RABUGEN (Suspension)

Each teaspoonful (5 ml) Suspension contains:
Domperidone 5 mg

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What is RABUGEN (Suspension)?

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.

Domperidone is 5-chloro-1-[1-[3-(2,3- dihydro-2-oxo-1*H*-benzimidazol-1-yl)propyl]piperidin-4-yl]-2,3dihydro-1*H*-benzimidazol-2-one, The empirical formula of Domperidone is $C_{22}H_{24}ClN_5O_2$ and its molecular weight is 425.9.

How much strength of RABUGEN (Suspension) is available?

RABUGEN (Suspension) is available at the strength of 5 mg per 5 ml – White color Suspension. It is supplied as PET bottle of 30 ml.

What is RABUGEN (Suspension) for?

Gastritis, chronic and subacute (treatment): Domperidone is indicated for treating symptoms associated with upper gastrointestinal motility disorders caused by chronic and subacute gastritis.
Gastroparesis, diabetic (treatment): Domperidone is indicated for treating symptoms associated with upper gastrointestinal motility disorders caused by diabetic gastroparesis.
Gastrointestinal symptoms due to dopamine agonist therapy (prophylaxis): Domperidone is indicated to prevent gastrointestinal symptoms associated with the use of dopamine agonist antiparkinsonian agents.

When should you not take RABUGEN (Suspension)?

Except under special circumstances, this medication should not be used when the following medical problem exists:
Gastrointestinal hemorrhage, mechanical obstruction or perforation (stimulation of gastrointestinal motility may aggravate these conditions)
Hepatic impairment (domperidone undergoes extensive first-pass metabolism. Drug accumulation may occur in patients with hepatic impairment)
Sensitivity to domperidone, Prolactinoma (domperidone may contribute to excessively high serum concentrations of prolactin in patients with a prolactin-releasing pituitary tumor).

How much and how often should you use RABUGEN (Suspension)?

Oral
Usual Adult Dose
Upper gastrointestinal motility disorders:
2 teaspoonful (10 mg base) 3 to 4 times a day 15 to 30 minutes before meals and at bedtime, if required.
Nausea and vomiting associated with dopamine agonist antiparkinsonian agents:
4 teaspoonful (20 mg base) 3 to 4 times a day.
Usual adult prescribing limits
Up to 20 mg 3 to 4 times a day.
Usual Pediatric Dose
Dosage has not been established.
Usual Geriatric Dose
See usual adult dose.

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❖ **What are the possible side effects of RABUGEN (Suspension)?**

Note: Some of the side effects associated with domperidone are an extension of its dopamine antagonist properties. Majorities of these side effects resolve spontaneously during continued therapy or are tolerated. However, more serious or troublesome side effects (e.g., galactorrhea, gynecomastia, or menstrual irregularities) can be dose-related and will respond to lowering the dose or discontinuing therapy.

Those indicating need for medical attention only if they continue or are bothersome
Incidence less frequent
CNS effects (dry mouth; headache), conjunctivitis(itching, redness, pain, or swelling of eye), endocrinological effects (hot flushes; menstrual irregularities), galactorrhea (breast milk flowing from the nipple), gynecomastia (excessive development of the breast in the male), mastalgia (pain in the breast), pruritas (itching), rash, stomatitis (swelling of the mouth), urticaria (hives).

Incidence rare
Asthenia (lack or loss of strength), CNS effects (dizziness; irritability; nervousness; thirst), change in urinary frequency, edema(swelling of face, hands, lower legs, or feet), extrapyramidal effects (difficulty in speaking; loss of balance or muscle control), astrointestinal effects (abdominal cramps; change in appetite; constipation; diarrhea; heartburn), leg cramps, lethargy (drowsiness; mental dullness ; sluggishness; tiredness; weakness), palpitations (fast, irregular, pounding, or racing heartbeat or pulse), dysuria
(burning, difficult, or painful urination).
Note: Extrapyramidal side effects will usually reverse spontaneously as soon as treatment is stopped.

