Size should be adjusted by the vendor as per available tooling.

Size: 150 x 250 mm

Front

MIRALAX 3350™

(Polyethylene glycol+Sodium chloride +Potassium chloride+Sodium bicarbonate)

Sachet

Sugar Free

POWDER FOR ORAL SOLUTION

Tutti Frutti Flavored

EFFECTIVE RELIEF FROM CONSTIPATION

میرالیکس 3350 ساشے

شوگرفری ٹوٹی فروٹی فلیورڈ

قبض کی مؤثر دوا

COMPOSITION:

Each sachet contains:

Polyethylene glycol ..... 13.125 g.

Sodium chloride ..... 350.7 mg.

Potassium chloride ..... 46.6 mg.

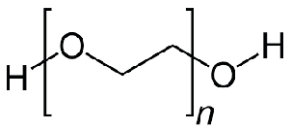
Sodium bicarbonate ..... 178.5 mg.

Product Specs.: Manufacturer's Specs.

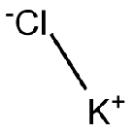
DESCRIPTION:

Polyethylene Glycol with potassium chloride, sodium bicarbonate and sodium chloride (for oral solution) is an osmotic laxative consisting of **Polyethylene Glycol, Sodium Bicarbonate, Sodium Chloride, Potassium Chloride** which are dissolved together in water, **MIRALAX 3350** (Polyethylene Glycol with potassium chloride, sodium bicarbonate and sodium chloride for oral solution (powdered form)

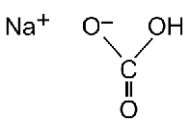
Polyethylene Glycol



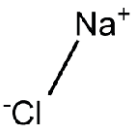
Potassium Chloride



Sodium Bicarbonate



Sodium Chloride



CLINICAL PHARMACOLOGY:

Mechanism of Action:

The primary mode of action is thought to be through the osmotic effect of Polyethylene Glycol with potassium chloride, sodium bicarbonate and sodium chloride, which causes water to be retained in the colon and produces a watery stool.

Pharmacodynamics:

MIRALAX 3350 induces diarrhea which rapidly cleanses the bowel, usually within four hours.

Pharmacokinetics:

The pharmacokinetics of **MIRALAX 3350** have not been studied in patients with renal or hepatic insufficiency. Available pharmacokinetic information for oral PEG3350 suggests that it is poorly absorbed.

INDICATIONS:

MIRALAX 3350 is a combination of PEG 3350, an osmotic laxative, and electrolytes indicated for cleansing of the colon in preparation for colonoscopy in adults and pediatric patients aged 6 months or greater.

DOSAGE AND ADMINISTRATION:

MIRALAX 3350, supplied as a powder, must be reconstituted with water before its use On day prior to colonoscopy, instruct patients to:

- Eat a light breakfast or have clear liquids (avoid red and purple liquids)
- If adding a **MIRALAX 3350** flavour pack, pour the contents of flavor powder into container prior to reconstitution.
- Early in the evening prior to colonoscopy, fill container containing **MIRALAX 3350** powder with lukewarm water to 4-liter fill line
- After capping container, shake vigorously several times.

Instruct patients to consume water or clear liquids during and after bowel preparation up until 2 hours before time of colonoscopy.

Adults:

Instruct patients to drink a total of up to 4 liters at a rate of 240 mL (8 oz.) every 10 minutes, until 4 liters are consumed or the rectal effluent is clear. Rapid drinking of each portion is preferred to drinking small amounts continuously. For NGT, rate is 20¬ 30 mL per minute (1.2 c 1.8 liters per hour).

Pediatric patients (aged 6 months or greater):

Pediatric patients should drink 25 mL/kg/hour until the stool is watery, clear, and free of solid matter. If pediatric patients are unable to drink the reconstituted **MIRALAX 3350** solution, the solution may be given by nasogastric (NGT). NGT administration is at the rate of 25 mL/kg/hour. The first bowel movements should occur approximately one hour after the start of **MIRALAX 3350** administration. Continue drinking until the watery stool is clear and free of solid matter.

