For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only

TRILAXA/GUTQUICK

1. **Generic Name**

   Liquid Paraffin, Milk of Magnesia & Sodium Picosulfate Suspension

2. **Qualitative and quantitative Composition:**

   Each 5 ml contains:

   Liquid Paraffin I.P. …… 1.25 ml

   Milk of Magnesia I.P. …… 3.75 ml

   Sodium Picosulfate B.P. …. 3.33 mg

   Excipients ……..q.s.

   Colours: Ponceau 4R & Carmoisine

   The excipients used are Citric Acid, Methyl Paraben, Propyl Paraben, Saccharin Sodium, Bronopol, Colloidal Silicon Dioxide, Carmoisine and Ponceau-4R.

3. **Dosage form and strength**

   Dosage form: Oral Suspension

   Strength: 1.25 ml + 3.75 ml + 3.33mg.

4. **Clinical particulars**

4.1. Therapeutic indication

It is indicated for symptomatic treatment of constipation in adults.

4.2. Posology and method of administration

Posology

The following dosages are recommended to be taken at night to produce evacuation the following morning.

It is recommended to start with the lowest dose. The dose may be adjusted up to the maximum recommended dose to produce regular stools.

The maximum recommended daily dose should not be exceeded.

For adults over 12 years (including the elderly):

5 to 20 ml orally as required. The maximum daily dose is 20ml.

Should not be used in children and adolescents under the age of 12 years.

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

Diluent: Can be diluted with purified water.

Method of administration

For oral administration.

4.3. Contraindications

It is contraindicated in patients with:

- Ileus or intestinal obstruction
- Severe painful and/or feverish acute abdominal conditions (e.g. appendicitis) potentially associated with nausea and vomiting
- Acute inflammatory bowel diseases
- Severe dehydration
- Known hypersensitivity to sodium picosulfate or any other component of the product
- Rare hereditary conditions that may be incompatible with an excipient of the product

4.4. Special warnings and precautions for use

Avoid prolonged use.

Caution should be exercised in administering this product to the elderly with possible renal impairment.

Should not be used in children and adolescents under the age of 12 years.

As with all laxatives, sodium picosulfate should not be taken on a continuous daily basis for more than five days without investigating the cause of constipation.

Long-term everyday use of stimulant laxatives may harm the intestinal function and should be avoided. If laxatives are needed every day the cause of the constipation should be investigated. This product should only be used if a therapeutic effect cannot be achieved by a change of diet or the administration of bulk forming agents.

Prolonged excessive use may lead to fluid and electrolyte imbalance and hypokalaemia.

Intestinal loss of fluids can promote dehydration. Symptoms may include thirst and oliguria. In patients suffering from fluid loss where dehydration may be harmful (e.g. renal insufficiency, elderly patients) sodium picosulfate should be discontinued and only be restarted under medical supervision.

Stimulant laxatives (including sodium picosulfate) do not help with weight loss.

If the symptoms worsen during the use of the medicinal product, a doctor or a pharmacist should be consulted.

Dizziness and/or syncope have been reported in patients. The details available for these cases suggest that the events would be consistent with defaecation syncope (or syncope attributable to straining at stool), or with a vasovagal response to abdominal pain related to the constipation, and not necessarily to the administration of sodium picosulfate itself.

4.5. Drugs interactions

There may be interference with the absorption of fat soluble vitamins.

The concomitant use of diuretics or adreno-corticosteroids may increase the risk of electrolyte imbalance if excessive doses are taken.

Electrolyte imbalance may lead to increased sensitivity to cardiac glycosides.

Concurrent administration of antibiotics may reduce the laxative action of this product.

4.6. Use in special populations (such as pregnant women, lactating women, paediatric patients, geriatric patients etc.)

Pregnancy

There are no adequate and well-controlled studies in pregnant women. Long experience has shown no evidence of undesirable or damaging effects during pregnancy. Avoid in early pregnancy or lactation.

Lactation

Clinical data show that neither the active moiety of sodium picosulfate (BHPM or bis-(p-hydroxyphenyl)-pyridyl-2-methane) nor its glucuronides are excreted into the milk of healthy lactating females.

Nevertheless, as with all medicines, it should not be taken in pregnancy, especially the first trimester, and during breast feeding unless the expected benefit is thought to outweigh any possible risk and only on medical advice.

