contra-indicated in case of intolerance for fructose, for glucose and galactose malabsorption syndrome, or for sucrase-isomaltase deficiency (rare metabolic diseases).

**Precautions for use**
- In case of gastric ulcer, it’s recommended to verify the lesion benignancy before treatment.
- Hepatic failure: after a single administration to cirrhotic patients, the AUC is increased and elimination is retarded. Do not exceed 30 mg per day.
- Renal failure: no adjustment of dosage regimen is necessary.
- In children: the efficacy and tolerance of lansoprazole have not been studied.
- In elderly patients: no dosage adjustment is necessary; when lansoprazole is administered to elderly patients, no increased frequency of undesirable effects was noted.

**Drug interactions and other interactions**
Association requiring a precaution to use:
+ gastro-intestinal topicals (salts, magnesium, aluminium and calcium oxides and hydroxydes).
Reduction of the lansoprazole digestive absorption. Take the gastro-intestinal topicals at different times from lansoprazole (2 hours if possible).

**Pregnancy and breast feeding**
**Pregnancy**
Studies carried out on animals have not established a teratogenic effect of the gastric-proton pump inhibitor. In the absence of animal teratogenic effect, a human malformative effect is not expected.
In fact, to date, substances which induce malformations in human have shown teratogenic effect in animal during well leading studies on two animal species.
Now, there is not enough data to value a possible malformation or foetotoxic effect of this drug when it is administered during pregnancy.
Consequently, for reason of prudence, excepted for very restricted and validated indications, it is advisable not to use this drug during pregnancy.

**Breast-feeding**
In the absence of studies of secretion of lansoprazole in human milk, the use of the drug has to be avoided during breast-feeding.

**Undesirable effects**
Have been reported:
- rare cases of diarrhoea, nausea, vomiting, abdominal pain, constipation,
- rare cases of headache and exceptionally dizzy sensation,
- very rare cases of pruritus, skin rash, urticaria,
- isolated and reversible increase of transaminases (hepatic enzymes),
- isolated cases of thrombocytopenia and leucopenia.
These symptoms, often transitory, are of moderate intensity and exceptionally have required to stop the treatment.
- Rare cases of gynecomastia have been reported,
- Exceptionally cases of hyponatremia have been reported, especially on elderly patient.

**Overdosage**
Except for symptomatic treatment, no specific therapeutic recommendation can be made in case of overdose.

**Pharmacodynamic properties**
**PROTON PUMP INHIBITOR**
(A: Digestive system and metabolism)
Lansoprazole is a specific inhibitor of the H+K+ATPase (proton pomp) in gastric parietal cells.
It decreases the acid secretion whatever the nature stimulation.
The eradication of *Helicobacter pylori* is accompanied by healing and a prolonged emission of gastrointestinal ulcer disease.

**Pharmacokinetic properties**
**Absorption and distribution:**
As lansoprazole is destroyed in an acid environment, it is orally administered in the form gastroresistant granules.
Absorption is rapid, and the maximum concentration is reached in around an hour and a half.
The concomitant absorption of foods reduces the bioavailability of lansoprazole but does not entail modification of activity on inhibition of acid secretion.
The proteinic fixation of lansoprazole is 97%.

**Metabolism and elimination:**
The 1/2 life of plasmatic elimination is around 1.4 hours. This does not change over the period of treatment. Lansoprazole is completely eliminated after hepatic biotransformation principally.
The metabolites are without any notable activity and have no particular toxicity. Elimination is principally biliary. The pharmacokinetic profile does not change for elderly patients but changes in patients with hepatic failure (cf. Precautions for use).
Lansoprazole and metabolites are not dialyzable.
Zollinger-Ellison syndrome:
- The initial dose recommended is 60 mg of lansoprazole daily. The dose must be adapted individually and the treatment followed as long as clinically required.
- For posology superior to 120 mg daily, the daily dosage must be divided in two.

Contraindications
- Allergy to lansoprazole.
- Warning and precautions for use

Warnings:
As for gastric antiacid drugs, lansoprazole encourage the development of intra-gastric bacteria by reducing volume and acidity of the gastric juice.

Because of saccharose, this medicinal product is contra-indicated in case of intolerance for fructose, for glucose and galactose malabsorption syndrome, or for sucrase-isomaltase deficiency (rare metabolic diseases).

Precautions for use:
- Gastric ulcer: before treatment, it’s recommended to check the lesion benignancy.
- Hepatic failure: after a single administration to cirrhotic patients, the area below the curve increases and elimination is delayed. Do not exceed 30 mg daily.
- Renal failure: no adjustment of dosage regimen is necessary.
- In children: the efficacy and tolerance of lansoprazole have not been studied.
- In elderly patients: no dosage adjustment is necessary; when lansoprazole is administered to elderly patients, no increased frequency of undesirable effects was noted.

Drug interactions and other interactions
Interaction involving precaution to use:
+ gastro-intestinal topicals (salts, magnesium, aluminium and calcium oxides and hydroxides).
Reduction of the lansoprazole digestive absorption. Take the gastro-intestinal topicals at different times from lansoprazole (2 hours if possible).

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Pharmacodynamic properties

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(A: Digestive system and metabolism)
Lansoprazole is an effective inhibitor of the H+K+ATPase (proton pump) in gastric parietal cells: it decreases the acid secretion whatever the nature stimulation.
The eradication of Helicobacter pylori is accompanied by healing and a prolonged remission of gastro-duodenal ulcer disease.

Pharmacokinetic properties

Absorption and distribution:
Lansoprazole is destroyed in acid medium. Therefore it should be administered by oral route as enteric capsules.
Lansoprazole is absorbed rapidly and maximum serum levels are reached within approximately 1.5 hours about.
Concomitant absorption of foods reduces the bioavailability of lansoprazole but does not entail modification of activity or inhibition of acid secretion.
The proteinic fixation of lansoprazole is 97%.

Metabolism and elimination:
The 1/2 life of plasmatic elimination is around 1.4 hours. This does not change over the period of treatment. Lansoprazole is completely eliminated after hepatic biotransformation principally.
The metabolites identified in plasma are without any notable activity and have no particular toxicity. Elimination is principally biliary. The pharmacokinetic profile does not change for elderly patients but changes in patients with hepatic failure (cf. Precautions for use).
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