therapy be required, an anti-parkinson drug may be used. Tardive dyskinesia has been reported during prolonged therapy and long-term treatment should be regularly reviewed. Raised serum prolactin levels, breast engorgement and lactorrhoea have been reported after the use of **Metoclopramide.** The conditions return to normal after withdrawal of the drug. As both **Metoclopramide** and the phenothiazines may cause dystonia, care should be exercised in the event of both drugs being prescribed concurrently. On no account should **Metoclopramide** ampoules be diluted for injection since this will upset the isotonicity and stability of the drug.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT: Overdosage of **Metoclopramide** may give rise to the dyskinetic reactions manifested as motor restlessness, agitation, irritability, spasm of facial and neck muscles and the muscles of the tongue. In severe cases opisthotonus can result. Anti-parkinson medications, will usually control these reactions.

AVAILABILITY:

Regelan Tablets: Each tablet contains: Metoclopramide HCl Anhyd. BP 10mg.
Regelan tablets are available in 3 diffrent packings,
Pack of 20 tablets in blister.
Pack of 100 tablets in blister.
Jar of 500 tablets.

Regelan injections: Each 2mL ampoule contains: **Metoclopramide** 10mg as **Metoclopramide** HCl USP. Pack of 10 ampoules.

STORAGE:

Store in a cool, dry place. Protect from direct sunlight. Keep out of the reach of children. To be dispensed on prescription only.

ریگیلان ٹیبلٹس/انجکشن 10 ملی گرام

میٹوکلوپرامائیڈ ہائیڈروکلورائیڈ

دھوپ، گرمی اور نمی سے محفوظ رکھیں۔
تمام دوائیں بچوں کی پہنچ سے دور رکھیں۔
صرف ڈاکٹر کے نسخہ پر فراہم کی جائے۔
خوراک: ڈاکٹر کی ہدایات کے مطابق استعمال کریں۔

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Manufactured by

Pharmedic Laboratories (Pvt) Limited.
16 Km. Multan Road, Lahore - Pakistan
Phone : 042 - 37511861 - 65, Fax : 042 - 37511396

Regelan

Metoclopramide HCl Tablets / Injections

PHARMACOLOGICAL CLASSIFICATION:
Anti-emetics and antivertigo preperations.

PHARMACOLOGICAL ACTION:
Metoclopramide is well absorbed by oral, subcutaneous, intra-muscular or rectal routes. Effects on the gastro-intestinal tract are observed within three to six minutes following parenteral therapy and within five to ten minutes following oral therapy. Approximately 50% of Metoclopramide is excreted unchanged in the urine.

Gastro-intestinal Action:
Metoclopramide increases the number, mean strength and total activity of gastric antral concentrations and also produces a significant increase in the strength of duodenal contractions. The synchronization of antral and duodenal contractions is improved in humans. These changes would all tend to increase the speed of gastric emptying, which has been observed radiologically and by other methods.

Metoclopramide simultaneously increases the motor action of the small intestine which results in a decrease in the small bowel transit time.

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 sphineter pressure. The increase in pressure seen after **Metoclopramide** therapy is directly proportional to the initial resting pressure and minimal or absent in those with very low resting pressures.

The action of **Metoclopramide** on the gastro intestinal tract is antagonised by atropine and other anticholinergic drugs if they are administered in the previous three hours.

Anti-emetic Action:
By exerting a central anti-emetic effect **Metoclopramide** controls nausea and vomiting caused by a wide variety of conditions. The anti-emetic action of **Metoclopramide** is not affected by atropine and other anticholinergic drugs.

Other Action: Metoclopramide stimulates prolactin secretion.

INDICATIONS:
Adults (20 years and over):
Digestive disorders:
Metoclopramide is of value in conditions associated with gastric stasis or hypomotility. It is therefore useful in the management of dyspepsia, flatulence and post-vargotomy syndrome.

Nausea and Vomiting:
Metoclopramide is an effective anti-emetic agent in the control of nausea and vomiting associated with the following conditions: intolerance to essential drugs possessing emetic properties, uraemic conditions, malignant disease, gastrointestinal disorders and post-anaesthetic vomiting.

