HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use MOVIPREP safely and effectively. See full prescribing information for MOVIPREP.

MOVIPREP® (PEG-3350, sodium sulfate, sodium chloride, potassium chloride, sodium ascorbate, and ascorbic acid for oral solution)
Initial U.S. Approval: 2006

----------RECENT MAJOR CHANGES----------

Warnings and Precautions (5.9) August/2012

----------INDICATIONS AND USAGE----------

MoviPrep is an osmotic laxative indicated for cleansing of the colon as a preparation for colonoscopy in adults 18 years or older. (1)

----------DOSAGE AND ADMINISTRATION----------

- Split-dose regimen: The evening before the colonoscopy, take the first liter of MoviPrep solution (one 8 ounce glass every 15 minutes) and then drink 16 ounces of clear liquid. On the morning of the colonoscopy, take the second liter of MoviPrep solution over one hour and then drink 16 ounces of clear liquid at least one hour prior to the start of the colonoscopy. (2)
- Evening only (full-dose) regimen: Around 6 PM in the evening before the colonoscopy, take the first liter of MoviPrep solution (one 8 ounce glass every 15 minutes) and then about 1½ hours later take the second liter of MoviPrep solution (one 8 ounce glass every 15 minutes). In addition, drink 32 ounces of clear liquid during the evening before the colonoscopy. (2)

----------DOSAGE FORMS AND STRENGTHS----------

- Powdered Form: 2 x Pouch A and 2 x Pouch B to be administered as an oral solution. (3)

----------CONTRAINDICATIONS----------

- Gastrointestinal (GI) obstruction (4)
- Bowel perforation (4)
- Gastric retention (4)
- Ileus (4)
- Toxic colitis or toxic megacolon (4)
- Hypersensitivity to any components of MoviPrep (4)

----------WARNINGS AND PRECAUTIONS----------

- Risk of fluid and electrolyte abnormalities, arrhythmias, seizures and renal impairment – encourage adequate hydration, assess concurrent medications, and consider laboratory assessments prior to and after use (5.1, 5.2, 5.3)
- Patients with impaired renal function or patients taking concomitant medications that affect renal function – use caution, ensure adequate hydration and consider testing (5.4)
- Suspected GI obstruction or perforation – rule out the diagnosis before administration (5.6)
- Patients at risk for aspiration —observe during administration (5.7)
- Glucose-6-phosphate dehydrogenase deficiency (G-6-PD) – use with caution (5.8)
- Contains phenylalanine (2.33 mg per treatment) (5.9)

----------ADVERSE REACTIONS----------

Most common adverse reactions for split dosing (incidence ≥ 5%) are malaise, nausea, abdominal pain, vomiting, and upper abdominal pain (6). The most common adverse reactions for evening only dosing (incidence ≥ 5%) are abdominal distension, anal discomfort, thirst, nausea, abdominal pain, sleep disorder, rigors, hunger, malaise, vomiting, and dizziness (6).

To report SUSPECTED ADVERSE REACTIONS, contact Salix Pharmaceuticals, Inc. at 1-800-508-0024 or FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch*.

----------DRUG INTERACTIONS----------

- Oral medications may not be absorbed when administered while taking MoviPrep. (7)

----------USE IN SPECIFIC POPULATIONS----------

- Pregnancy: No human or animal data. Use only if clearly needed. (8.1)

See 17 for PATIENT COUNSELING INFORMATION.

Revised: August/2012

FULL PRESCRIBING INFORMATION: CONTENTS*

* Sections or subsections omitted from the full prescribing information are not listed

FULL PRESCRIBING INFORMATION

1. INDICATIONS AND USAGE

MoviPrep is an osmotic laxative indicated for cleansing of the colon as a preparation for colonoscopy in adults 18 years of age or older.

2. DOSAGE AND ADMINISTRATION

The MoviPrep dose for colon cleansing for adult patients is 2 liters (approximately 64 ounces) of MoviPrep solution (with 1 additional liter of clear liquid) taken orally prior to the colonoscopy in one of the following ways:

1) **Split-dose MoviPrep regimen:** The evening before the colonoscopy, take the first liter of MoviPrep solution over one hour (one 8 ounce glass every 15 minutes) and then drink 0.5 liters (approximately 16 ounces) of clear liquid. Then, on the morning of the colonoscopy, take the second liter of MoviPrep solution over one hour and then drink 0.5 liters of clear liquid at least one hour prior to the start of the colonoscopy; or

2) **Evening only (full-dose) MoviPrep regimen:** Around 6 PM in the evening before the colonoscopy, take the first liter of MoviPrep solution over one hour (one 8 ounce glass every 15 minutes) and then about 1.5 hours later take the second liter of MoviPrep solution over one hour. In addition, take 1 liter (approximately 32 ounces) of additional clear liquid during the evening before the colonoscopy.

