Leaflet size as per (**Olabex Capsule**)
WnsFeild Pharmaceuticals

Front

DERBY™
(ITOPRIDE HCI)

ڈربی

COMPOSITION:
DERBY Tablet 50 mg:
Each film coated tablet contains:
Itopride Hydrochloride ..... 50 mg.
Product Specs.: Innovator

DERBY Tablet 150 mg:
Each film coated tablet contains:
Itopride Hydrochloride ..... 150 mg.
Product Specs.: Innovator

DESCRIPTION:
Itopride is a dopamine D2 antagonist with acetylcholinesterase inhibitory actions. It has been formulated to provide immediate release. It is chemically designated as N-1 4-(2-(Dimethylamino) ethoxy]benzyl]-,4- dimethoxyl-bezamide.

CLINICAL PHARMACOLOGY:
Mechanism of Action: Itopride has anticholinesterase (ACHE) activity as well as dopamine D2 receptor antagonistic activity. It is well established that M3 receptors exist on the smooth muscle layer throughout the gut and acetylcholine (ACh) released from enteric nerve endings stimulates the contraction of smooth muscle through M3 receptors. The enzyme AChE hydrolyses the released ACh, inactivates it and thus inhibits the gastric motility leading to various digestive disorders. Besides ACh, dopamine is present in significant amounts in the gastrointestinal tract and has several inhibitory effects on gastrointestinal motility, including reduction of lower esophageal sphincter and intragastric pressure. These effects appear to result from suppression of ACh release from the myenteric motor neurons and are mediated by the D2 subtype of dopamine receptors. Itopride, by virtue of its dopamine D2 receptor antagonism, removes the inhibitory effects on Ach release. It also inhibits the enzyme AchE which prevents the degradation of ACh. The net effect is an increase in ACh concentration, which in turn, promotes gastric motility, increases the lower esophageal sphincter pressure, accelerates gastric emptying and improves gastro-duodenal coordination. This dual mode of action of Itopride is unique and different from the actions of other prokinetic agents available in the market.

INDICATIONS:
Itopride is used in the treatment of gastrointestinal symptoms:
- Functional Dyspepsia
- Non-Ulcer Dyspepsia
- Sensation of bloating
- Early Satiety
- Upper abdominal pain or discomfort
- Anorexia
- Heartburn
- Nausea and Vomiting

DOSAGE AND ADMINISTRATION:
The recommended dose of Itopride for adult patients is 150 mg daily [one tablet (50 mg) taken orally three times a day before meal]. The dose maybe reduced according to the patient age and symptoms. In clinical studies, itopride has been administered up to 8 weeks.

PRECAUTIONS:
Itopride enhances the action of acetylcholine and may produce cholinergic side effects.

SPECIAL POPULATIONS:
Pregnancy & lactation:
There are no adequate and well- controlled studies in pregnant women therefore Itopride should not be used during pregnancy unless the benefits outweigh the potential risk. There are no known effects of Itopride on labor or delivery. Because Itopride 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.

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Children: Safety of itopride in children <16 years has not been established.
Elderly:
In general, appropriate caution should be exercised in the administration and monitoring of itopride hydrochloride in elderly patients reflecting the greater frequency of decreased hepatic, renal function and of concomitant disease or other drug therapy.

DRUG INTERACTIONS:
Metabolic interactions are not expected since Itopride is primarily metabolized by flavine monooxygenase and not be CYP450. No changes in protein binding have been seen with co-administration of warfarin, diazepam, diclofenac sodium, tictopidine hydrochloride, nifedipine, and nicardipine hydrochloride. Since Itopride has gastrokinetic effects, 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. Anti-ulcer drugs like cimetidine, ranitidine, teorenone and cetraxate do not affect the prokinetic action of Itopride. Anticholinergic drugs may reduce the action of Itopride.

ADVERSE REACTIONS:
The following adverse events have been reported in patients receiving Itopride.:
- **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 tremors
- **Gastrointestinal disorders:** Diarrhea, constipation, abdominal pain, increased saliva and nausea
- **Hepato-Biliary disorders:** Jaundice
- **Skin and subcutaneous tissue disorders:** Rach, redness, and itching

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

INSTRUCTIONS:
- Store below 30°C.
- Protect from heat, sunlight & moisture.
- Keep out of the reach of children.
- To be sold on the prescription of a registered medical practitioner only.

PRESENTATION:

DERBY Tablet 50 mg	:	Pack of 3 x 10 tablets.
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ہدایات:
۳۰ درجہ سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔
گرمی، دھوپ اور نمی سے بچائیں۔
بچوں کی پہنچ سے دور رکھیں۔
صرف مستند ڈاکٹر کے نسخہ پر فروخت کریں۔

Manufactured by:
WnsFeild Pharmaceuticals.
Plot # 122, Block A, Phase V, Industrial Estate, Hattar, Pakistan.

FOR FURTHER INFORMATION PLEASE CONTACT:

CCL
Marketed by:
CCL Pharmaceuticals (Pvt.) Ltd.
62 Industrial Estate, Kot Lakhpat, Lahore, Pakistan.

zoom view Front

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