SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Loflatil 2 mg/125 mg Film Coated Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film coated tablet contains:
Loperamide Hydrochloride USP….. 2 mg
Simethicone USP ….. 125 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Film-coated tablets.
Yellow coloured, capsule shaped, film-coated tablets with a break line on one side.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Loflatil is indicated for symptomatic treatment of acute diarrhoea accompanied with abdominal discomfort, including bloating, spasmodic pain and meteorism.

4.2 Posology and method of administration

Posology

Adults:
The initial dose is 2 tablets singly, then it is used 1 tablet after each act of defecation, but not more than 4 tablets per day. The duration of usage is not more than 2 days.

Children above 12 years old:
The initial dose is 1 tablet singly, then it is used 1 tablet after each act of defecation, but not more than 4 tablets per day. The duration of usage is not more than 2 days.

Elderly patients:
The dose adjustment is not necessary for the treatment of elderly patients.

Kidney dysfunction:
The dose adjustment is not necessary for patients with kidney dysfunction.

Liver dysfunction:
Despite the fact that pharmacokinetic data on the effects of the preparation in patients with liver dysfunction is not available, Loflatil should be used with caution in such patients because of slowing of metabolism of the first passage. (see “Appropriate safety measures in administration”).

Children:
It is administered to children above 12 years old.

4.3 Contraindications

Individual hypersensibility to components of the preparation. Constipation, ileus. Patients with rare congenital forms of fructose intolerance, lactase deficiency, malabsorption of glucose-galactose or sucrase-isomaltase deficiency.
Loflatil is not used for primary therapy of patients with:

- acute dysentery, which is characterized by presence of blood in stool and fever;
- acute ulcerative colitis;
- pseudomembranous colitis associated with broad spectrum of antibiotics;
- bacterial enterocolitis caused by invasive microorganisms, including Salmonella, Shigella and Campylobacter;
- liver dysfunction necessary for metabolism of the preparation, as far as it may cause a relative overdose.

Loflatil must not be used at all if necessary to avoid the inhibition of peristalsis due to possible risk of significant complications, including ileus, megacolon and toxic megacolon.

4.4 Special warnings and precautions for use

Patients with diarrhea, especially children, may have dehydration and electrolyte imbalance. In such cases the most important measure is the use of replacement therapy to replenish fluids and electrolytes. In case of clinical effect absence within 48 hours the use of Loflatil preparation should be discontinued and a patient should consult a doctor to clarify the diagnosis.
Patients with secondary immunodeficiency syndrome, who use Loflatil in case of diarrhea, should immediately discontinue the treatment in case of first signs of abdominal distention. There are isolated reports of cases of toxic megacolon in AIDS patients with infectious colitis, both of viral and bacterial origin, during the treatment with Loperamide Hydrochloride.
Despite the fact that pharmacokinetic data for patients with liver dysfunction is not available, Loflatil should be used with caution in such patients because of slowing of metabolism of the first passage. Patients with liver dysfunction should be under close supervision of a physician in order to timely detect signs of toxic central nervous system.
Agents that prolong the transit time may cause the development of toxic megacolon in patients of this group.

Loflatil should not be used when it is necessary to avoid the inhibition of peristalsis. It is necessary to discontinue immediately the preparation use, if it is developed constipation, bloating or partial intestinal obstruction.

4.5 Interaction with other medicinal products and other forms of interaction

There is no information about clinical significant drug interaction of Loperamide Hydrochloride or Simeticone with other medicines.
There were reports on interactions with medicines, which have similar pharmacological properties. Agents that have inhibitory effects on central nervous system are not simultaneously used with Loflatil in children.
Co-administration of Loperamide (at a dose of 16 mg) with inhibitors of P-glycoprotein (quinidine, ritonavir) caused an increasing of plasma level of Loperamide by 2–3 times. Clinical significance of such pharmacokinetic interaction during administration of Loperamide at recommended doses (2 mg to 8 mg of maximum daily dose) is unknown.

4.6 Fertility, pregnancy and lactation

Experience of Loperamide and Simethicone use during pregnancy is limited, so the preparation can be administered only if the expected benefit to the mother overweights the potential risk to the fetus.

A small amount of Loperamide have been detected in breast milk, so Loflatil administration during lactation is not recommended.

4.7 Effects on ability to drive and use machines

During the preparation treatment it is necessary to avoid driving a motor transport and operating potentially dangerous mechanisms.