WARNINGS & PRECAUTIONS:

Serious fluid and electrolyte abnormalities:

Advise patients to hydrate adequately before, during, and after the use of **MIRALAX 3350**. If a patient develops significant vomiting or signs of dehydration after taking MIRALAX 3350 consider performing post-colonoscopy lab tests (electrolytes, creatinine, and BUN). Fluid and electrolyte disturbances can lead to serious adverse events including cardiac arrhythmias, seizures and renal impairment. Patients with electrolyte abnormalities should have them corrected before treatment with **MIRALAX 3350**. **MIRALAX 3350** should be used with caution in patients using concomitant medications that increase the risk of electrolyte abnormalities [such as diuretics, angiotensin converting enzyme (ACE)-inhibitors or angiotensin receptor blockers (ARBs)] or in patients with known or suspected hyponatremia. Consider performing pre-dose and post-colonoscopy laboratory tests (sodium, potassium, calcium, creatinine, and BUN) in these patients.

Cardiac arrhythmias:

There have been rare reports of serious arrhythmias associated with the use of ionic osmotic laxative products for bowel preparation. Use caution when prescribing **MIRALAX 3350** for patients at increased risk of arrhythmias (e.g., patients with a history of prolonged QT, uncontrolled arrhythmias, recent myocardial infarction, unstable angina, congestive heart failure, or cardiomyopathy). Pre-dose and post-colonoscopy ECGs should be considered in patients at increased risk of serious cardiac arrhythmias.

Seizures:

There have been rare reports of generalized tonic-clonic seizures and/or loss of consciousness associated with use of bowel preparation products in patients with no prior history of seizures. The seizure cases were associated with electrolyte abnormalities (e.g., hyponatremia, hypokalemia, hypocalcemia, and hypomagnesemia) and low serum osmolality. The neurologic abnormalities resolved with correction of fluid and electrolyte abnormalities. Use caution when prescribing **MIRALAX 3350** for patients with a history of seizures and in patients at increased risk of seizure, such as patients taking medications that lower the seizure threshold (e.g., tricyclic antidepressants), patients withdrawing from alcohol or benzodiazepines, or patients with known or suspected hyponatremia.

Back

Renal impairment:
Use with caution in patients with impaired renal function or patients taking concomitant medications that affect renal function (such as diuretics, angiotensin converting enzyme inhibitors, angiotensin receptor blockers, or non-steroidal anti-inflammatory drugs). Advise these patients of the importance of adequate hydration, and consider performing pre-dose and post-colonoscopy laboratory tests (electrolytes, creatinine, and BUN) in these patients. 5.5 (Colonic) Mucosal Ulceration, Ischemic Colitis and Ulcerative Colitis Osmotic laxatives may produce colonic mucosal aphthous ulcerations and there have been reports of more serious cases of ischemic colitis requiring hospitalization. Concurrent use of stimulant laxatives and **MIRALAX 3350** may increase the risk and is not recommended. The potential for mucosal ulcerations resulting from the bowel preparation should be considered when interpreting colonoscopy findings in patients with known or suspected inflammatory bowel disease.
Use in patients with significant gastrointestinal disease: If gastrointestinal obstruction or perforation is suspected, perform appropriate diagnostic studies to rule out these conditions before administering **MIRALAX 3350**. If a patient experiences severe bloating, abdominal distension, or abdominal pain, administration should be slowed or temporarily discontinued until symptoms abate. Use with caution in patients with severe ulcerative colitis.
Aspiration patients:
With impaired gag reflex and patients prone to regurgitation or aspiration should be observed during the administration of **MIRALAX 3350**. Use with caution in these patients.
Not for direct ingestion:
The contents of each jug must be diluted with water to a final volume of 4 liters (4 L) and ingestion of additional water is important to patient tolerance. Direct ingestion of the undissolved powder may increase the risk of nausea, vomiting, dehydration, and electrolyte disturbances.

ADVERSE REACTIONS:
Nausea, abdominal fullness and bloating are the most common adverse reactions (occurred in up to 50% of patients) to administration of **MIRALAX 3350**. Abdominal cramps, vomiting and anal irritation occur less frequently. These adverse reactions are transient and usually subside rapidly. Isolated cases of urticaria, rhinorrhea, dermatitis and (rarely) anaphylactic reaction have been reported which may represent allergic reactions.
Published literature contains isolated reports of serious adverse reactions following the administration of PEG-electrolyte solution products in patients over 60 years of age. These adverse events include upper GI bleeding from Mallory-Weiss Tear, esophageal perforation, asystole, sudden dyspnea with pulmonary edema, and "butterfly-like" infiltrates on chest X-ray after vomiting and aspirating PEG.

