Winpride 50mg Tablets

(Itopride HCl)

ون پرائد

(آئیٹوپرائیڈ ہائیڈروکلورائیڈ)

Read all of this leaflet carefully before you start taking this medicine

Keep this leaflet you may need to read it again.

If you have further question, please ask your doctor or your pharmacist.

This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

Please note that your doctor may have prescribed this medicine for another illness or at a dose other than those mentioned in this leaflet. If this is the case, please follow the instructions of your doctor

COMPOSITION

Each tablet contains 50mg of itopride hydrochloride

INDICATIONS

Winpride (Itopride Hydrochloride) 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

CONTRA INDICATIONS

Winpride (Itopride Hydrochloride) is contraindicated in patients with known hypersensitivity to itopride Hydrochloride or any of the Excipients. WINPRIDE should not used in patients in whom an increase in gastroinestinal motility could be harmful e.g. gastrointestnal Haemorrhage, mechanical obstruction or perforation.

DOSAGE AND ADMINISTRATION

The recommended dose of WINPRIDE (itopride Hydrochioride) for adult patients is 150mg daily [one tablet (50mg) taken orally three times a day before meals]. The dose may be reduced according to the patient's age and symptoms (See Precautions).

CLINICAL PHARMACOLOGY

Mechanism of Action Winpride (Itopride Hydrochloride) activates gastrointestinal propulsive motility due to its dopamine D2 antagonizing activity and acetyl-cholinesterase inhibitory activity Itopride activates acetylcholine release and inhibits its degradation.

Pharmacokinetics

- Winpride (Itopride Hydrochloride) also has antiemetic action through interaction with D2 receptors located in the chemoreceptor trigger zone.
- Winpride (Itopride Hydrochloride) has been shown to accelerate gastric empty in human.
- The action of Winpride is highly specific for the upper gastrointestinal tract. Winpride does not affect serum gastrin levels

Pharmacokinetic Properties

absorption Winpride (Itopride Hydrochloride) is rapidly and almost completely absorbed from the gastronitestinal tract. Relative bioavailability is calculated to be 60% due to liver first pass metabolism. There is no effect of food on bioavailabilty. Peak plasma levels (Cmax. 0.28 ug/ml) are reached after 0.5 to 0.75 hours after 50 mg of itopride Hydrochioride.

Following multiple oral doses ranging from 50mg to 200mg tid. Itopride Hydrochloride and its metabolites showed linear pharmacokinetics over treatment period of seven days, with minimal accumulation.

Distribution

Approximately 96% of Winpride (Itopride Hydrochloride) is bound to plasma proteins. Albumin accounts for most of the binding Alpha-1 acid-glyeoprotein account for less than 1.5% of binding

Metabolism

Winpride (Itopride hydrochloride) undergoes extensive hepatic metabolism in humans. Three (3) metabolites have been identified of which only one exerts minor activity without pharmacological relevance (approximately 2-3 % of that of hopride). The primary metabolite in hurmans is the N-oxide, generated by oxidation of the tertiary amine N-dimethyl group. Winpride is metabolized by a flavin dependent mono oxygenase (FMQ3). The abundance and efficiency of the human FMO-isozymes can be subject to gentic polymorphisms, which can lead to a rare dutosomal recessive condition known as trimethylammuria (fishodor syndrome).

Excretion

Winpride (Itopride HCl and its metabolite are primarily excreated in the urine.The urinary excretions of Winpride and its N-oxide were 3.7% and 75.4%, respectively, in healthy subjects after oral administration of a single theraperapeutic dos. The terminal phase half-life of Winpride was approximately six: (6) hours

PRECAUTIONS

General

Winpride (Itopride Hydrochloride) enhances the action of acetylcholine and may produce cholinergic side effects.

DRUG INTERACTIONS

Metabolic interactions are not expected since Winpride (Itopride Hydrochloride) is primarily metabolized by fluvine monoxy genase and not by CYP450 no change in protein binding havebeen seen with co-administration of warfarin, diazepam, diclofenac sodium, ticlopidine hydrochloride, nifedipine, and nicardipine hyrdochlordie. Since Winpride has gastrokinetic effect it could influence the absorption of concomitantly orally administered drugs.

Hepato-billary disorders

Particular caution Should be taken with drugs with a narrow therapetic index, sustained release or enteric coated formulation. Anti-uicer drugs like cimetidine, ranitidine, teprenone and certaxate do not affect the prokinetic action of itopride. Anticholinergic drugs may reduce the action of WINPRIDE.

PREGNANCY & LACTATION

There are no adequate and well controlled studies in pregnant women. Therefore, Winpride (Itopride hydrochloride) should not be used during pregnancy unless the benefits outweight the potential risks. There are no known effect of Winpride on labor or delivery. Because Winpride is excreated 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.

PEDIATRIC USE

Safety of this product in children under the age of 16 has not been established.

GERIATRIC USE

In general, appropriate caution should be exercised in elderly patients because the greater frequency of decreased hepatic, renal function, and of concomitant disease or other drug therapy.

SIDE EFFECTS

The following adverse effects have been reported in patients receiving Winpride (Itopride Hydrochloride).

Blood and lymphatic system disorders

Leukopenia and thrombocytopenia

Immune system disorder

Anaphylacloid reaction

Endocrine disorders

Increased prolactine level and gynecomastia.

Nervous system disorders.

Dizziness headache and tremor.

Gastrointestinal disorders

Diarrhea, constipation, abdominal pain, increased saliva, nausea and 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 has been no reported cases of overdose in human. In case of excessive overdose the usual measures of gastric lavage and symptomatic therapy should be applied.

STORAGE

Store between 15°C.to 30°C. Do not use beyond the expiration date.

HOW SUPPLIED

Winpride (Itopride Hydrochloride) tablets are supplied in blister pack of 1 x 10's

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

ٹیبلٹ کو توڑے یا چبائے بغیر پانی سے نگل لیں۔

ہدایات: ٹھنڈی اور خشک جگہ پر بچوں کی دسترس سے دور رکھیں اور سورج کی روشنی سے بچائیں۔

Please read the contents carfully before use.

This package insert is continually updated from time to time

ORTA SINCE 1954

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