4.8 Undesirable effects

Below side effects are classified as follows: very common (≥ 1 / 10), common (≥ 1 / 100, <1 / 10); uncommon (≥ 1 / 1, 000, <1 / 100), rare (≥ 1 / 10 000, <1 / 1000); very rare (<1 / 10,000) including isolated reports.

Allergic reactions: uncommon – skin rash; very rare – urticaria, itch, isolated reports – angioedema, bullous eruptions (including Stevens-Johnson syndrome), erythema multiforme, toxic epidermal necrolysis, anaphylactic shock, anaphylactoid reaction.

Digestive tract: common – taste change, dry mouth, nausea, uncommon – constipation; very rare – megacolon (including toxic megacolon), intestinal obstruction, abdominal pain, vomiting, bloating, dyspepsia, meteorism.

Nervous system: uncommon – drowsiness, very rare – dizziness, depression of consciousness, depression, headache, tremor, fatigue.

Urinary system: isolated reports – urinary retention.

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 EFDA yellow Card Scheme, online at https://primaryreporting.who-umc.org/ET or toll-free call 8482 to Ethiopian food and drug authority (EFDA).

4.9 Overdose

Symptoms
In case of overdose (including overdose caused by liver dysfunction) it is possible a central nervous system depression (stupor, disorders of moving coordination, drowsiness, miosis, increasing of muscles tonus, respiratory depression) and paralytic ileus, urinary retention. In children the depression of CNS may occur more frequently.

Treatment
In case of overdose symptoms the patient should be introduced Naloxone as antidote. Since half-life of Loperamide is more than half-life of Naloxone (1 to 3 hours) it may be necessary an additional introduction of Naloxone. It is required a round-the-clock monitoring of respiratory function. It is necessary a close monitoring of patient's condition for not less than 48 hours to identify possible CNS depression.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antiperistaltic agents. Loperamide, combinations, ATC code: A07DA53

5.1 Pharmacodynamic properties

Loperamide Hydrochloride binds to opioid receptors of intestine wall that leads to inhibition of propulsive motility, slowing movement of intestinal content and enhancement of water resorption and electrolytes. Loperamide does not change physiological intestinal flora and improves the tone of anal sphincter that prevents fecal incontinence and reduces the amount of defecation urge to defecate.
Simethicone is an inert surface-active compound, which has defoaming properties and therefore relieves the symptoms associated with diarrhea, including bloating, abdominal discomfort, bloating and cramping.

The authority/EFDA will review new information on this medicinal product at least every year and this SmPC will be updated as necessary.

5.2 Pharmacokinetic properties

Average half-life period of Loflatil in human is 10.8 hours and varies 9 to 14 hours. Loperamide Hydrochloride is readily absorbed from the intestine, but is almost completely extracted and metabolised by liver, where it is conjugated and excreted with the bile as
conjugated metabolites. As a result of intense metabolism of the first passage plasma concentrations of unchanged Loperamide are very low. Loperamide metabolites are primarily excreted with faeces. Simethicone is not absorbed from the digestive tract at all.

5.3 Preclinical safety data

Not applicable

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Microcrystalline cellulose, Magnesium aluminium silicate, Lactose monohydrate, Dicalcium phosphate dihydrate, Stearic acid, Colloidal silicon dioxide, Croscarmellose sodium, Povidone K30, Polyvinyl alcohol, Talc, Titanium dioxide, PEG (Macrogol), Lecithin, Iron oxide yellow.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Store below 30°C.
Keep all medicines out of reach of children.

6.5 Nature and contents of container

10 tablets are packed in a blister. 1 or 10 such blisters are packed in a carton along with packaging insert (1x10's & 10x10's).

6.6 Special precautions for disposal <and other handling>

No special requirements for disposal.

7. MARKETING AUTHORISATION HOLDER

Kusum Healthcare Pvt. Ltd.
SP-289(A), RIICO Industrial Area,
Chopanki, Bhiwadi, Dist. Alwar, Rajasthan, India

8. MARKETING AUTHORISATION NUMBER(S)

06689/07094/NMR/2018

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

19 October 2021

10. DATE OF REVISION OF THE TEXT

08/2023

11. REFERENCES

SmPC published on electronic medicines compendium
https://www.medicines.org.uk/emc#gref

The MHRA published product information
https://products.mhra.gov.uk/

Human medicine European public assessment report
https://www.ema.europa.eu/en/medicines