1.3.1.1 PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

SCHEDULING STATUS

S4

PROPRIETARY NAME AND DOSAGE FORM

CLOPAMON INJECTION 10 mg/2 ml

COMPOSITION

Each ampoule of CLOPAMON INJECTION 10 mg/2 ml contains 10 mg of metoclopramide

Excipients:

Sodium chloride, water for injection

Sugar free

CATEGORY AND CLASS

A 5.7.2 Anti-emetics and antivertigo preparations

PHARMACOLOGICAL ACTION

Pharmacodynamic properties

Gastrointestinal action: metoclopramide increases the number, mean strength and total activity of gastric antral contractions and also produces a significant increase in the strength of duodenal contractions. These changes would all tend to increase the speed of gastric emptying, which has been observed radiologically and by other methods. Metoclopramide has no effect on gastric secretion or on the cardiovascular system.

Metoclopramide has an effect on the gastro-oesophageal junction of the stomach, producing an increase in cardiac sphincter pressure. The increase in pressure seen after administration of metoclopramide is directly proportional to the initial resting pressure and is minimal or absent in those with very low resting pressures.

The action of metoclopramide on the gastrointestinal tract is antagonised by atropine and other anticholinergic medicine if they are administered in the previous 3 hours.

Anti-emetic action: metoclopramide acts on the chemo-emetic trigger zone to produce a central anti-emetic effect. The anti-emetic action of metoclopramide is not affected by atropine and other anticholinergic medicine.

Other action: metoclopramide stimulates prolactin secretion.

INDICATIONS

Digestive disorders: CLOPAMON INJECTION 10 mg/2 ml is of value in any condition associated with gastric status or hypomotility. It is, therefore, useful in the management of post-vagotomy syndrome.

Nausea and vomiting: CLOPAMON INJECTION 10 mg/2 ml is an effective anti-emetic medicine in the control of nausea and vomiting associated with the following conditions: drug-induced nausea and vomiting, uraemic conditions, malignant disease, gastrointestinal disorders and post anaesthetic vomiting.

Diagnostic radiology: CLOPAMON INJECTION 10 mg/2 ml speeds gastric emptying and dilates the duodenal bulb. It is, therefore, particularly useful in the following situations:

(a) where barium meal studies are delayed by spasm of the duodenal cap making

examination for the presence of an ulcer difficult;

(b) to facilitate examination of the hypotonic stomach with delayed emptying (gastric stasis and pyloric canal syndrome);

(c) to control or prevent nausea and vomiting of barium which occurs in a small minority of patients undergoing barium meal examination.

Duodenal intubation: The action of CLOPAMON INJECTION 10 mg/2 ml in promoting stomach emptying, combined with its anti-emetic effect, has proved a very useful aid to gastrointestinal intubation procedures.

CONTRAINDICATIONS

CLOPAMON INJECTION 10 mg/2 ml is contraindicated in the following conditions:

- when stimulation of muscular contractions might adversely affect gastrointestinal conditions, such as in gastrointestinal haemorrhage, obstruction or perforation or immediately after surgery;
- in patients with phaechromocytoma as hypertensive crises have been reported;
- epileptic patients due to risk of increased frequency and severity of seizures;
- porphyria.

WARNINGS AND SPECIAL PRECAUTIONS

Safety in pregnancy has not been established.

Children, young patients and the elderly should be treated with care as they are at increased risk of extrapyramidal reactions.

On no account should CLOPAMON INJECTION 10 mg/2 ml ampoules be diluted for injection since this will upset the isotonicity and stability of the medicine.

Patients on prolonged therapy should be reviewed regularly.

Care should also be taken when CLOPAMON INJECTION 10 mg/2 ml is administered to patients with renal impairment or to those at risk of fluid retention as in hepatic impairment.

INTERACTIONS

Caution should be observed when using CLOPAMON INJECTION 10 mg/2 ml in patients taking other medicine that can also cause extrapyramidal reactions, such as the phenothiazines.

Increased toxicity may occur in patients receiving lithium.

Caution is advised with other centrally-active medicine including antidepressants, antiepileptics and sympathomimetics.

Antimuscarinic medicines and opioid analgesics antagonise the gastrointestinal effects of CLOPAMON INJECTION 10 mg/2 ml.

The absorption of other medicine may be affected by CLOPAMON INJECTION 10 mg/2 ml.

It may diminish absorption from the stomach e.g. with digoxin or enhance absorption from the small intestine e.g. with aspirin or paracetamol.

CLOPAMON INJECTION 10 mg/2 ml may prolong suxamethonium-induced neuromuscular blockade.

It may also increase prolactin blood-concentrations and therefore interfere with medicine

which have a hypoprolactinaemic effect e.g. bromocriptine.

HUMAN REPRODUCTION

Safety in pregnancy has not been established.

DOSAGE AND DIRECTIONS FOR USE

Parenteral

Adults and children over 14 years:

10 mg (1 ampoule) 1 to 3 times daily IV or IM depending on the severity of the condition.

Children 5 to14 years:

2,5 mg (0,5 ml of 10 mg/2 ml ampoule) IV or IM twice daily in a tuberculin syringe.

Children 3 to 5 years:

1 mg (0,2 ml of 10 mg/2 ml ampoule) IV or IM twice daily in a tuberculin syringe.

Children 1 to 3 years:

0,5 mg (0,1 ml of 10 mg/2 ml ampoule) IV or IM in a tuberculin syringe twice daily.

Dosage for diagnostic radiology

Intravenous:

10 mg to 20 mg (1 to 2 ampoules) 5 to 15 minutes before the barium meal.

Intramuscular:

10 mg to 20 mg (1 to 2 ampoules) 10 to 15 minutes before the barium meal.

SIDE EFFECTS

CLOPAMON INJECTION 10 mg/2 ml is a dopamine antagonist and may cause extrapyramidal symptoms which usually occur as acute dystonic reactions, especially in young female patients.

Parkinsonism and tardive dyskinesia have occasionally occurred, usually during prolonged treatment in elderly patients.

Other adverse effects include restlessness, drowsiness, dizziness, headache and bowel upsets such as diarrhoea.

Hypotension, hypertension and depression may occur.

There are isolated reports of blood disorders, hypersensitivity reactions, neuroleptic malignant syndrome and urinary incontinence. CLOPAMON INJECTION 10 mg/2 ml stimulates prolactin secretion and may cause galactorrhoea or related disorders.

Transient increases in plasma aldosterone concentrations have been reported.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENTS

Symptoms

Overdosage of CLOPAMON INJECTION 10 mg/2 ml could give rise to dyskinetic reactions manifested as motor restlessness, agitation, irritability, spasm of facial and neck muscles and the muscles of the tongue. In severe cases opisthotonos can result.

Treatment

Anti-Parkinson medications, e.g. procyclidine, will usually control these reactions.

IDENTIFICATION

Clear, colourless liquid.

PRESENTATION

1 x 2 ml clear glass ampoules. 10 ampoules are packed in a polystyrene container together with a leaflet.

STORAGE INSTRUCTIONS

Store at or below 25 °C.

Protect from light.

Should inadvertent exposure occur, reject ampoules showing a yellow discolouration.

Keep in original packaging until required for use.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

P/5.7.2/53

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

PHARMACARE LIMITED

Healthcare Park

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