

VOVADO

(Itopride HCl)
50mg Tablets

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DESCRIPTION:

VOVADO (Itopride HCl) is a prokinetic benzamide derivative. It inhibits dopamine and have a gastrokinetic effect.

QUALITATIVE AND QUANTITATIVE COMPOSITION:

VOVADO (Itopride HCl) is available for oral administration as:

VOVADO Tablet 50mg

Each film coated tablet contains:
Itopride Hydrochloride.....50mg
(Product Specs.: Sigma)

CLINICAL PHARMACOLOGY:

Mechanism of Action:

VOVADO (Itopride hydrochloride) activates gastrointestinal propulsive motility due to its dopamine D₂ antagonizing activity and acetylcholinesterase inhibitory activity. Itopride activates acetylcholine release and inhibits its degradation.

Higher acetylcholine increases GI peristalsis, increases the lower oesophageal sphincter pressure, stimulates gastric motility, accelerates gastric emptying and improves gastro-duodenal coordination.

VOVADO (Itopride hydrochloride) also has antiemetic action through interaction with D₂ receptors located in the chemoreceptor trigger zone.

PHARMACOKINETICS:

Absorption:

Itopride HCl is rapidly and almost completely absorbed from the gastrointestinal tract. Relative bioavailability is calculated to be 60% due to liver first pass metabolism. Peak plasma levels are reached after 0.5-0.75 hr after 50mg of itopride HCl.

Following multiple oral doses ranging from 50-200 mg 3 times daily, itopride HCl and its metabolites showed linear pharmacokinetics over a treatment period of 7 days, with minimal accumulation.

Distribution:

Approximately 96% of itopride HCl is bound to plasma proteins. Albumin accounts for most of the binding. α 1-acid glycoprotein accounts for <15% of binding.

Metabolism:

Itopride HCl undergoes extensive hepatic metabolism in humans. Three metabolites have been identified, of which only one exerts minor activity without pharmacological relevance (approximately 2-3% of that of itopride HCl). The primary metabolite in humans is the N-oide generated by oxidation of the tertiary amine N-dimethyl group. Itopride HCl is metabolized by a flavin-dependent monooxygenase (FMO3).

Excretion:

Itopride HCl and its metabolites are primarily excreted in the urine. The urinary excretions of itopride HCl and its N-oide were 3.7% and 75.4%, respectively, after oral administration of a single therapeutic dose. The terminal phase half-life of itopride HCl is approximately 6 hrs.

Special Population:

Children:

Safety of itopride HCl in children <16 years has not been established.

Elderly:

Appropriate caution should be exercised in the administration and monitoring of itopride HCl in elderly patients reflecting the greater frequency of decreased hepatic, renal function and of concomitant disease or other drug therapy.

Patients with fish odor syndrome:

The abundance and efficiency of the human FMO-isozymes can be subject to genetic polymorphisms, which can lead to a rare autosomal recessive condition known as trimethylaminuria. Therefore, the half-life of itopride HCl may be longer in trimethylaminuria (fish odor syndrome) patients.

INDICATIONS:

VOVADO (Itopride HCl) Tablet is used in the treatment of gastrointestinal symptoms of:

- Functional Dyspepsia
- Non-ulcer Dyspepsia (chronic gastritis) i.e.
 - Sensation of bloating.
 - Early satiety.
 - Upper abdominal pain or discomfort.
 - Anorexia.
 - Heartburn.
 - Nausea.
 - Vomiting.

DOSEAGE AND METHOD OF ADMINISTRATION:

The recommended dose of **VOVADO** (Itopride hydrochloride) for adult patients is 150 mg daily (one tablet 50 mg) taken orally three times a day before meals).

The dose may be reduced according to the patient's age and symptoms

CONTRAINDICATIONS:

VOVADO is contraindicated in patients;

- With known hypersensitivity to itopride HCl.
- In whom an increase in gastrointestinal motility could be harmful e.g., gastrointestinal hemorrhage, mechanical obstruction or perforation.

PRECAUTIONS:

- Itopride HCl should be used with caution since it enhances the action of acetylcholine. Also, caution is advised in treatment of patients suffering from Parkinson's disease and conditions involving dopamine regulation issues.

- Itopride HCl should not be used aimlessly for a long term when no improvement of gastrointestinal symptoms is observed.

Pregnancy:

Itopride HCl should be used in pregnant women or in women who may possibly be pregnant only if the expected therapeutic benefits outweigh the possible risks associated with treatment. The safety of itopride HCl in pregnant women has not been established.

Lactation:

VOVADO is excreted in milk, and because of the potential for adverse reactions in nursing infants, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

DRUG INTERACTIONS:

- Itopride HCl has gastrokinetic effects, therefore, it could influence the absorption of concomitantly orally administered drugs. Particular caution should be taken with drugs with a narrow therapeutic index, sustained-release or enteric-coated formulations.
- Concomitant administration with anticholinergic drugs e.g. Tiquizium bromide, scopolamine butyl bromide, timpepidium bromide, etc. may reduce the action of Itopride HCl.

ADVERSE REACTIONS:

The following adverse events have been reported in patients receiving itopride HCl:

Blood and Lymphatic System Disorders:

Leukopenia and thrombocytopenia.

Immune System Disorders:

Anaphylactoid reaction.

Endocrine Disorders:

Increased prolactin level and gynecomastia.

Nervous System Disorders:

Dizziness, headache and tremor.

Gastrointestinal Disorders:

Diarrhea, constipation, abdominal pain, increased saliva, and nausea.

Hepatobiliary Disorder:

Jaundice.

Skin and Subcutaneous Tissue Disorders:

Rash, redness and itching.

Investigations:

Increased AST (SGOT), increased ALT (SGPT), increased gamma-GTP, increased alkaline phosphatase and increased bilirubin.

OVERDOSAGE:

There have been no reported cases of overdose in humans. In case of excessive overdose, the usual measures of gastric lavage and symptomatic therapy should be applied.

INSTRUCTIONS:

- Store below 30°C
- Protect from light & moisture
- Keep out of reach of children
- To be sold on prescription of a registered medical practitioner.*

HOW SUPPLIED:

VOVADO (Itopride HCl) 50mg Tablets are available in pack of 10's.

**SIGMA
PHARMA**

Manufactured By:
SIGMA PHARMA (International Private Limited.)
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دیکھنا اور پانی سے چائیں۔ چول کی کچل سے دور رکھیں۔
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