SPECIAL POPULATIONS:
Pregnancy:
Pregnancy Category C.
Animal reproduction studies have not been performed with **MIRALAX 3350**. It is also not known if **MIRALAX 3350** can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. **MIRALAX 3350** should be given to a pregnant woman only if clearly needed.
Nursing mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when **MIRALAX 3350** is administered to a nursing woman.
Pediatric use: Safety and effectiveness of **MIRALAX 3350** in pediatric patients aged 6 months and older is supported by evidence from adequate and well-controlled clinical trials of **MIRALAX 3350** in adults with additional safety and efficacy data from published studies of similar formulations. Use of **MIRALAX 3350** in children younger than 2 years of age should be carefully monitored for occurrence of possible hypoglycemia, as this solution has no caloric substrate. Dehydration has been reported in one child and hypokalemia has been reported in 3 children.
Geriatric use: Clinical studies of **MIRALAX 3350** did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients.

CONTRAINDICATIONS:
MIRALAX 3350 is contraindicated in the following conditions:
- Gastrointestinal (GI) obstruction, ileus, or gastric retention
- Bowel perforation
- Ileus
- Toxic colitis or toxic megacolon
- Hypersensitivity to any components of **MIRALAX 3350**

DRUG INTERACTIONS:
- ***Drugs that may increase risks due to fluid and electrolyte abnormalities:*** Use caution when prescribing **MIRALAX 3350** for patients with conditions, or who are using medications that increase the risk for fluid and electrolyte disturbances or may increase the risk of adverse events of seizure, arrhythmias, and prolonged QT in the setting of fluid and electrolyte abnormalities. Consider additional patient evaluations as appropriate.
- ***Potential for altered drug absorption:*** Oral medication administered within 1 hour of the start of administration of **MIRALAX 3350** may be flushed from the gastrointestinal tract and the medication may not be absorbed.
- ***Stimulant laxatives:*** Concurrent use of stimulant laxatives and **MIRALAX 3350** may increase the risk of mucosal ulceration or ischemic colitis. Avoid use of stimulant laxatives (e.g., bisacodyl, sodium picosulfate) while taking **MIRALAX 3350.**

DIRECTIONS FOR USE:
Pour the contents of the sachet in half filled (125 ml) glass of water and mix until the contents of the sachet completely dissolve then drink it.

DOSAGE FOR CONSTIPATION: Adults, adolescent and elderly 1-3 sachets in a day. For long term 1-2 sachets in a day or as directed by the physician.

DOSAGE FOR FAECAL IMPACTION: Dissolve 8 sachets in 1 liter of water and consume within 6 hours or as directed by the physician.

INSTRUCTIONS:
- Store below 30°C.
- Protect from heat, sunlight & moisture.
- Keep out of the reach of children.
- To be sold on the prescription of a registered medical practitioner only.

PRESENTATION:
MIRALAX 3350 Sachet : Pack of 1 x 10 sachets.

Manufactured by:
WnsFeild Pharmaceuticals.
Plot # 122, Block A, Phase V, Industrial Estate, Hattar, Haripur, Pakistan.

FOR FURTHER INFORMATIONS PLEASE CONTACT:

Marketed by:
CCL Pharmaceuticals (Pvt.) Ltd.
62 Industrial Estate, Kot Lakhpat, Lahore, Pakistan.

ترکیب استعمال:
ساشے کے پاؤڈر کو آدھا گلاس (۱۲۵ ملی لیٹر) پانی میں ڈالیں اور اس وقت تک حل کریں جب تک کہ ساشے کا پاؤڈر اچھی طرح حل نہ ہو جائے پھر اس کو پی لیں۔

خوراک برائے قبض:
بالغوں، نوعمر اور بوڑھوں کیلئے ایک دن میں ۱ سے ۳ ساشے۔ طویل عرصے کیلئے ایک دن میں ۱ سے ۲ ساشے یا ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

خوراک برائے فیکل امپیکشن:
ایک لیٹر پانی میں ۸ ساشے ڈال کر ۶ گھنٹے کے اندر استعمال کریں یا ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

ہدایات:
۳۰ درجہ سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔
گرمی، دھوپ اور نمی سے بچائیں۔ بچوں کی پہنچ سے دور رکھیں۔
صرف مستند ڈاکٹر کے نسخہ پر فروخت کریں۔