Core Safety Profile

Active substance:	**Lactitol**
Pharmaceutical form(s)/strength:	**Chewable tablets, 5g** **Oral solution, 66,67%** **Powder for oral solution, 100%**
P-RMS:	**AT/H/PSUR/0019/001**
Date of FAR:	**05.05.2010**

Annex I
Lactitol monohydrate
Agreed Core Safety Profile

4.3 Contraindications

Hypersensitivity to lactitol or to any of the excipients.
Importal produces its effect in the colon and is therefore contra-indicated in all cases where intestinal transit is not assured (intestinal occlusion, etc.). As with all laxatives, Importal should not be used in the case of any symptoms or suspicion of organic lesion of the digestive tract and in the case of any unexplained abdominal pain or rectal bleeding. Faecal impaction should be treated using alternative means prior to the use of laxatives.
Breastfed babies and infants with autosomal recessive hereditary fructose intolerance.
Importal is contra-indicated in galactosaemia. The incomplete metabolism of lactitol may result in the development of fructosemia and galactosaemia and their sequelae.
Preexisting fluid electrolytes imbalance.

4.4 Special warnings and precautions for use

- Prolonged use of laxatives without interruption should be avoided;
- All cases of chronic constipation should first be treated by fibre-rich diet, sufficient intake of fluids or physical activity;
- In order not to disturb the electrolyte balance caused by an overdose-induced diarrhoea, the physician should try at the onset of treatment to determine the optimal dosage (see 4.2. Posology and method of administration) to achieve one daily bowel movement in constipated patients and two daily bowel movements in cirrhotic patients.

Elderly or debilitated patients receiving long-term treatment with Importal should have their serum electrolytes monitored regularly.
As for all laxatives, pre-existing fluid electrolyte imbalance should be corrected before starting treatment.
Following treatment with Importal, hydrogen may accumulate in the bowel. Patients who need to undergo electrocauterisation procedures should therefore, have a thorough bowel cleansing with a non-fermentable solution.

- Patients who complain of nausea should be advised to take Importal during meal-times;
- In the case of ileostomy or colostomy Importal is not recommended. In cases of particularly stubborn constipation, a physician should be consulted.

Babies and infants: Importal should be used only if recommended by a physician.
Patients with rare hereditary problems of fructose intolerance, galactose intolerance, galactosaemia, glucose-galactose malabsortion or lactase deficiency should not use Importal.

4.5 Interactions with other medicinal products and other forms of interaction

Since antacids and neomycin can neutralise the stool acidifying effect of lactitol, they should not be given concomitantly with lactitol to cirrhotic patients with hepatic encephalopathy; both substances, however, do not alter the laxative effect in constipated patients.
Like all laxatives, Imporal may increase the potassium loss caused by other drugs (e.g., thiazo-diuretics, corticosteroids, carbenoxolone, amphothericin B). Potassium deficiency may enhance the risk of toxic effects of cardioglycosides in patients receiving concomitant therapy.
Lactitol has a negligible caloric value (2 kcal/g or 8.5 kJ/g) and has no effect on insulinaemia or blood glucose levels and can thus be administered to diabetic patients.

4.6 Pregnancy and lactation

Experience with Imporal in pregnant women is limited. Although animal experiments have shown no teratogenic potential, it is nevertheless recommended that, as for all drugs, during the first trimester of pregnancy, Imporal should only be used in the case of strict necessity.
Although the passage of lactitol into breast milk has not been studied, it appears unlikely to have any clinical relevance since it is only minimally absorbed.

4.7 Effects on ability to drive and use machines

Imporal has no influence on the ability to drive or use machinery.

4.8. Undesirable effects

At the start of treatment, Imporal may produce abdominal discomfort mainly flatulence and seldom abdominal pain or sometimes an abdominal distension. Such effects tend to diminish or disappear after a few days of regular intake of Imporal.
Occasionally nausea, gastrointestinal sounds abnormal or pruritus ani have been reported as well as vomiting in rare cases. Because of inter-individual variation, some patients may experience diarrhoea at the recommended dosage. A dosage reduction will overcome this.
Adverse reactions are listed below, by system organ class and frequency. Frequencies are defined as: very common (≥1/10), common (≥1/100 to <1/10), uncommon (≥1/1,000 to <1/100), rare (≥1/10,000 to <1/1,000) or very rare (<1/10,000).

Gastrointestinal disorders:
Very rare: vomiting, abdominal pain, abdominal discomfort, abdominal distension, diarrhea, pruritus ani, nausea, flatulence.
Not known: gastrointestinal sounds abnormal.

4.9. Overdose

Diarrhoea is a sign of overdose. It can be stopped by decreasing the dosage. It may also result in an alteration of serum electrolytes which may need correcting.