Summary of Product Characteristics

1. Name of the medicinal product:
ITOFAST (Itopride Hydrochloride Capsules 150mg)

2. Qualitative and quantitative composition
Each hard gelatin capsule contains:
Itopride Hydrochloride.....150mg

For a list of excipients, see Section 6.1.

3. Pharmaceutical form
Capsule: A Red/Clear Transparent colour hard gelatin capsule containing white color sustained release pellets.

4. Clinical particulars

4.1 Therapeutic indications
Treatment of gastrointestinal symptoms of functional, non-ulcer dyspepsia, like feelings of bloating, gastric fullness, discomfort to pain in epigastrium, anorexia, heartburn, nausea and vomiting.

4.2 Posology and method of administration
The recommended dose for adults is 150 mg daily, i.e. 1 capsule a day before a meal or as directed by a physician. Not recommended for children younger than 12 years.

4.3 Contraindications
Itofast capsules must not be used in patients in whom increased gastrointestinal motility could be harmful, e.g. in patients with gastrointestinal haemorrhage, mechanical obstruction or perforation.

4.4 Special warnings and precautions for use
Itopride potentiates acetylcholine action and can induce side anticholinergic effects.

4.5 Interaction with other medicinal products and other forms of interaction
No interaction was detected when itopride was administered concomitantly with warfarin, diazepam, diclofenac, ticlopidine, nifedipine and nicardipine. Drug-drug interactions that arise due to cytochrome P450 metabolism are not assumed because itopride is metabolised mainly by flavine monooxygenase.

4.6 Pregnancy and Lactation
Itopride can be used in pregnant women or women in that pregnancy cannot be excluded only if therapeutic benefits outweigh possible risks considerably. It is not recommended for breast-feeding women.

4.7 Effects on ability to drive and use machines

Although no effects on ability to drive and use machines have been found, impairment of alertness cannot be ruled out since dizziness may occur very rarely.

4.8 Undesirable effects

Headache, abdominal pain, diarrhoea and nausea are among those adverse reactions that have been most commonly reported in clinical trials.

Reporting of Suspected Adverse Reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

Healthcare professionals are asked to report any suspected adverse reactions via the national pharmacovigilance reporting system.

4.9 Overdose

Overdose was not experienced in humans. In case of overdose the usual measures of gastric lavage and symptomatic therapy should be applied.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Itopride activates the gastrointestinal propulsive motility by dopamine D2 receptors antagonistic action and acetylcholine esterase inhibitory action. Itopride activates acetylcholine release and inhibits its degradation.

5.2 Pharmacokinetic properties

Absorption: Itopride is absorbed rapidly and almost completely from gastrointestinal tract. Relative bioavailability about 60% is due to first-pass effect. Food does not affect bioavailability of the product. Distribution About 96% of itopride is bound on plasma proteins, mainly albumin. Less than 15% of itopride bound part is bound on alpha-1-acid-glycoprotein.Biotransformation Itopride is extensively metabolised in liver in humans. Three metabolites were identified of which only one manifests minor activity without pharmacological significance (about 2 to 3% of itopride effect. Elimination: Itopride and its metabolites are primarily excreted by urine.

5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber.

6. Pharmaceutical Particulars

6.1 List of Excipients

Hard gelatin capsule

6.2 Incompatibilities

Not applicable.

6.3 Shelf-Life

24 Months

6.4 Special Precautions for Storage

Store below 30°C. Protect from light & moisture.

6.5 Nature and Content of container

Commercial Presentation: 4's, 10's, 20's, 30's & 100's.
1x10's Alu-Alu Blister: Each Alu-Alu blister is packed with 10capsules in an opaque Alu-Alu blister
pack. 1 such Alu-Alu blister is packed in printed carton.

6.6 Special precautions for disposal and other handling

Not applicable

7. Marketing Authorization Holder

Innocia Lifesciences Pvt. Ltd.,
Block A, No.12, Balaji Nagar, Ambattur, Chennai-600 053,
India.

8. Marketing Authorization Number

H2022/CTD7894/2059ER

9. Date of first authorization/renewal of the authorization

22/07/2021

10. Date of revision of the text

22/07/2021