Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Maxolon Paediatric 1mg/ml oral drops, solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

The liquid contains metoclopramide hydrochloride equivalent to 1 mg/ml of the anhydrous substance.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral drops, solution

Clear, colourless, oral drops, solution with a citrus odour.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

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

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

4.2 Posology and method of administration

Route of administration

Oral.

The dosage recommendations given below should be strictly adhered to if side-effects of the dystonic type are to be avoided. It should be noted that total daily dosage of Maxolon, especially for children and young adults, should not normally exceed 0.5 mg/kg body weight.

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.

Young adults and children: Maxolon should only be used after careful examination to avoid masking an underlying disorder, e.g. cerebral irritation. In the treatment of this group attention should be given primarily to body weight and treatment should commence at the lower dosage where stated.

Oncology Indication:

9-14 years	30 kg and over:	5 mg three times daily
5-9 years	20-29 kg:	2.5 mg three times daily
3-5 years	15-19 kg:	2 mg two to three times daily
1-3 years	10-14 kg:	1 mg two to three times daily
Under 1 year	Up to 10 kg:	1 mg twice daily

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:

Children:	9-14 years	5 mg
	5-9 years	2.5 mg
	3-5 years	2 mg
	Under 3 years	1 mg

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.

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 extrapyramidal 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.

Various extrapyramidal reactions to metoclopramide, 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.

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.

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

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 extrapyramidal 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 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

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

None, but see 4.8.

4.8 Undesirable effects

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.

Very rarely hypersensitivity, including anaphylaxis, has been reported.

Rarely diarrhoea, drowsiness, restlessness, confusion and anxiety have been reported in patients receiving metoclopramide therapy. 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 instability 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.

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.

Extremely rarely cases of red cell disorders such as methaemoglobinaemia 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.

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

In cases of overdosage, acute dystonic reactions have occured. Should treatment of a dystonic reaction be required, an anticholinergic anti-parkinsonian drug, or a benzodiazepine may be used.

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

Hydroxyethylcellulose
Methyl parahydroxybenzoate (E218)
Propyl parahydroxybenzoate (E216)
Saccharin sodium
Citric acid monohydrate
Soluble lemon oil
No. 1 lime flavour
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

Unopened: 3 years.
Opened: 14 days.

6.4 Special precautions for storage

Do not store above 30°C.
Keep the bottle in the outer carton in order to protect from light

6.5 Nature and contents of container

Amber glass bottles containing 15 ml of liquid with a plastic screw cap and replacement plastic screw cap with dropper pipette.

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

Check carton seal is intact before first use. Discard cap and replace with pipette.

7 MARKETING AUTHORISATION HOLDER

Rosemont Pharmaceuticals Ltd
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Braithwaite Street
Leeds LS11 9XE
UK

8 MARKETING AUTHORISATION NUMBER

PA 312/21/2

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st April 1979
Date of last renewal: 1st April 2009

10 DATE OF REVISION OF THE TEXT

February 2011