

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1. TRADE NAME OF THE MEDICINAL PRODUCT**

Antimet Tablets.

### **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each tablet contains Metoclopramide Hydrochloride B.P. equivalent to 10mg of anhydrous Metoclopramide Hydrochloride.

### **3. PHARMACEUTICAL FORM**

Round, white, shallow convex tablets marked 'a' on one face and 'M/10' on the other for oral administration to human beings.

### **4. CLINICAL PARTICULARS**

#### **4.1 Therapeutic Indications**

Adults 20 years and above

- 1) Disorders of the gastrointestinal tract associated with delayed gastric emptying e.g. reflux oesophagitis, hiatus hernia and post-vagotomy syndrome.
- 2) Nausea and vomiting associated with administration of some cytostatic drugs and radiotherapy.
- 3) Diagnostic procedures, e.g. barium studies 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 gastrointestinal intubation.

#### **4.2 Posology and method of administration**

Antimet tablets are for oral administration.

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 metoclopramide, especially for children and young adults, should not exceed 0.5mg/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.

## Medical Indication:

### Oral

Adults 20 years and over: 10mg 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 and children: Metoclopramide should only be used after careful examination to avoid masking and 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.

Young adults:

15-19 years 60kg and over: 10mg three times daily

30-59kg: 5mg three times daily

Tablets should not be used in children under the age of 15 years. A liquid presentation should be used in the younger age group: more accurate dosage is facilitated by the use of a Paediatric Liquid.

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

Adults: 20 years and over 10-20mg

Young Adults 15-19 years 10mg

### **4.3 Contraindications**

Use in patients hypersensitive to metoclopramide.

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 patient with porphyria.

#### **4.4 Special warnings and special precautions for use**

The incidence of extrapyramidal reactions especially in children and young adults may increase if a daily dosage higher than 0.5mg/kg is administered (see 'side effects').

Because tardive dyskinesia 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.

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

Serum prolactin levels may be raised by this drug.

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).

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

The neuroleptic malignant syndrome has been reported with metoclopramide in combination with neuroleptics as well as with metoclopramide monotherapy (See *Undesirable effects*).

#### **4.5 Interactions with other medicaments and other forms of interaction**

Concomitant use of anticholinergic drugs may inhibit the favourable effects on gastro-intestinal motility.

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

Metoclopramide may potentiate the effects of alcohol.

Since extra pyramidal 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. Concurrent use of neuroleptic agents may give rise to tardive dyskinesia. (See *Undesirable effects*).

#### **4.6 Pregnancy and lactation**

Antimet 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**

Metoclopramide may cause drowsiness and patient should be warned not to drive or to operate machinery if affected.

#### **4.8 Undesirable effects**

Various extrapyramidal reactions to metoclopramide, usually of the dystonic type, may occur. These include facial spasm, trismus, rhythmic protrusion of the tongue, a bulbous type of speech, spasm of extra ocular muscles including oculogyric crises, unnatural positioning of head and shoulders. 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 CPK and must be treated urgently (recognised treatments include dantrolene and bromocriptine). Metoclopramide should be stopped immediately if this syndrome occurs.

Other adverse effects include bowel upset, drowsiness, restlessness and anxiety. Occasional disturbances of cardiac rhythm.

Tardive dyskinesia, which may be persistent, has been reported as a side effect in elderly patients undergoing long-term therapy with metoclopramide.

#### **4.9 Overdose**

Symptoms of overdosage may include drowsiness, disorientation and extrapyramidal reactions. If overdosage is recent, the stomach should be emptied by aspiration and lavage and appropriate and supportive measures should be employed. 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. Gastric and duodenal peristalsis is increased, the pyloric sphincter is relaxed and the resting tone of the gastro-oesophageal sphincter is increased.

#### **5.2 Pharmacokinetic properties**

Absorption from the gut is rapid, and the drug undergoes significant first-pass 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**

Lactose Ph.Eur  
Maize Starch Ph.Eur  
Povidone Ph.Eur  
Colloidal Silicon Dioxide U.S.P. ( Aerosil 200)  
Magnesium Stearate Ph.Eur

### **6.2 Incompatibilities**

None Known

### **6.3 Shelf life**

48 Months for Securitainers(Un-opened)

### **6.4 Special Precautions for storage**

Do not store above 25°C.  
Store in the original container in order to protect from light and moisture.

### **6.5 Nature and contents of container**

Polypropylene securitainers with temper evident polypropylene caps.  
Pack sizes: 100, 500 and 1,000 tablets.  
Pack of 28, 56, 84 and 112 tablets in Securitainer.

### **6.6 Instructions for use / handling**

Use as directed by the physician.  
Keep out of the reach and sight of children.

## **7. MARKETING AUTHORIZATION HOLDER**

Antigen Pharmaceuticals Ltd.  
Roscrea  
Co. Tipperary

**8. MARKETING AUTHORIZATION NUMBER**

PA 73/60/1

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

13th May 1981/13th January 2006

**10. DATE OF (PARTIAL) REVISION OF THE TEXT**

January 2009