Preparation of the MoviPrep solution:
MoviPrep solution is prepared by emptying the contents of 1 pouch A and 1 pouch B into a suitable glass container (or the container provided) and adding to the container 1 liter of lukewarm water. Mix the solution to ensure that the ingredients are completely dissolved. If the patient prefers, the MoviPrep solution can be refrigerated prior to drinking. The reconstituted solution should be used within 24 hours.

No additional ingredients (e.g., flavorings) should be added to the MoviPrep solution.

After consumption of the first liter of MoviPrep solution, the above mixing procedure should be repeated with the second pouch A and pouch B to reconstitute the second liter of the MoviPrep solution.

3. DOSAGE FORMS AND STRENGTHS

MoviPrep is available in a carton that contains 4 separate pouches (2 of pouch A and 2 of pouch B). Each pouch A contains 100 grams of polyethylene glycol (PEG) 3350, NF, 7.5 grams of sodium sulfate, USP, 2.691 grams of sodium chloride, USP, and 1.015 grams of potassium chloride, USP, plus the following excipients: aspartame, NF (sweetener), acesulfame potassium, NF (sweetener), and lemon flavoring. Each pouch B contains 4.7 grams of ascorbic acid, USP and 5.9 grams of sodium ascorbate, USP.

4. CONTRAINDICATIONS

MoviPrep is contraindicated in the following conditions:

- Gastrointestinal (GI) obstruction
- Bowel perforation
- Gastric retention
- Ileus
- Toxic colitis or toxic megacolon
- Hypersensitivity to any components of MoviPrep *[see DESCRIPTION (11)]*

5. WARNINGS AND PRECAUTIONS

5.1 Serious Fluid and Electrolyte Abnormalities

Advise patients to hydrate adequately before, during, and after the use of MoviPrep. If a patient develops significant vomiting or signs of dehydration after taking MoviPrep 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 MoviPrep. MoviPrep 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. [*See DRUG INTERACTIONS* (7.1)]

5.2 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 MoviPrep 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.

5.3 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 MoviPrep 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.

5.4 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 MoviPrep 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.

5.6 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 MoviPrep. 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.

5.7 Aspiration

Patients with impaired gag reflex and patients prone to regurgitation or aspiration should be observed during the administration of MoviPrep. Use with caution in these patients.

5.8 Glucose-6-phosphate dehydrogenase (G-6-PD) deficiency

Since MoviPrep contains sodium ascorbate and ascorbic acid, MoviPrep should be used with caution in patients with glucose-6-phosphate dehydrogenase (G-6-PD) deficiency, especially G-6-PD deficiency patients with an active infection, with a history of hemolysis, or taking concomitant medications known to precipitate hemolytic reactions.

5.9 Contains Phenylalanine

Phenylketonurics: Contains aspartame 233 mg per treatment which corresponds to 131 mg of phenylalanine per treatment (after hydrolysis of the aspartame molecule in-vivo to aspartic acid and phenylalanine).

6. ADVERSE REACTIONS

6.1 Clinical Studies Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice.

In the MoviPrep trials, abdominal distension, anal discomfort, thirst, nausea, and abdominal pain were some of the most common adverse reactions to MoviPrep administration. Since diarrhea was considered as a part of the efficacy of MoviPrep, diarrhea was not defined as an adverse reaction in the clinical studies. Tables 1 and 2 display the most common drug-related adverse reactions of MoviPrep and its comparator in the controlled MoviPrep trials.

Table 1: The Most Common Drug-Related Adverse Reactions[1] (≥ 2%) in the Study of MoviPrep vs. 4 Liter Polyethylene Glycol plus Electrolytes Solution

	MoviPrep® (split dose) N=180	**4L PEG + E[2] N=179**
	n (% = n/N)	**n (% = n/N)**
Malaise	35 (19.4)	32 (17.9)
Nausea	26 (14.4)	36 (20.1)
Abdominal pain	24 (13.3)	27 (15.1)
Vomiting	14 (7.8)	23 (12.8)
Upper abdominal pain	10 (5.6)	11 (6.1)
Dyspepsia	5 (2.8)	2 (1.1)

