Perimo Suspension

پیریمو سسپنشن

(Domperidone)

(ڈومپیری ڈون)

COMPOSITION:
Each ml Contains:
Domperidone.....1 mg

INDICATIONS:
Adults: The relief of the symptoms of nausea and vomiting.
Children Over 12 Year of age: the relief of the symptoms of nausea and vomiting
CONTRAINDICATIONS:
Domperidone is contraindicated in the following situations:
-Known hypersensitivity to Domperidone or any of the excipients
-Prolactin-releasing pituitary tumour (prolactinoma).
-When stimulation of the gastric motility could be harmful, e.g, in patients with gastro-intestinal haemorrhage, mechanical obstruction or perforation.
-In patients with moderate or severe hepatic impairment.
-In patients who have known existing prolongation of cardiac conduction intervals, particularly QTc patients with significant electrolyte disturbances or underlying cardiac diseases.
-Co-administration with QT prolonging drugs
-Concomitant use of strong CYP3A4 inhibitors and QT prolonging drugs with the exception of apomorphine. When the benefit is greater then risk.

PHARMACODYNAMIC PROPERTIES:
Mechanism of action: Domperidone is a dopamine antagonist with anti-emetic properties, Domperidone does not readily cross the blood-brain barrier. In Domperidone users, especially in adults, extrapyramidal side effects are very rare, but Domperidone promotes the release of prolactin from the pituitary. Its anti-emetic effect may be due to a combination of peripheral (gastrokinetic) effects and antagonism of dopamine receptors in the chemoreceptor trigger zone, which lies outside the blood-brain barrier in the area postrema.
Studies in man have shown oral Domperidone to increase lower oesophaegeal pressure, improve antroduodenal motility and accelerate gastric emptying. There is no effect on gastric secretion.

PHARMACOKINETIC PROPERTIES:
Absorption: In fasting subjects, Domperidone is rapidly, absorbed after oral administration, with peak plasma concentrations at 30 to 60 minutes. The low absolute bioavailability of oral Domperidone (approximately 15%) is due to an extensive first-pass metabolism in the gut wall and liver. Patients with gastro-intestinal complaints should take Domperidone 15-30 minutes before a meal. The time of peak absorption is slightly delayed and the AUC somewhat increased when the oral drug is taken after a meal.
Distribution: Oral Domperidone does not appear to accumulate or induce its own metabolism; a peak plasma level after 90 minutes of 21 ng/ml after two weeks of oral administration of 30 mg per day was almost the same as that of 18 ng/ml after the first dose. Domperidone is 91-93% bound to plasma proteins.
Excretion: Urinary and faecal excretions amount to 31 and 66% of the oral dose respectively. The proportion of the drug excreted unchanged is small (10% of faecal excretion and approximately 1% of urinary excretion). The plasma half-life after a single oral dose is 7-9 hours in healthy subjects but is prolonged in patients with severe renal insufficiency.

DOSAGE AND ADMINISTRATION:
It is recommended to take oral Domperidone before meals. If taken after meals, absorption of the drug is somewhat delayed.
Therapy should not exceed 07 days of continuous treatment without medical consultation.
Adults and adolescents (over 12 years and weighing 35 kg or more): Usual dose is 10ml taken up to three times per day, Do not take more than 30ml per day.
Renal Impairment: Since the elimination half-life of Domperidone is prolonged in severe renal impairment, on repeated administration, the dosing frequency of Domperidone should be reduced to once or twice daily depending on the severity of the impairment, and the dose may need to be reduced. Such patients on prolonged therapy should be reviewed regularly.
Hepatic Impairment:
Domperidone oral suspension is contraindicated in moderate to severe hepatic impairment.

