in association with other drugs acting at central dopamine receptors, such as levodopa, bromocriptine and pergolide.

Concomitant use of ‘Maxalon’ with ciclosporin or suxamethonium may increase plasma levels of either ciclosporin or suxmethonium.

Since metoclopramide influences gastrointestinal motility and absorption, the dosage of other drugs used concomitantly may possibly need adjustment.

This product may potentiate the effects of alcohol.

‘Maxolon should be used with care in association with other drugs acting at central dopamine receptors, such as levodopa, bromocriptine and pergolide.

Since extra-pyramidal reactions may occur with metoclopramide and phenothiazines, and tetrabenazine, care should be exercised when both are used concurrently.

The effects of certain other drugs with potential central stimulant effects, e.g. monoamine oxidase inhibitors and sympathomimetics, may be modified when prescribed with metoclopramide and their dosage may need to be adjusted accordingly.

The use of Maxolon with serotonergic drugs may increase the risk of serotonin syndrome.

4.6 Fertility, pregnancy and lactation

Animal tests in several mammalian species and clinical experience have not indicated a teratogenic effect. Nevertheless ‘Maxolon’ should only be used when there are compelling reasons and is not advised during the first trimester.

Metoclopramide is excreted in breast milk and should not be given to nursing mothers.

4.7 Effects on ability to drive and use machines

‘Maxolon’ may cause drowsiness, dyskinesia and dystonias which could affect the vision and also interfere with the ability to drive and operate machinery.

4.8 Undesirable effects

Blood and lymphatic system disorders
Extremely rare cases of red blood cell disorders such as methaemoglobinaemia, which could be related to NADH cytochrome b5 reductase deficiency particularly in neonates, and sulphaemoglobinaemia have been reported, particularly at high doses of metoclopramide. If this occurs the drug should be withdrawn. Methaemoglobinaemia may be treated using methylene blue.

Immune System disorders
Very rarely hypersensitivity, including anaphylactic / anaphylactoid reactions, have been reported (including symptoms such as tongue swelling / oedema).

Endocrine disorders
Raised serum prolactin levels have been observed during metoclopramide therapy: this may result in galactorrhoea, irregular periods and gynaecomastia.

Psychiatric disorders
Rarely, restlessness, confusion, agitation and anxiety have been reported in patients receiving metoclopramide therapy. Depression has been reported extremely rarely.

Nervous system disorders
Extra-pyramidal symptoms: acute dystonia and dyskinesia, parkinsonian syndrome, akathisia, even following administration of a single dose of the drug, particularly in children and young adults (se section 4.4). The incidence of dystonic reactions, particularly in children and young adults, is increased if daily dosages higher than 0.5mg per kg of body weight are administered. Dystonic reactions include: spasm of the facial muscles, trismus, rhythmic protrusion of the tongue, a bulbar type of speech, spasm of extra-ocular muscles including oculogyric crisis, unnatural positioning of the head and shoulders and opisthotonos. There may be a generalized increase in muscle tone. The majority of reactions occur within 36 hours of starting treatment and the effects usually disappear within 24 hours of withdrawal of the drug. Should treatment of a dystonic reaction be required an anti-cholinergics anti-Parkinsonian drug, or a benzodiazepine may be used.

Tardive dyskinesia, which may be persistent, has been reported as a side effect in elderly patients undergoing long-term therapy with metoclopramide. Prolonged therapy in such patients should be carefully reviewed. The likelihood of the occurrence of this serious effect is increased when neuroleptic agents are used concurrently.

Very rare occurrences of the neuroleptic malignant syndrome have been reported. This syndrome is potentially fatal and comprises hyperpyrexia, altered consciousness, muscle rigidity, autonomic instability and elevated levels of creatine phosphokinase (CPK) and must be treated urgently (recognized treatments include dantrolene and bromocriptine). Metoclopramide should be stopped immediately id this syndrome occurs.

Drowsiness, dizziness and tremor may occur.

Eye disorders
Visual disturbances have been reported.

Cardiac disorders
Very rare reports of abnormalities of cardiac conduction (bradycardia, aystole, heart block, sinus arrest and cardiac arrest) have been reported following intravenous administration.

Vascular disorders
Acute hypertension may occur in patients with phaeochromocytoma (see section 4.3 Contraindications). Hypotension has also been reported.

Respiratory, thoracic and mediastinal disorders
Dyspnoea may occur.

Gastrointestinal disorders
Diarrhoea

Skin and subcutaneous tissue disorders
A small number of skin reactions such as rashes, urticaria, pruritus and angioedema have also been reported.

General disorders and administration site conditions
Oedema

4.9 Overdose

In cases of overdosage, acute dystonic/extra-pyramidal reactions have occurred. Should treatment of a dystonic/extra-pyrimidal reaction be required, an anti-cholinergic, anti-parkinsonian drug (in adults only), or a benzodiazepine (in adults or children) may be used.

Treatment for extrapyrimidal disorders is only symptomatic (benzodiazepines in children).

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Metoclopramide is a benzamide derivative which acts peripherally to enhance cholinergic action at muscarinic synapses and in the central nervous system to antagonise dopamine.

5.2 Pharmacokinetic properties

Absorption from the gut is rapid and the drug undergoes significant first-pass hepatic metabolism. It is excreted in the urine as unchanged drug and metabolites in both free and conjugated form. The drug is also excreted in breast milk.

5.3 Preclinical safety data

No additional data available.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maize starch (dried)
Colloidal anhydrous silica
Magnesium stearate
Pregelatinised maize starch
Lactose monohydrate

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf-life expiry date of this product shall be the date shown on the container and outer package of the product on the market in the country of origin.

6.4 Special precautions for storage

Do not store above 30ºC.

6.5 Nature and contents of container

Packs of 84 tablets in PVC aluminium blister strip.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

PCO Manufacturing
Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA 465/202/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

7th September 2007

10 DATE OF REVISION OF THE TEXT

September 2012