

1. NAME OF THE MEDICINAL PRODUCT

Metoclopramide Injection BP 10mg/2ml

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 2ml contains metoclopramide hydrochloride equivalent to 10mg of anhydrous metoclopramide hydrochloride.

3. PHARMACEUTICAL FORM

Solution for injection.
Clear colourless sterile solution.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Adults 20 years and over:

- 1) Disorders of the gastro-intestinal tract associated with delayed gastric emptying, such as 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.

Young adults and children

The use of Metoclopramide in patients under 20 years should be restricted to the following:

Vomiting associated with radiotherapy and intolerance to cytotoxic drugs, as an aid to gastro-intestinal intubation.

4.2 Posology and method of administration

Route of Administration:

By intramuscular or slow intravenous injection.

METOCLOPRAMIDE INJECTION BP 10MG IN 2ML PA 73/84/1
Clean SmPC

Posology:

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

<u>(1) and (2) above</u>	
<u>Adults:</u>	10mg 3 times daily intramuscular or intravenous.
<u>Young Adults</u>	
<u>15 - 20 years:</u>	5 - 10mg 3 times daily intramuscular or intravenous commencing with the lower dose.
<u>Children</u>	
<u>5 - 14 years:</u>	2.5 - 5mg 3 times daily intramuscular or intravenous commencing with the lower dose.
<u>(3) Above</u>	
A single dose of metoclopramide may be given 5 - 10 minutes before the examination.	
<u>Adults:</u>	10 - 20mg
<u>Children</u>	
<u>5 - 14 years:</u>	2.5 - 5mg
<u>(4) Above</u>	
<u>Adults:</u>	10mg intramuscular up to 3 times daily, administered approximately 30 minutes prior to administration of oral analgesic.
<u>Young Adults</u>	
<u>15 - 20 years:</u>	5mg intramuscular up to 3 times daily, administered approximately 30 minutes prior to administration of oral analgesic.
<u>Elderly</u>	As for Adults above.

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 gastro-intestinal haemorrhage, mechanical obstruction or perforation.

METOCLOPRAMIDE INJECTION BP 10MG IN 2ML PA 73/84/1
Clean SmPC

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).

Metoclopramide 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 Metoclopramide in patients with a history of atopy (including asthma) or porphyria.

4.5 Interaction with other medicinal products and other forms of interactions

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

Since metoclopramide influences gastro-intestinal 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, phenothiazines care should be exercised when both are used concurrently.

METOCLOPRAMIDE INJECTION BP 10MG IN 2ML PA 73/84/1
Clean SmPC

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 Metoclopramide with serotonergic drugs may increase the risk of serotonin syndrome

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

There have been rare reports of drowsiness in association with metoclopramide therapy and patients should be advised not to drive or to operate machinery if affected.

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 Creatine Phosphokinase (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.

METOCLOPRAMIDE INJECTION BP 10MG IN 2ML PA 73/84/1
Clean SmPC

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.
There have been very rare reports of abnormalities of cardiac conduction (e.g. bradycardia and heart block) in association with I.V metoclopramide.

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

Possible symptoms of overdosage include drowsiness, disorientation and extrapyramidal reactions. Treatment is symptomatic and supportive. An anti-Parkinson drug or benzodiazepine may be used to treat dystonic reactions.

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 antagonize 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 further information other than that which is included in other sections of the Summary of Product Characteristics.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium Metabisulphite
Sodium Chloride
Water for Injections

METOCLOPRAMIDE INJECTION BP 10MG IN 2ML PA 73/84/1
Clean SmPC

Hydrochloric Acid
Sodium Hydroxide.

6.2 Incompatibilities

Metoclopramide is reported to be incompatible with sodium bicarbonate, cephalothin sodium and other cephalosporins, and chloramphenicol. Do not mix with other drugs unless compatibility is known.

6.3 Shelf life

Unopened: 3 years

The Product should be used immediately after opening

6.4 Special precautions for storage

Keep the ampoule in the original carton in order to protect from light.
Do not store above 25°C.

6.5 Nature and contents of container

Clear glass one-point-cut (OPC) ampoules, glass type I Ph Eur.
Pack size: 10 x 2ml ampoules.

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

For single use only

If only part used, discard the remaining solution.

7. **MARKETING AUTHORIZATION HOLDER**

Antigen Pharmaceuticals Ltd.,
Roscrea,
County Tipperary.
Ireland.

8. **MARKETING AUTHORIZATION NUMBER**

PA 73/84/1.

9. **DATE OF FIRST AUTHORIZATION/RENEWAL OF AUTHORIZATION**

11 October 1984/11 October 2004

METOCLOPRAMIDE INJECTION BP 10MG IN 2ML PA 73/84/1
Clean SmPC

10. DATE OF (PARTIAL) REVISION OF THE TEXT

November 2008