บริษัท ยูนีซัน จำกัด
UNISON LABORATORIES CO., LTD.

Healthcare Service Since 1956

39 หมู่ที่ 4 ตำบลคลองอุดมชลจร อำเภอเมืองฉะเชิงเทรา จังหวัดฉะเชิงเทรา 24000 โทรศัพท์ 038-564930-32 โทรสาร 038-564929
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15 cm. FRONT

27 cm.

Print : Fit to Page

RABUGEN Suspension

ANTI-EMETIC/ DOPAMINERGIC BLOCKING AGENT

Each 5 mL contains:

Domperidone 5 mg

PRODUCT DESCRIPTION:

White suspension

MECHANISM OF ACTION:*

Pharmacology

Dopaminergic blocking agents: Gastrointestinal emptying (delayed) adjunct; peristaltic stimulant: The gastroprokinetic properties of Domperidone are related to its peripheral dopamine receptor blocking properties. Domperidone facilitates gastric emptying and decreases small bowel transit time by increasing esophageal and gastric peristalsis and by lowering esophageal sphincter pressure.

Antiemetic: The antiemetic properties of dopamine are related to its dopamine receptor blocking activity at both the chemoreceptor trigger zone and at the gastric level.

Pharmacokinetics

It is rapidly absorb, does not cross the blood brain barrier and has very high protein binding. It undergoes first pass and gut wall metabolism. It is metabolized by hydroxylation and oxidative N-dealkylation. Elimination half life is about 7 hours after oral administration. It is excreted through renal (31%) and feces (66%) following an oral dose of 40 mg.

INDICATION:

1.The dyspeptic symptom complex that is often associated with delayed gastric emptying, gastro-esophageal reflux and esophagitis:

- Epigastric sense of fullness, early satiety, feeling of abdominal distention, upper abdominal pain;
- Bloating, eructation, flatulence
- Nausea and vomiting
- Heartburn with or without regurgitations of gastric contents in the mouth

2. Nausea and vomiting of functional, organic, infectious or dietetic origin or induced by radiotherapy or drug therapy. A specific indication is nausea and vomiting induced by dopamine agonists as used in Parkinson's disease (such as L-dopa and bromocriptine)

DOSAGE AND ADMINISTRATION:

Oral

It is recommended to take oral RABUGEN Suspension before meals. If taken after meals, absorption of the drug is somewhat delayed.

1. Adults and adolescents (over 12 years and weighing 35 kg or more)

10 mL to 20 mL (of oral suspension containing Domperidone 1 mg per mL) three to four times per day, with a maximum daily dose of 80 mL.

2. Infants and Children

0.25 - 0.5 mg/kg three to four times per day with a maximum daily dose of 2.4 mg/ kg (but do not exceed 80 mg per day)

PRECAUTION:

Use during lactation

The total amount of Domperidone excreted in human breast milk is expected to be less than 7µg per day at the highest recommended dosing regimen. It is not known whether this is harmful to the newborn. Therefore breast-feeding is not recommended for mothers who are taking RABUGEN.

Use in infants

Neurological side effects are rare (see "Side Effects" section). Since metabolic functions and the blood-brain barrier are not fully developed in the first months of life the risk of neurological side effects is higher in young children. Therefore, it is recommended that the dose be determined accurately and followed strictly in neonates, infants, toddlers and small children.

Overdosing may cause extrapyramidal symptoms in children, but other causes should be taken into consideration.

Use in liver disorders

Since Domperidone is highly metabolized in the liver, RABUGEN should be not be used in patients with hepatic impairment.

Renal insufficiency

In patients with severe renal insufficiency (serum creatinine > 6 mg/100 mL, i.e.> 0.6 m mol/L) the elimination half-life of Domperidone was increased from 7.4 to 20.8 hours, but plasma drug levels were lower than in healthy volunteers. Since very little unchanged drug is excreted via the kidneys, it is unlikely that the dose of a single administration needs to be adjusted in patients with renal insufficiency. However, on repeated administration, the dosing frequency 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.