WARNINGS AND PRECAUTIONS:
Domperidone has been associated with prolongation of the QT interval on the electrocardiogram. During post-marketing surveillance, there have been very rare cases of QT prolongation and torsades de pointes in patients taking domperidone. These reports included patients with confounding risk factors, electrolyte abnormalities and concomitant treatment which may have been contributing factors.
Epidemiological studies showed that domperidone was associated with an increased risk of serious ventricular arrhythmias or sudden cardiac death. A higher risk was observed in patients older than 60 years, patients taking daily doses greater than 30mg, and patients concurrently taking QT_prolonging drugs or CYP3A4 inhibitors.
Domperidone should be used at the lowest effective dose in adults and adolescents 12 years of age and older..
Domperidone is contraindicated in patients with known existing prolongation of cardiac conduction intervals, particularly QTc, in patients with significant electrolyte disturbances (hypokalaemia, hyperkalaemia, hypomagnesaemia), or bradycardia, or in patients with underlying cardiac diseases such as congestive heart failure due to increased risk of ventricular arrhythmia. Electrolyte disturbances (hypokalaemia, hyperkalaemia, hypomagnesaemia) or bradycardia are known to be conditions increasing the proarrythmic risk.
Renal impairment: Since the elimination half-life of Domperidone is prolonged in severe renal impairment, on repeated administration, the dosing frequency of Domperidone should be reduced to once or twice daily depending on the severity of the impairment, and the dose may need to be reduced. Such patients on prolonged therapy should be reviewed regularly.
Pregnancy and breastfeeding:
Talk to your doctor or pharmacist before taking Domperidone Suspension if you:
- are pregnant, might become pregnant or think you may be pregnant are breast-feeding.
- Small amounts of Domperidone have been detected in breast milk.
Domperidone may cause unwanted side effects affecting the heart in a breast-fed baby. Domperidone should be used during breast feeding only if your physician considers this clearly necessary.
Ask your doctor for advice before taking this medicine.

DRUG INTERACTIONS:
The main metabolic pathway of Domperidone is through CYP3A4. In vitro data suggest that the concomitant use of drugs that significantly inhibit this enzyme may result in increased plasma levels of Domperidone.
With the combination of oral Domperidone 10mg four times daily and ketoconazoie 200mg twice daily, a mean QTc prolongation of 9.8 msec was seen over the observation period, with changes at individual time points ranging from 1.2 to 17.5 msec. With the combination of Domperidone 10mg four times daily and oral erythromycin 500mg three times daily, mean QTc over the observation period was prolonged by 9.9 msec, with changes at individual time points ranging from 1.6 to 14.3 msec. Both the Cmax and AUC of Domperidone at steady state were increased approximately three-fold in each of these interaction studies.

ADVERSE EFFECTS:
The adverse reactions are rare: exceptionally some transient intestinal cramps have been reported.
Extrapyramidal phenomenon are rare in young children and exceptional in adults; they reverse spontaneously and completely as soon as the treatment is stopped. As the pituitary gland is located out side the blood brain barrier. Domperidone may induce an increase to the plasma prolactin level. In rare cases this hyperprolactinaemia may give rise to neuro-endocrinological phenomenon such as galactorrhoea and gynaecomastia. When the blood brain barrier is immature (as in infants) or impaired the possible occurrence of neurological side effects can not be totally excluded. Rare allergic reactions, such as rash and urticaria have also been reported.

OVERDOSE:
Symptoms: Symptoms of overdosage may include agitation, altered consciousness, convulsions, disorientation, somnolence and extrapyramidal reactions.
Treatment: There is no specific antidote to Domperidone, but in the event of overdose, gastric lavage as well as the administration of activated charcoal, may be useful. Close medical supervision and supportive therapy is recommended.

Dosage:
As prescribed by the physician.

INSTRUCTIONS:
Store in a dry place below 30°C and protect from sunlight. Keep out of reach of children.
To be sold on prescription of a registered medical practitioner only.

PRESENTATION:
Perimo Suspension: 120ml suspension filled in amber colored PET bottle.

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔
ہدایات: خشک جگہ پر ۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔
بچوں کی دسترس سے دور رکھیں۔سورج کی روشنی سے بچائیں۔
صرف مستند ڈاکٹر کے نسخہ پر فروخت کریں۔

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ISO 9001:2015 Certified Company