07.2026

רופא/ה רוקח/ת נכבד/ה,

ברצוננו להודיעך על עדכון בעלון לרופא של:

Imodium Capsules

חומר פעיל:

Loperamide hydrochloride 2 mg

התוויה מאושרת:

IMODIUM is indicated for control and symptomatic relief of acute diarrhea in adults and adolescents aged 12 years and older.

להלן עלון לרופא כפי שעודכן בהתאם לעלון אסמכתא (טקסט מסומן ירוק משמעותו עדכון ~~קו חוצה~~ ו~~אדום~~ משמעו מחיקה):

SUMMARY OF PRODUCT CHARACTERISTICS

4.3 Contraindications

This medicine is contraindicated:

- ~~Hypersensitivity~~ hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
- In c~~C~~hildren less than 12 years of age.~~under the age of 12 years~~.
- in patients with acute dysentery, which is characteri~~z~~z~~z~~ed by blood in the stool and high fever.~~;~~
- in patients with acute ulcerative colitis. ~~or pseudomembranous colitis due to the use of broad-spectrum antibiotics;~~
- in patients with bacterial enterocolitis caused by invasive organisms including Salmonella, Shigella and Campylobacter.
- in patients with pseudomembranous colitis associated with the use of broad-spectrum antibiotics.

Imodium must not be used when inhibition of peristalsis is to be avoided due to the possible risk of significant sequelae including ileus, megacolon and toxic megacolon.
~~In general, the use of loperamide HCl is contraindicated in all cases in which inhibition of peristalsis should be initiated due to the possible risk of significant consequences such as ileus, megacolon and toxic megacolon.~~
Imodium must be discontinued promptly when ileus, constipation or abdominal distension develop.
…

4.4 Special warnings and precautions for use

T~~he t~~reatment of diarrhea with Imodium~~loperamide HCl~~ is only symptomatic. Whenever an underlying etiology can be determined, specific treatment should be given when appropriate.
…

4.5 Interaction with other medicinal products and other forms of interaction

Non-clinical data have shown ~~demonstrated~~ that loperamide is a ~~a substrate of~~ P-glycoprotein substrate.

Kenvue Hellas Commercial Single Member S.A.
Office I Mindspace - Greenwork Business Park Building D, Yakum 6097200

Concomitant administration of loperamide (~~in a~~ 16 mg single dose) with quinidine, or ritonavir, which are both(~~both~~ P-glycoprotein inhibitors~~)~~, resulted in a~~showed two~~2 ~~–~~to ~~three~~3-fold increase~~s~~ in loperamide plasma levels ~~of loperamide~~.
The clinical relevance of this pharmacokinetic interaction with P-glycoprotein inhibitors, when loperamide is given at ~~the~~ recommended ~~doses~~dosages ~~(from 2 mg to a maximum of 16 mg per day,)~~ is unknown.

The concomitant administration of loperamide (~~in a~~ 4 mg single dose) and~~with~~ itraconazole, an inhibitor of~~a~~ CYP3A4 and P-glycoprotein, resulted ~~inhibitor, showed~~ in a ~~three~~3- to ~~four~~4-fold increase in loperamide plasma concentrations~~levels of loperamide~~. In the same study ~~, gemfibrozil,~~ a CYP2C8 inhibitor, gemfibrozil, increased~~showed~~ loperamide by approximately ~~a two~~2-fold ~~increase in plasma levels of loperamide~~. The combination of itraconazole and gemfibrozil resulted in ~~showed~~ a ~~four~~4-fold increase in peak plasma levels of loperamide and a ~~thirteen~~13-fold increase in total plasma exposure. These increases were not associated with ~~effects on the~~ central nervous system (CNS) effects as measured ~~as detected~~ by psychomotor tests (i.e., ~~e.g.~~ subjective drowsiness ~~vertigo~~ and the Digit Symbol Substitution Test).

The c~~The c~~oncomitant administration of loperamide (~~in a~~ 16 mg single dose) and~~with~~ ketoconazole, an inhibitor of CYP3A4 and P-glycoprotein ~~inhibitor~~, resulted in ~~showed~~ a ~~five~~5-fold increase in loperamide plasma concentrations. ~~levels of loperamide.~~ This increase was not associated with increased pharmacodynamic effects as measured ~~observed~~ by pupillometry.

Concomitant treatment with oral desmopressin resulted in a ~~three~~3-fold increase ~~in~~ of desmopressin plasma concentrations ~~of desmopressin~~, presumably due to slower gastrointestinal motility.