Use with Ketoconazole

A slight increase of QT interval (mean less than 10 msec) was reported in a drug-drug interaction study with oral Ketoconazole. Even if the significance of this study is not fully clear, alternative the rapeutic options should be considered if antifungal treatment is required. (See "Drug Interaction Section).

Product Name	Code No.	Dimension	Packaging Type	Thickness
RABUGEN Susp.	IRML 0022	W 15 x L 27 cm.	กระดาษอาร์ต	60 g (0.08 mm.)

PM Specification

Designed by:

Checked by:

Approved by: (Only Pattern and Color)

Rabugen Susp._Insert_Front_IRML 0022_By...Ja
11/07/12

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PREGNANCY AND LACTATION:
Studies have not been done in humans. Not recommended for used during pregnancy unless the benefit outweighs the potential hazard.
It is distributed into breast milk. Low concentrations of Domperidone are found in the breast milk. Therefore, nursing is not recommended by mothers receiving Domperidone unless the expected benefits outweigh any potential risk.

SIDE EFFECT:
Immune System Disorder: Very rare; Allergic reaction
Endocrine disorder: Rare; increased prolactin levels
Nervous system disorders: Very rare; extrapyramidal side effects
Gastrointestinal disorders: Rare; gastro-intestinal disorders, including very rare transient intestinal cramps
Skin and subcutaneous tissue disorders: Very rare; urticaria
Reproductive system and breast disorders: Rare; galactorrhoea, gynecomastia, amenorrhea.
As the hypophysis is outside the blood brain barrier, Domperidone may cause an increase in prolactin levels. In rare cases this hyperprolactinaemia may lead to neuroendocrinological side effects such as galactorrhea, gynecomastia and amenorrhea. Extrapyramidal side effects are very rare in neonates and infants, and exceptional in adults. These side effects reverse spontaneously and completely as soon as the treatment is stopped.

CONTRAINDICATION:
Except under special circumstances, this medication should not be used when the following medical problems exists: Gastrointestinal hemorrhage, mechanical obstruction or perforation; Hepatic impairment; Sensitivity to Domperidone; Prolactinoma

DRUG INTERACTION:
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. In vivo interaction studies with Ketoconazole revealed a marked inhibition of Domperidone's CYP3A4 mediated first pass metabolism by Ketoconazole. A pharmacokinetic study has demonstrated that the AUC and the peak plasma concentration of Domperidone is increased by a factor 3 when oral Ketoconazole is administered concomitantly (at steady state). A slight QT prolonging effect (mean less than 10 msec) of this combination was detected, which was greater than the one seen with Ketoconazole alone. A QT prolonging effect could not be detected when Domperidone was given alone in patients with no co-morbidity, even at high oral doses (up to 160 mg/day).
The results of this interaction study should be taken into account when prescribing Domperidone concomitantly with strong CYP3A4 inhibitors: for example: Ketoconazole, Ritonavir and Erythromycin.

OVERDOSE AND TREATMENT:
The following are the symptoms of Domperidone overdosage: Arrhythmia, drowsiness, disorientation, extrapyramidal reactions, and hypotension.
Note: Symptoms are self-limiting and disappears within 24 hours.
There is no specific antidote or specific agent for Domperidone overdose. However, anticholinergic agents, antiparkinsonian medications, or antihistamines with anticholinergic properties may be useful in controlling the extrapyramidal reactions associated with Domperidone toxicity.
To enhance elimination: Gastric lavage as well as the administration of activated charcoal may be useful in facilitating the elimination of Domperidone.
Supportive care: Close observation and supportive therapy are recommended.

SHELF LIFE:
Two (2) years

STORAGE:
Store at temperature of not more than 30°C.

SUPPLY:
Bottle 30 mL

Manufactured by:
UNISON LABORATORIES CO., LTD.
39 Moo 4, Klong Udomcholjorn, Muang Chachoengsao,
Chachoengsao 24000 Thailand

Marketing Authorization Holder/ Importer:
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11400 Ayer Itam, Penang, Malaysia

C-ML/040512-04(MJ)
(emc-medicines; * USPDI: Micromedex Healthcare Series 2006)

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