Martin Dow

Laxoberon® Drops

لیگزوبرون® ڈراپس

1. COMPOSITION

Laxoberon® Drops:
Each ml contains:
Sodium Picosulfate, BP.....7.5mg

2. DESCRIPTION

The active ingredient in Laxoberon® is Sodium Picosulfate. Sodium picosulfate is a locally acting laxative from the triarylmethane group, which after bacterial cleavage in the colon, has a dual action with stimulation of the mucosa of both the large intestine and of the rectum.

3. THERAPEUTIC INDICATIONS

For short term relief of constipation.
For complaints that require easier bowel emptying.

4. DOSAGE AND ADMINISTRATION

Unless otherwise prescribed by the doctor, the following dosages are recommended.

For constipation
The drops enable an exact dosage adapted to individual needs. It is recommended to start treatment with the lower dose indicated in the age group and then increase or decrease it drop by drop depending on the stool consistency achieved and desired. The recommended maximum daily dose should not be exceeded.

Adult:
10-20 drops (5-10 mg sodium picosulfate) per day

Teenagers and Children over 10 years:
10-20 drops (5-10 mg sodium picosulfate) per day

Children from 4 to 10 years:
5 to 10 drops (2.5-5 mg sodium picosulfate) per day

Laxoberon® should only be given to children over 4 years of age and adolescents on the advice of a doctor. Laxoberon® is contraindicated in children below 4 years of age.

In the management of constipation, once regularity has restarted dosage should be reduced and can usually be discontinued.

Method of administration:
For oral use. If necessary, Laxoberon® can be taken once a day, preferably in the evening. The calculated mean onset of action of about 10 hours ensures an undisturbed night's sleep after taking the drops in the evening. Expect one or two soft voids the next morning. The drops are taken with the help of a spoon or in some liquid.

Duration of Use:
Prolonged use should be avoided. The need for continued use must be checked after 1 week by the doctor, who will determine the required duration of use on a case-by-case basis.

5. CONTRAINDICATIONS

- Hypersensitivity to the active substance, active substances of the triarylmethane group or any of the excipients.
- Ileus or intestinal obstruction.
- Severely painful and/or feverish acute abdominal discomfort (e.g. Appendicitis) possibly associated with nausea and vomiting.
- Acute inflammatory diseases of the gastrointestinal tract.
- Severe dehydration.
- Children under 4 years old.

6. SPECIAL WARNINGS AND PRECAUTIONS

- Laxoberon® , like all laxatives, is not intended for continued daily use or for prolonged use without investigation of the cause of the constipation.
- Prolonged excessive use of laxatives can lead to fluid or electrolyte imbalance and potassium deficiency.
- Cases of dizziness and/or syncope have been reported with the use of Laxoberon®. Available information suggests defecation-related syncope (caused by the increase in pressure during defecation) or a vasovagal response to constipation-related abdominal pain. The incidents may be causally related to the constipation (which prompted the patients to use laxatives) and are not necessarily related to the use of Laxoberon® drops.
- In principle, when using Laxoberon® , care must always be taken to ensure sufficient drinking water intake. A long-term daily intake of laxatives should be avoided by appropriate dietary measures, such as high-fiber food.
- Children and adolescents should not take laxatives without medical advice.
- Regular intake or intake of higher than recommended doses of Laxoberon® drops for bulimia represents abuse that can lead to significant overdoses and must be avoided.
- No studies on the effects on the ability to drive and use machines have been performed. However, patients should be cautioned that dizziness and/or syncope may occur due to the vasovagal response (e.g. to abdominal spasms). If such side effects occur, patients should avoid activities that require increased alertness (e.g. participation in road traffic, operating machines).

7. DRUG INTERACTIONS

- The concomitant use of diuretics or adreno-corticosteroids may increase the risk of electrolyte imbalance if excessive doses of Laxoberon® are taken. Electrolyte imbalance may lead to increased sensitivity to cardiac glycosides.
- Concurrent administration of broad-spectrum antibiotics may reduce the laxative action of this product.

8. ADVERSE REACTIONS
Very common: Diarrhea
Common: Abdominal discomfort, cramps, pain, flatulence
Occasionally: Vomiting, nausea, dizziness
Not known: Allergic reactions, syncope, skin reactions such as angioedema, drug eruption, skin rash and pruritus.

The occurrence of dizziness and syncope after ingestion of sodium picosulfate appears to be consistent with a vasovagal response (eg, to abdominal cramps and defecation).

Long-term or high-dose use of Laxoberon® often leads to increased loss of water, potassium and other salts. This can lead to disturbances in heart function and muscle weakness, especially if you are taking diuretics or corticosteroids at the same time.

9. SPECIAL POPULATION
Pregnancy: There are no adequate and well-controlled studies in pregnant women. Many years of experience have shown no evidence of undesirable or harmful effects during pregnancy. Therefore, Laxoberon® should only be used during pregnancy, especially in the first trimester, on the advice of a doctor.

