

Summary of Product Characteristics for Pharmaceutical Products

1. Name of the medicinal product

HYDRILAXE sachet, powder for oral solution

2. Qualitative and quantitative composition

Each 14gm sachet of HYDRILAXE contains the following active ingredients:

Each 14gm Sachet Contains:

Sodium Chloride BP 350.70 mg

Sodium Bicarbonate BP 178.50 mg

Potassium Chloride BP 46.60mg

Macrogol 3350 (Polyethylene Glycol) BP
13.125 g

Mannitol

Sucralose (Micronized)

For a full list of excipients, see section 6.1.

3. Pharmaceutical form

Powder for oral solution.

Light orange to orange free flowing powder having pleasant orange flavour odour.

4. Clinical particulars

4.1 Therapeutic indications

For the treatment of chronic constipation. HYDRILAXE is also effective in resolving faecal impaction, defined as refractory constipation with faecal loading of the rectum and/or colon.

4.2 Posology and method of administration

Chronic constipation

A course of treatment for constipation with HYDRILAXE does not normally exceed 2 weeks, although this can be repeated if required.

As for all laxatives, prolonged use is not usually recommended. Extended use may be necessary in the care of patients with severe chronic or resistant constipation, secondary to multiple sclerosis or Parkinson's Disease, or induced by regular constipating medication in particular opioids and antimuscarinics.

Adults, adolescents and the elderly: 1-3 sachets daily in divided doses, according to individual response.

For extended use, the dose can be adjusted down to 1 or 2 sachets daily. Children (below 12 years old): Not recommended. Alternative HYDRILAXE products are available for children.

Faecal impaction

A course of treatment for faecal impaction with HYDRILAXE does not normally exceed 3 days.

Adults, adolescents and the elderly: 8 sachets daily, all of which should be consumed within a 6 hour period.

Children (below 12 years old): Not recommended. Alternative HYDRILAXE products are available for children.

Patients with impaired cardiovascular function: For the treatment of faecal impaction the dose should be divided so that no more than two sachets are taken in any one hour.

Patients with renal insufficiency: No dosage change is necessary for treatment of either constipation or faecal impaction.

Method of administration

Each sachet should be dissolved in 125 ml water. For use in faecal impaction 8 sachets may be dissolved in 1 litre of water.

4.3 Contraindications

Intestinal perforation or obstruction due to structural or functional disorder of the gut wall, ileus, severe inflammatory conditions of the intestinal tract, such as Crohn's disease and ulcerative colitis and toxic megacolon.

Hypersensitivity to the active substances or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Diagnosis of impaction/faecal loading of the rectum should be confirmed by physical or radiological examination of the abdomen and rectum.

Mild adverse drug reactions are possible as indicated in Section 4.8. If patients develop any symptoms indicating shifts of fluids/electrolytes (e.g. oedema, shortness of breath, increasing fatigue, dehydration, cardiac failure) HYDRILAXE should be stopped immediately and electrolytes measured, and any abnormality should be treated appropriately.

The absorption of other medicinal products could transiently be reduced due to an increase in gastro-intestinal transit rate induced by HYDRILAXE (see section 4.5).

4.5 Interaction with other medicinal products and other forms of

interaction

Macrogol raises the solubility of medicinal products that are soluble in alcohol and relatively insoluble in water.

There is a possibility that the absorption of other medicinal products could be transiently reduced during use with HYDRILAXE (see section 4.4). There have been isolated reports of decreased efficacy with some concomitantly administered medicinal products, e.g. anti-epileptics.

4.6 Fertility, pregnancy and lactation

Pregnancy

There are limited amount of data from the use of HYDRILAXE in pregnant women. Studies in animals have shown indirect reproductive toxicity (see section 5.3). Clinically, no effects during pregnancy are anticipated, since systemic exposure to macrogol 3350 is negligible. HYDRILAXE can be used during pregnancy.

Breastfeeding

No effects on the breastfed newborn/infant are anticipated since the systemic exposure of the breast-feeding woman to Macrogol 3350 is negligible.

HYDRILAXE can be used during breast-feeding.

Fertility

There are no data on the effects of HYDRILAXE on fertility in humans. There were no effects on fertility in studies in male and female rats (see section 5.3).

4.7 Effects on ability to drive and use machines

HYDRILAXE has no influence on the ability to drive and use machines.

4.8 Undesirable effects

Reactions related to the gastrointestinal tract occur most commonly.

These reactions may occur as a consequence of expansion of the contents of the gastrointestinal tract, and an increase in motility due to the pharmacologic effects of HYDRILAXE. Mild diarrhoea usually responds to dose reduction.

