Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Metocyl 10 mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains Metoclopramide 10 mg (as hydrochloride).

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet
White, round, convex tablet.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

(a) Metocyl is indicated in the treatment of disorders of the gastrointestinal tract associated with delayed gastric emptying.

(b) Metocyl is indicated in the treatment of nausea and vomiting, including that associated with the administration of some cytostatic drugs and radiotherapy.

(c) Metocyl is also indicated for diagnostic procedures, e.g. barium studies and duodenal intubation.

4.2 Posology and method of administration

Route of Administration: Oral.

Recommended Dosage Schedule:

The maximum daily dose, especially for children and young adults should not exceed 0.5 mg/kg body weight.

For indications (a) and (b) above:

Adults 20 years and over
10 mg three times daily. For patients of less than 60kg see below.

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.

Young Adults 15 – 19 years
60kg and over: 5 – 10 mg three times daily commencing with the lower dose. 30-59kg:5mg three times daily.

Children (under 15 years)
Tablets should not be used in children under the age of 15 years. A syrup formulation should be used to facilitate more accurate dosing.

For indications (c) above:

A single dose of Metocyl may be given 5 to 10 minutes before the examination.
Subject to body weight consideration (above) the following dosages are recommended:

Adults 20 years and over: 10-20mg.

Young adults 15-19 years: 10mg.

4.3 Contraindications

Metocyl should not be used in patients with phaeochromocytoma, nor in epileptic patients, 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 pervious history of hypersensitivity to metoclopramide or excipients.

4.4 Special warnings and precautions for use

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.

Various extrapyramidal reactions to Metocyl, usually of the dystonic type, can occur. The incidence of these reactions in children and young adults may increase if a daily dosage, higher than 0.5 mg/kg is administered.

Use of this drug may increase extrapyramidal side effects, including facial spasm, trismus, rhythmic protrusion of the tongue, a bulbar type of speech, spasm of extra ocular muscles including oculogyric crises, unnatural positioning of head and shoulders and opisthotonos. There may be a generalised increase in muscle tone. The majority of reactions occur within 36 hours of starting treatment and the affects usually disappear within 24 hours of withdrawal of the drug. Should treatment of a dystonic reaction be required an anticholinergic anti-parkinsonian drug, or a Benzodiazepine may be used.

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

Serum prolactin levels may be raised by this drug.

Recent reports have associated the prolonged use of metoclopramide in patients over 50 years with the development of tardive dyskinesia, which has been persistent or only slowly reversible after drug withdrawal. The likelihood of the occurrence of this serious effect is increased when neuroleptic agents are used concurrently.

Restlessness, anxiety and also impairment of driving ability and motor co-ordination.

Patients receiving this drug should be reviewed for response to treatment after 10 – 14 days.

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

4.5 Interaction with other medicinal products and other forms of interaction

Concomitant use of anticholinergic drugs may inhibit the favourable effects on gastrointestinal motility.

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.

Since dystonic reactions may occur with metoclopramide and phenothiazines, care should be exercised when both are used concurrently.

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

4.6 Pregnancy and lactation

This product should not be used in pregnancy and lactation unless considered absolutely essential by the physician.

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

4.7 Effects on ability to drive and use machines

Patients taking Metocyl Tablets should be warned about impairment of driving ability and motor co-ordination.

4.8 Undesirable effects

Some side effects are known for Metocyl and these are described under 4.4 Special Warnings and Special Precautions For Use.

Other side effects include drowsiness, restlessness, confusion, anxiety and also impairment of driving ability and motor co-ordination. Depression has been reported extremely rarely.

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

Extremely rarely cases of red cell disorders such as methaemoglobinaemia and sulphaemoglobinaemia have been reported, particularly at high dose of metoclopramide. If this occurs the drug should be withdrawn.

Anaphylactic reactions, angioedema, urticaria and rash have been reported very rarely.

Acute hypertension may occur in patients with phaeochromocytoma (see section 4.3 contraindications).

4.9 Overdose

Should treatment of a dystonia reaction be required, an anti-parkinson drug or benzodiazepine may be used.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC code and description: A03Fa01 propulsive. Metoclopramide is a benzamide derivative which acts peripherally to enhance cholinergic action on 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

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Dried maize starch
Microcrystalline cellulose
Talc
Colloidal Silicon Dioxide

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

5 years.

6.4 Special precautions for storage

Do not store above 25°C.
Blister Packs: Store in the original package.
Securitainers: Store in the original container.

6.5 Nature and contents of container

Metocyl Tablets are blister packed in cardboard cartons in units of 20 tablets, 100 tablets and sample packs of 10 tablets.

Metocyl Tablets are also available in securitainers in quantities of 100 and 500 tablets.

Not all pack sizes may be marketed.

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 MARKETING AUTHORISATION HOLDER

Rowa Pharmaceuticals Ltd.
Bantry
County Cork

8 MARKETING AUTHORISATION NUMBER

PA 74/10/2

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 23 April 1986

Date of last renewal: 23 April 2006

10 DATE OF REVISION OF THE TEXT

October 2006