It is expected that drugs with similar pharmacological properties may potentiate loperamide's~~the~~ effect ~~of Imodium,~~ and that drugs that accelerate gastrointestinal transit may decrease its effect.

…

4.8 Undesirable effects

Adults and c~~C~~hildren aged ≥12 years

The safety of l~~L~~operamide HCl was ~~has been~~ evaluated in 2755 adults and children aged ≥ 12 years who participated in 26 controlled and uncontrolled clinical trials of ~~with~~ loperamide HCl used for the treatment of acute diarrhea.

The most commonly reported (i.e. ~~with an incidence~~ ≥1% incidence) adverse drug reactions (ADRs) in clinical trials with loperamide HCl in ~~for the treatment of~~ acute diarrhea were ~~the following~~: constipation (2.7%), flatulence (1.7%), headache (1.2%) and nausea (1.1%).

Table 1 displays ~~shows the~~ ADRs that have been reported with the use of loperamide HCl from either clinical trial~~s~~ (acute diarrhea) or post-marketing experience.

The frequency categories use the following convention~~The frequency of the adverse reactions presented in Table 1 is defined according to the following convention~~:
~~Very~~ very common (≥1/10);
~~Common~~ common (≥1/100 to <1/10);
~~Uncommon~~ uncommon (≥1/1,000 to <1/100);
~~Rare~~ rare (≥1/10,000 to <1/1,000);
~~Very~~ very rare (<1/10,000);
~~Not~~ not known (cannot be estimated from the available data).
…

4.9 Overdose

Symptoms:
In case ~~the event~~ of overdose ~~(~~(including relative overdose due to hepatic dysfunction) CNS depression (stupor, coordination abnormality, somnolence, miosis, muscular hypertonia and~~,~~ respiratory depression), constipation, urinary retention and ileus may occur.
…

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: antipropulsives, ATC code: A07DA03

Loperamide binds to the opiate ~~opioid~~ receptor~~s~~ in the ~~intestinal wall,~~ gut wall, reducing propulsive peristalsis, increasing intestinal transit time and enhancing resorption of water and electrolytes. Loperamide increases the tone of the anal sphincter, which helps reduce faecal incontinence and urgency.
…

5.3 Preclinical safety data

Preclinical data reveal no hazard for humans based on conventional studies of single and repeated dose toxicity, genotoxicity, carcinogenicity and toxicity to reproduction and development.

5.3.1 GENERAL TOXICOLOGY
Loperamide show low acute toxicity. Chronic toxicity studies suggest NOAELs ranging from 0.3 to 10 mg/kg with no adverse effects except reduction in body weight gain at doses higher than the Maximum Human Use Level.

5.3.2 GENETIC TOXICOLOGY
Loperamide is non mutagenic in in vitro and in vivo assays.

5.3.3 CARCINOGENICITY
There is no preclinical data available. However, loperamide is considered noncarcinogenic due to its non-mutagenic potential and no carcinogenic effects or abnormalities reported in the chronic oral studies conducted in rats up to 40 mg/kg and 6, 12 and 18 months of treatment.

5.3.4 TERATOGENICITY
In reproduction and developmental studies, loperamide had no effects on peri- and post-natal development up to the dose of 20 mg/kg/day.

5.3.5 FERTILITY
Loperamide has no adverse effect on fertility in male rats up to 40mg/kg. In female rats 10 mg/kg was reported with no adverse effects on fertility.

~~Acute and chronic studies on loperamide showed no specific toxicity. Results of in vivo and in vitro studies carried out indicated that loperamide is not genotoxic. In reproduction studies, very high doses (40 mg/kg/day – 20 times the maximum human use level (MHUL)), based on body surface area dose comparison (mg/m^2), loperamide impaired fertility and fetal survival in association with maternal toxicity in rats. Lower doses (≥ 10mg/kg/day – 5 times MHUL) revealed no effects on maternal or fetal health and did not affect peri- and post-natal development.~~

~~Non-clinical in vitro and in vivo evaluation of loperamide indicates no significant cardiac electrophysiological effects within its therapeutically relevant concentration range and at significant multiples of this range (up to 47-fold. However, at extremely high concentrations associated with overdoses (see section 4.4), loperamide has~~

~~cardiac electrophysiological actions consisting of inhibition of potassium (hERG) and sodium currents, and arrhythmias.~~

Revised in ~~09~~07.~~2025~~2026.

העלון נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות www.health.gov.il וניתן לקבלו מודפס על ידי פניה לבעל הרישום.

בברכה
Kenvue Hellas Commercial
Single Member S.A.