Other: Metoclopramide may be effective in certain cases of chronic hiccoughs.

Diagnostic radiology: Metoclopramide 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 patients undergoing barium meal examination.
(d) To speed up the transit time of barium through the small bowel. Intravenous **Metoclopramide** given after the barium swallow is recommended for this purpose because oral administration could give rise to radiographically poor examination.

Duodenal Intubation: The action of **Metoclopramide** in promoting stomach emptying, combined with its anti-emetic effect, has proved a useful aid to gastro-intestinal intubation procedures.

Young Adults and Children: The use of **Metoclopramide** in patients under 20 years should be restricted to the following: Severe intractable vomiting of known cause. As an aid to gastro-intestinal intubation and diagnostic radiology.

CONTRA-INDICATIONS: Animal tests in several mammalian species have shown no teratogenic effects but **Metoclopramide** is not recommended during pregnancy. Cases of hypertensive crisis have reportedly been associated with **Metoclopramide** after administration to patients with phaeochromocytoma. Until furthur evaluated, **Metoclopramide** should not be given to patients with suspected or confirmed phacochromocytoma. Hypersensitivity to any of the ingredients.

DOSAGE AND DIRECTION FOR USE:
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 normally exceed 0.5 mg/kg body mass. **Metoclopramide** should only be used after careful examination to avoid masking an underlying disorder. eg. cerebral irritation. In the treatment of young adults and children attention should be given primarily to body mass and treatment should commence at the lower dosage where stated.

Oral Adults 15 years and over, with a mass of 60 kg or more: 10 mg (1 x 10 mg tablet) 3 times daily.
Adults 15 years and over, with a mass of less than 60 kg: 5 mg (0.5 x 10 mg tablet) 3 times daily.
Children 9 - 14 years (30 kg and over): 5 mg (0.5 x 10 mg tablet) 3 times daily.
Children 5 - 9 years (20 - 29 kg): 2.5 mg 3 times daily.
Children 3 - 5 years (15 - 19 kg): 2 mg 2 - 3 times daily.
Children 1 - 3 years (10 - 14 kg): 1 mg 2 - 3 times daily.
Children under 1 year (up to 10 kg): 1 mg twice daily.
Parenteral: Adults 15 years and over, with a mass of 60 kg or more: 10 mg (1 ampoule) 1 - 3 times daily I.V. or I.M. depending on the severity of the condition.
Adults 15 years and over, with a mass of less than 60 kg: 5 mg (1.0 mL of a 10 mg/2 mL ampoule) I.V. or I.M. 1 - 3 times daily.
Children 5 - 14 years: 2.5 mg (0.5 mL of 10 mg/2 mL ampoule) I.V. or I.M. twice daily.

Children 3 - 5 years: 1 mg (0.2 mL of 10 mg/2 mL ampoule) I.V. or I.M. twice daily.
Children 1 - 3 years: 0.5 mg (0.1 mL of 10mg/2 mL ampoule) I.V. or I.M. twice daily.
Dosage for Diagnostic Radiology:
Intravenous: 10 - 20 mg (1 - 2 ampoules) 5 - 15 minutes before the barium meal.
Intramuscular: 10 - 20 mg (1 - 2 ampoules) 10 - 15 minutes before the barium meal.

SIDE - EFFECTS AND SPECIAL PRECAUTIONS: Subjective feeling of restlessness have been reported: Anxiety or agilation may occur, especially after rapid injection and rare cases of acute depression have been reported. Various extrapyramidal dystonic-like reactions could occur, the findings include spasm of facial and/or estraocular muscles. trismus, a bulbar type of speech and unnatural positioning of the head and shoulders. There may be a general increase in muscle tone. The incidence of these in children and young adults may be increased if the total daily dose of **Metoclopramide** exceeds 0.5 mg/kg body mass. The majority of these reactions occur within 36 hours of starting treatment and disappear within 24 hours of withdrawal of the drug. Should active