Fertility

No studies on the effect on human fertility have been conducted. Non-clinical studies did not reveal any effect on fertility.

4.7. Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed.

However, patients should be advised that due to a vasovagal response (for example, due to abdominal spasm), dizziness and /or syncope may be experienced. If patients experience abdominal spasm they should avoid potentially hazardous tasks such as driving or operating machinery.

4.8. Undesirable effects

Anal seepage of paraffin and consequent anal irritation can occur after prolonged use.

Granulomatous reactions caused by absorption of small quantities of liquid paraffin.

Lipoid pneumonia (by accidental inhalation) may occur and therefore caution is required in patients with swallowing difficulties.

Adverse events have been ranked under headings of frequency using the following convention:

Very common (≥ 1/10); common (≥ 1/100, < 1/10); uncommon (≥ 1/1000, <1/100); rare (≥ 1/10000, <1/1000); very rare (<1/10000); not known – cannot be estimated from the available data.

Immune system disorders

Not known: Hypersensitivity*

Nervous system disorders

Uncommon: Dizziness

Not known: Syncope*

Dizziness and syncope occurring after taking sodium picosulfate appear to be consistent with a vasovagal response (for example, due to abdominal spasm, defaecation).

Gastrointestinal disorders

Very common: Diarrhoea

Common: Abdominal discomfort, abdominal pain, abdominal cramps.

Uncommon: Nausea, vomiting.

Skin and subcutaneous tissue disorders

Not known: Skin reactions* such as angioedema*, drug eruption*, rash*, pruritus*.

*This adverse event has been observed in post-marketing experience. With 95% certainty, the frequency category is not greater than uncommon, but might be lower. A precise frequency

estimation is not possible as the adverse event did not occur in a clinical trial database of 1020 patients.

Reporting of 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. Report suspected adverse reactions via any point of contact available at www.torrentpharma.com.

4.9. Overdose

If large quantities are ingested, withdraw medication. Supportive treatment may be required.

Symptoms: If high doses are taken diarrhoea, abdominal cramps and a clinically significant loss of fluid, potassium and other electrolytes can occur.

Furthermore, cases of colonic mucosal ischaemia have been reported in association with doses considerably higher than those recommended for the routine management of constipation.

Laxatives when taken in chronic overdosage may cause chronic diarrhoea, abdominal pain, hypokalaemia, secondary hyperaldosteronism and renal calculi. Renal tubular damage, metabolic alkalosis and muscle weakness secondary to hypokalaemia have also been described in association with chronic laxative abuse.

Therapy: Within a short time of ingestion, absorption can be minimised 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.

5. Pharmacological properties

5.1. Mechanism of Action

Liquid Paraffin acts as a lubricant.

Milk of Magnesia has antacid properties.

Sodium picosulfate 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.

5.2. Pharmacodynamic properties

Liquid Paraffin, taken internally is widely used to alleviate constipation.

Milk of Magnesia also acts as a mild saline laxative.

Sodium picosulfate is a locally acting laxative from the triarylmethane group. Stimulation of the mucosa of the large intestine results in colonic peristalsis, with promotion of accumulation of water, and consequently electrolytes, in the colonic lumen. This results in stimulation of defaecation, reduction of transit time and softening of the stool. Stimulation of the rectum causes 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.

5.3. Pharmacokinetic properties

Liquid Paraffin

Excessive use of Liquid Paraffin may lead to anal seepage and irritation and may, if emulsified, give rise to granulomatous reactions.

Milk of Magnesia

There is some evidence that Magnesium salts may cause decreased absorption of the active

ingredients of other medications. e.g. Digoxin.

Sodium picosulfate

Absorption and Distribution

After oral ingestion, sodium picosulfate reaches the colon without any appreciable absorption. Therefore, enterohepatic circulation is avoided.

Biotransformation

Sodium picosulfate is converted into the active laxative compound, bis-(p- hydroxyphenyl)-pyridyl-2-methane (BHPM), via bacterial cleavage in the distal segment of the intestine.

Elimination

Following conversion, only small amounts of BHPM are absorbed and are almost completely conjugated in the intestinal wall and the liver to form the inactive BHPM glucuronide. After oral administration of 10 mg sodium picosulfate 10.4% of the total dose was excreted as BHPM glucuronide in urine after 48 hours. In general, urinary excretion decreases when higher doses of sodium picosulfate are being administered.