❖ **What other medicine or food should be avoided while taking RABUGEN (Suspension)?**

Note: Combinations containing any of the following drug classes, depending on the amount present, may also interact with this medication.
Anticholinergic drugs (concomitant administration of anticholinergic agents may minimize the effects of domperidone)
Azole antifungals (the main metabolic pathway of domperidone is through CYP3A4; as inhibitors of CYP3A4, azole antifungals can block the metabolism of domperidone, resulting in increased plasma concentrations of domperidone; caution is indicated in the combined use of domperidone and azole antifungals).
Human immunodeficiency virus (HIV) protease inhibitors (the main metabolic pathway of domperidone is through CYP3A4; as inhibitors of CYP3A4, HIV protease inhibitors can block the metabolism of domperidone, resulting in increased plasma concentrations of domperidone; caution is indicated in the combined use of domperidone and HIV protease inhibitors)
Macrolide antibiotics (the main metabolic pathway of domperidone is through CYP3A4; as inhibitors of CYP3A4, macrolide antibiotics can block the metabolism of domperidone, resulting in increased plasma concentrations of domperidone; caution is indicated in the combined use of domperidone and macrolide antibiotics).
Monoamine oxidase (MAO) inhibitors (use caution when using domperidone with MAO inhibitors)
Nefazodone (the main metabolic pathway of domperidone is through CYP3A4; as an inhibitor of CYP3A4, nefazodone can block the metabolism of domperidone, resulting in increased plasma concentrations of domperidone; caution is indicated in the combined use of domperidone and nefazodone)
Sustained-release or enteric-coated formulations of drugs (since domperidone enhances gastric and small intestinal motility, it may accelerate absorption of drugs from the small bowel while slowing absorption of drugs taken up from stomach, particularly those with sustained-release or enteric-coated formulations)

❖ **What should you do if you miss a dose of RABUGEN (Suspension)?**

Taking as soon as possible; not taking if almost time for next dose; not doubling doses.

❖ **How should you keep RABUGEN (Suspension)?**

Store at temperature not exceeding 30°C, in a well-closed container.

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❖ **What are the signs and symptoms of RABUGEN (Suspension) overdose?**

The following are the symptoms of Domperidone overdosage: Arrhythmia, drowsiness, disorientation, extrapyamidal reactions, hypotension.
Note: Symptoms are self limiting and disappears within 24 hours.

❖ **What to do when you have taken more than the recommended dosage of RABUGEN (Suspension)?**

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.

❖ **What care that should be taken when taking RABUGEN (Suspension)?**

Carcinogenicity/Tumorigenicity
Studies conducted in rodents demonstrate that chronic administration of dopamine receptor blocking agents result in an increase in mammary neoplasms. However, neither clinical nor epidemiological studies conducted to date have shown an association between long-term administration of these medications and mammary tumorigenesis; the available evidence is considered too limited to be conclusive at this time.
Pregnancy
Studies have not been done in humans. Not recommended for used during pregnancy unless the benefit outweighs the potential hazard. Animal studies have not shown that domperidone has any teratogenic or primary embryotoxic effects on the fetus.
Breast-feeding
It is distributed into breast milk. Low concentrations of domperidone are found in the breastmilk. Therefore, nursing is not recommended by mothers receiving domperidone unless the expected benefits outweigh any potential risk.
Pediatrics
The safety and efficacy in children have not been established.

❖ **When should you consult your doctor?**

see Care That Should Be Taken Section.

❖ **RABUGEN (Suspension) is manufactured by:**

UNISON LABORATORIES COMPANY, LIMITED
160 Soi Onnuch Sukhumvit Rd.,
Ladkrabung, Bangkok 10520 THAILAND

❖ **Imported and distributed by:**

MEDISPEC (M) SDN BHD
No. 55 & 57, Lorong Sempadan 2, (Off Boundary Road)
11400 Ayer Itam, Penang, MALAYSIA

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