Lactation: Clinical data show that neither the active compound sodium picosulfate nor its glucuronides are excreted in the breast milk of healthy breastfeeding women. Based on the pharmacokinetic properties of the active substance, the use of Laxoberon® in breastfeeding women can be considered.

10. CLINICAL PHARMACOLOGY
Mechanism of Action: Sodium Picosulfate is a locally acting laxative from the triarylmethane group, which after bacterial cleavage in the colon, has the dual action of stimulating the mucosa of both the large intestine causing peristalsis and of the rectum causing increased motility and a feeling of rectal fullness. The rectal effect may help to restore the "call to stool" although its clinical relevance remains to be established.

As a laxative that acts on the colon, sodium picosulfate specifically stimulates the natural process of emptying in the lower gastrointestinal tract. Therefore, sodium picosulfate does not alter the digestion and absorption of calories or essential nutrients in the small intestine. Sodium picosulfate has no effect in the stomach and can therefore also be given to gastric sensitive and ulcer patients. Laxoberon® affects neither the liver function nor the intestinal flora.

With Laxoberon®, the consistency of the stool can be controlled depending on the dose, so that the stool can be emptied gently and without stressing the patient.

11. OVERDOSAGE
Symptoms:
If high doses are taken diarrhea, abdominal cramps and a clinically significant loss of potassium and other electrolytes can occur. This may also lead to increased sensitivity to cardiac glycosides. Furthermore, cases of colonic mucosal ischemia have been reported in association with doses of Sodium Picosulfate considerably higher than those recommended.

Laxatives in chronic overdosage are known to cause chronic diarrhea, abdominal pain, hypokalemia, secondary hyperaldosteronism and renal calculi. Renal tubular damage, metabolic alkalosis, and muscle weakness secondary to hypokalemia have also been described as consequences of chronic laxative abuse.

Therapy:
Within a short time of ingestion, absorption can be minimized or prevented by inducing vomiting or by gastric lavage. Replacement of fluids and correction of electrolyte imbalance may be required. Administration of antispasmodics may be of some value.

12. HOW SUPPLIED
Presentation
Laxoberon® Drops : Available in 15ml pilfer proof plastic bottle in unit carton.
Available in 30ml pilfer proof plastic bottle in unit carton.

Storage
Store below 30 °C.
Protect form light and heat.
Keep all medicines out of the reach of children.

۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔
روشنی اور گرمی سے محفوظ رکھیں۔
تمام دوائیں بچوں کی پہنچ سے دور رکھیں۔

Manufactured by:
Martin Dow Marker Ltd
7, Jail Road, Quetta, Pakistan.
13004277

لیگزوبرون™ ٹیبلیٹس/لیکوئیڈ

اہم معلومات:

خصوصیات:

لیگزوبرون™ ایک موثر اور مفید قبض کشا دوا ہے۔ یہ خون میں جذب نہیں ہوتی بلکہ کولون (Colon) کی اندرونی جھلی (Mucosal Membrane) پر براہ راست عمل کر کے اسکی حرکت کو معمول کے مطابق بناتی ہے جس سے رفع حاجت معمول کے مطابق ہوتی ہے اور غیر ضروری پیچیدگیاں بھی پیدا نہیں ہوتیں۔

علامات:

لیگزوبرون™ قبض کی تمام صورتوں مثلاً بستر تک محدود مریضوں، غذا یا ماحول کی تبدیلی کے باعث بیماری، ہاضمہ کی خرابی وغیرہ میں موثر ہے۔
لیگزوبرون™ ریڈیوگرافی (ایکس رے) کے ذریعہ تشخیص میں بھی کارآمد ہے۔

خوراک اور ترکیب استعمال:

تاوقتیکہ ڈاکٹر نے کسی اور طرح تجویز نہ کیا ہو:

گولیاں : ۵ ملی گرام

بالغ افراد اور ۱۰ سال سے بڑے بچّوں کیلئے:
اتا دو گولیاں رات کو سوتے وقت۔

لیکوئیڈ : ۵ ملی گرام فی ۵ ملی لیٹر

بالغ افراد اور ۱۰ سال سے بڑے بچّوں کیلئے:
اتا دو چائے کے چمچے رات کو سوتے وقت۔

۴ تا ۱۰ سال کے بچّوں کے لئے:
۱/۲ تا ایک چائے کا چمچہ رات کو سوتے وقت۔

Laxoberon™
Tablets
(Sodium Picosulfate)
Liquid
(Sodium Picosulfate) BP

Contact laxative

COMPOSITION:

Each tablet contains	:	Sodium Picosulfate BP ..... 5 mg
Each 5 ml contains	:	Sodium Picosulfate Monohydrate BP ..... 5 mg

DESCRIPTION
The active ingredient in Laxoberon™ is Sodium Picosulfate which is a stimulant laxative.

THERAPEUTIC INDICATIONS
Laxoberon™ is used for relief of constipation.
Laxoberon™ gently stimulate the muscles of the bowel (large intestine). This brings predictable, overnight relief from constipation, helping to return the body to its natural rhythm.