Pharmacokinetic/Pharmacodynamic relationship(s)

Consequently, the onset of action of the preparation is usually between 6 - 12 hours, which is determined by the release of the active substance (BHPM). There is no direct or inverse relationship between the laxative effect and plasma levels of the active moiety.

6. Nonclinical properties

6.1. Animal Toxicology or Pharmacology

No pre-clinical data is available for liquid paraffin and milk of magnesia.

Sodium picosulfate was maternotoxic (severe diarrhoea) in rats and rabbits at exposures ≥ 810 fold above the maximum recommended human daily dose [MRHDD] based on mg/m2. Embryotoxicity (increased incidence of early resorptions) was observed at maternotoxic doses in rats and rabbits and was considered secondary to maternotoxicity. There were no other reported effects on embryofetal development, pre- and postnatal development and fertility parameters at exposures up to 81-fold above the MRHDD based on mg/m^2.

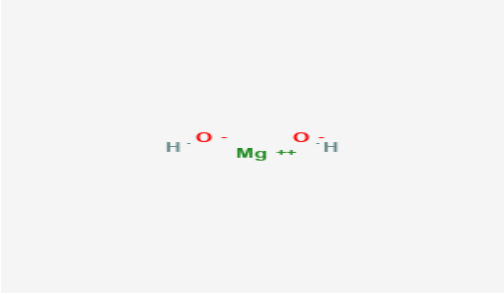
7. Description

Liquid Paraffin

Liquid Paraffin is purified mixture of liquid hydrocarbons obtained from petroleum.

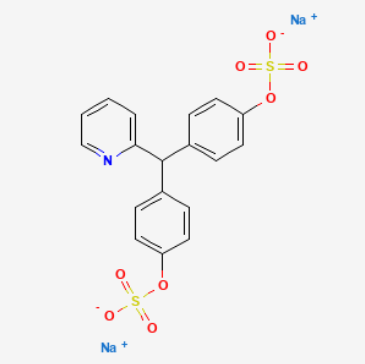
Milk of magnesia

Milk of magnesia is magnesium dihydroxide. The empirical formula is H_2MgO_2, and its molecular weight is 58.320 g/mol. The chemical structure of Milk of magnesia is:



Sodium Picosulfate

Sodium Picosulfate is disodium; [4-[pyridin-2-yl-(4-sulfonatooxyphenyl)methyl]phenyl] sulfate. The empirical formula is $C_{18}H_{13}NNa_2O_8S_2$, and its molecular weight is 481.4 g/mol. The chemical structure of Sodium Picosulfate is:



Trilaxa/GutQuick

Trilaxa & GutQuick is Pink coloured suspension.

The excipients used are Citric Acid, Methyl Paraben, Propyl Paraben, Saccharin Sodium, Bronopol, Colloidal Silicon Dioxide, Carmoisine and Ponceau-4R.

8. Pharmaceutical particulars

8.1. Incompatibilities

Not applicable

8.2. Shelf-life

Do not use later than date of expiry.

8.3. Packaging information

Trilaxa and GutQuick is available in white colour PET bottle of 200ml & 170ml.

8.4. Storage and handing instructions

Store at a temperature not exceeding 30^{o}C, protected from light. Do not freeze.

Keep the medicine out of reach of children.

Precautions: It should not be taken in case of nausea, vomiting or abdominal Pain.

Prolonged use is not recommended.

Shake well before use.

Keep out of reach of children.

9. Patient Counselling Information

Ask the patients to inform the treating physicians in case of any of the below:

- Have any allergies.
- Have kidney or liver problems.
- Are pregnant or plan to become pregnant.
- Are breastfeeding or plan to breastfeed.
- Have any serious illness

- Are taking any medicines (prescription, over-the-counter, vitamins, or herbal products)

10. Details of manufacturer

Pharma Force Lab (Unit-II)

Plot No.:83-86, Industrial Area Gondpur,

Tehsil Paonta Sahib, District Sirmour -173025 (H.P.)

11. Details of permission or licence number with date

Mfg. Lic. No.: S-MNB/09/43, issue on 13.12.2024

12. Date of revision

NA

MARKETED BY

TORRENT PHARMACEUTICALS LTD.

IN/TRILAXA/GUTQUICK 200 ml and 170 ml/MAR-2026/01/PI