The frequency of the adverse effects is not known as it cannot be estimated from the available data.

System Organ Class	Adverse Event
Immune system disorders	Allergic reactions, including anaphylaxis, angioedema, dyspnoea, rash, urticaria and pruritus.
Skin and subcutaneous tissue disorders	Erythema.

Metabolism and nutrition disorders	Electrolyte disturbances, particularly hyperkalaemia and hypokalaemia.
Nervous system disorders	Headache.
Gastrointestinal disorders	Abdominal pain, diarrhoea, vomiting, nausea, dyspepsia, abdominal distension, borborygmi, flatulence and anorectal discomfort.
General disorders and administration site conditions	Peripheral oedema.

Reporting of suspected adverse reactions: Healthcare professionals are requested to report any suspected adverse reactions to report any suspected adverse reactions to the National Regulatory Authority.

4.9 Overdose

Severe pain or distension can be treated by nasogastric aspiration. Extensive fluid loss by diarrhoea or vomiting may require correction of electrolyte disturbances.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Osmotically acting laxatives. ATC code: A06A D65

Macrogol 3350 acts by virtue of its osmotic action in the gut, which induces a laxative effect.

Macrogol 3350 increases the stool volume, which triggers colon motility via neuromuscular pathways. The physiological consequence is an improved propulsive colonic transportation of the softened stools and a facilitation of the defecation. Electrolytes combined with macrogol 3350 are exchanged across the intestinal barrier (mucosa) with serum electrolytes and excreted in faecal water without net gain or loss of sodium, potassium and water.

For the indication of faecal impaction controlled comparative studies have not been performed with other treatments (e.g. enemas). In a non-comparative study in 27 adult patients, HYDRILAXE cleared the faecal impaction in 12/27 (44%) after 1 day's treatment; 23/27 (85%) after 2 days' treatment and 24/27 (89%) at the end of 3 days.

Clinical studies in the use of HYDRILAXE in chronic constipation have shown that the dose needed to produce normal formed stools tends to reduce over time. Many patients respond to between 1 and 2 sachets a day, but this dose should be adjusted depending on individual response.

5.2 Pharmacokinetic properties

Macrogol 3350 is unchanged along the gut. It is virtually unabsorbed from the gastro-intestinal tract. Any macrogol 3350 that is absorbed is excreted via the urine.

5.3 Preclinical safety data

Preclinical studies provide evidence that macrogol 3350 has no significant

systemic toxicity potential, based on conventional studies of pharmacology, repeated dose toxicity and genotoxicity.

There were no direct embryotoxic or teratogenic effects in rats even at maternally toxic levels that are a multiple of 66 x the maximum recommended dose in humans for chronic constipation and 25 x for faecal impaction. Indirect embryofetal effects, including reduction in fetal and placental weights, reduced fetal viability, increased limb and paw hyperflexion and abortions, were noted in the rabbit at a maternally toxic dose that was 3.3 x the maximum recommended dose in humans for treatment of chronic constipation and 1.3 x for faecal impaction. Rabbits are a sensitive animal test species to the effects of GI-acting substances and the studies were conducted under exaggerated conditions with high dose volumes administered, which are not clinically relevant. The findings may have been a consequence of an indirect effect of HYDRILAXE related to poor maternal condition as the result of an exaggerated pharmacodynamic response in the rabbit. There was no indication of a teratogenic effect. There are long-term animal toxicity and carcinogenicity studies involving macrogol 3350. Results from these and other toxicity studies using high levels of orally administered high molecular weight macrogols provide evidence of safety at the recommended therapeutic dose.

6. Pharmaceutical particulars

6.1 List of excipients

Mannitol, Sucralose (Micronized), Orange Flavour (Powdarome Orange 4153), Sunset Yellow FCF.

6.2 Incompatibilities

None known.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Sachet: Store protected from moisture at a temperature not exceeding 30°C. Reconstituted solution should be use immediately.

6.5 Nature and contents of container

10 Sachets of printed laminate foil, 14 gm each packed in a carton along with an insert.

6.6 Special precautions for disposal and other handling

No special requirements.

7. Marketing authorisation holder

Bliss GVS Pharma Ltd.,
102, Hyde Park, Saki-Vihar Road, Andheri
(East) Mumbai – 400 072 India

8. Marketing Authorization Number

H2024/CTD8263/16825

**9. Date of first authorization/renewal of
the authorization**

August 20, 2024.

10. Date of revision of the text

August 20, 2024.