DOSAGE AND ADMINISTRATION
Tablet: Adults, 1 - 2 tablets.

Liquid: Unless otherwise prescribed by the doctor, the following dosages are recommended

Adults and children over 10 years:
One to two 5ml spoonfuls (5 -10mg) at night.

Children under 10 years:
Not to be taken by children under 10 years without medical advice.
Children (4-10 years):
Half to one 5ml spoonful (2.5 – 5mg) at night.
Children under 4 years:
The recommended dosage is 250 micrograms per kilogram body weight.
In the management of constipation, once regularity has restarted dosage should be reduced and can usually be discontinued.

CONTRAINDICATIONS
- Not to be used in patients with ileus, intestinal obstruction, acute surgical abdominal conditions like acute appendicitis, acute inflammatory bowel diseases, and in severe dehydration.
- Not to be used in patients with a known hypersensitivity to Sodium Picosulfate or any other component of the product.
- Patients with rare hereditary problems of fructose intolerance should not take this medicine.

SPECIAL WARNINGS AND PRECAUTIONS
As with all laxatives, Sodium Picosulfate Oral Solution should not be taken on a continuous daily basis for long periods. Patients who need to take laxatives frequently should do so under medical supervision. They should also get their cause of constipation investigated. Prolonged excessive use may lead to fluid and electrolytic imbalance, hypokalemia and may cause onset of rebound constipation. Not to be taken by children under 10 years without medical advice.

DRUG INTERACTIONS
- The concomitant use of diuretics or adreno-corticosteroids may increase the risk of electrolyte imbalance. However, this situation only arises if excessive doses are taken.
- Concurrent administration of broad-spectrum antibiotics may reduce the laxative action of this product.

CLINICAL PHARMACOLOGY

Mechanism of Action:

Sodium Picosulfate is a locally acting laxative from the triarylmethane group, which after bacterial cleavage in the colon, has the dual action of stimulating the mucosa of both the large intestine causing peristalsis and of the rectum causing increased motility and a feeling of rectal fullness. The rectal effect may help to restore the "call to stool" although its clinical relevance remains to be established.

Pharmacokinetics:
After oral ingestion, sodium picosulfate reaches the colon without any appreciable absorption. Therefore, enterohepatic circulation is avoided. By bacterial cleavage the active form, the free diphenol, is formed in the colon. Consequently, there is an onset of action between 6 – 12 hours, which is determined by the release of the active substance from the preparation. After administration, only small amounts of the drug are systemically available. Urinary excretion reflects low systemic burden after oral administration.

OVERDOSAGE

Symptoms: If high doses are taken diarrhea, abdominal cramps and a clinically significant loss of potassium and other electrolytes can occur. This may also lead to increased sensitivity to cardiac glycosides. Furthermore, cases of colonic mucosal ischemia have been reported in association with doses of Sodium Picosulfate considerably higher than those recommended for the routine management of constipation.

Laxatives in chronic overdosage are known to cause chronic diarrhea, abdominal pain, hypokalemia, secondary hyperaldosteronism and renal calculi. Renal tubular damage, metabolic alkalosis and muscle weakness secondary to hypokalemia have also been described in association with chronic laxative abuse.

Therapy: Within a short time of ingestion, absorption can be minimized or prevented by inducing vomiting or by gastric lavage. Replacement of fluids and correction of electrolyte imbalance may be required. This is especially important in the elderly and the young. Administration of antispasmodics may be of some value.

SPECIAL POPULATION

Pregnancy: There are no reports or undesirable or damaging effects during pregnancy or to the fetus. Nevertheless, medicines should not be used in pregnancy, especially in first trimester unless the benefits outweigh any possible risk.

Nursing mothers: Although the active ingredient is not known to be excreted in breast milk, use of this product in breast feeding is not recommended.

ADVERSE REACTIONS
The following adverse effects related to the gastrointestinal tract may rarely be seen with Picosulfate use: Abdominal discomfort or distention, abdominal pain, borborygmus, nausea, vomiting and diarrhea.

دستیابی:

گولیاں : ۵ ملی گرام ۱۰۰ گولیاں

لیکوئیڈ : ۵ ملی گرام فی ۵ ملی لیٹر ۱۲۰ ملی لیٹر

خصوصی احتیاط:

۳۰ ڈگری سینٹی گریڈ سے کم درجۂ حرارت پر رکھیں۔

روشنی اور گرمی سے محفوظ رکھیں۔

تمام دوائیں بچّوں کی پہنچ سے دور رکھیں۔

بچوں میں لیگزوبرون™ ڈاکٹر کے مشورے کے بغیر استعمال نہ کریں۔

Presentation:

Tablets 5 mg	- 100's
Liquid 5 mg/5 ml	- 120 ml

Store below 30^{O}C.
Protect from light and heat.
Keep all medicines out of the reach of children.
To be sold on prescription of a registered medical practitioner only.

Manufactured by:
Martin Dow Marker Ltd
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