[1] Drug-related adverse reactions were adverse events that were possibly, probably, or definitely related to the study drug.
[2] 4L PEG + E is 4 liter Polyethylene Glycol plus Electrolytes Solution

Table 2: The Most Common Drug-Related Adverse Reactions[1] (≥ 5%) in the Study of MoviPrep vs. 90 mL Oral Sodium Phosphate Solution

	MoviPrep® (evening-only) (full dose) N=169	**90 mL OSPS[2] N=171**
	n (% = n/N)	**n (% = n/N)**
Abdominal distension	101 (59.8)	70 (40.9)
Anal discomfort	87 (51.5)	89 (52.0)
Thirst	80 (47.3)	112 (65.5)
Nausea	80 (47.3)	80 (46.8)
Abdominal pain	66 (39.1)	55 (32.2)
Sleep disorder	59 (34.9)	49 (28.7)
Rigors	57 (33.7)	51 (29.8)
Hunger	51 (30.2)	121 (70.8)
Malaise	45 (26.6)	90 (52.6)
Vomiting	12 (7.1)	14 (8.2)
Dizziness	11 (6.5)	31 (18.1)
Headache	3 (1.8)	9 (5.3)
Hypokalemia	0 (0)	10 (5.8)
Hyperphosphatemia	0 (0)	10 (5.8)

[1] Drug-related adverse reactions were adverse events that were possibly, probably, or definitely related to the study drug. In addition to the recording of spontaneous adverse events, patients were also specifically asked about the occurrence of the following symptoms: shivering, anal irritations, abdominal bloating or fullness, sleep loss, nausea, vomiting, weakness, hunger sensation, abdominal cramps or pain, thirst sensation, and dizziness.
[2] OSPS is Oral Sodium Phosphate Solution

Isolated cases of urticaria, rhinorrhea, dermatitis, and anaphylactic reaction have been reported with PEG-based products and may represent allergic reactions.

Published literature contains isolated reports of serious adverse events following the administration of PEG-based products in patients over 60 years of age. These adverse events included upper gastrointestinal bleeding from a Mallory-Weiss tear, esophageal perforation, asystole, and acute pulmonary edema after aspirating PEG-based preparation.

6.2 Postmarketing Experience

In addition to adverse reactions reported from clinical trials, the following adverse events have been identified during post-approval use of MoviPrep. Because they are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure. These events have been chosen for inclusion due to either their seriousness, frequency of reporting or causal connection to MoviPrep, or a combination of these factors.

General: Hypersensitivity reactions including anaphylaxis (some of which were severe, including shock), rash, urticaria, pruritis, lip, tongue and facial swelling, dyspnea, chest tightness and throat tightness. Fever, chills and dehydration.

7. DRUG INTERACTIONS

7.1 Drugs That May Increase Risks Due to Fluid and Electrolyte Abnormalities

Use caution when prescribing MoviPrep for patients with conditions, or who are using mediations 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. [*See WARNINGS (5)]*

7.2 Potential for Altered Drug Absorption

Oral medication administered within 1 hour of the start of administration of MoviPrep may be flushed from the gastrointestinal tract and the medication may not be absorbed.

8. USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Category C. Animal reproduction studies have not been performed with MoviPrep. It is also not known if MoviPrep can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. MoviPrep should be given to a pregnant woman only if clearly needed.

8.3 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 MoviPrep is administered to a nursing woman.

8.4 Pediatric Use

The safety and effectiveness of MoviPrep in pediatric patients has not been established.

8.5 Geriatric Use

Of the 413 patients in clinical studies receiving MoviPrep, 91 (22%) patients were aged 65 or older, while 25 (6%) patients were over 75 years of age. No overall differences in safety or effectiveness were observed between geriatric patients and younger patients, and other reported clinical experience has not identified differences in responses between geriatric patients and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

10 OVERDOSAGE

There have been no reported cases of overdose with MoviPrep. Purposeful or gross accidental ingestion of more than the recommended dose of MoviPrep might be expected to lead to severe electrolyte disturbances, including hyponatremia and/or hypokalemia, as well as dehydration and hypovolemia, with signs and symptoms of these disturbances. The patient who has taken an overdose should be monitored carefully, and treated symptomatically for complications.

11 DESCRIPTION

MoviPrep (PEG-3350, sodium sulfate, sodium chloride, potassium chloride, sodium ascorbate, and ascorbic acid for oral solution) is an osmotic laxative consisting of 4 separate pouches (2 of pouch A and 2 of pouch B) containing white to yellow powder for reconstitution. Each pouch A contains 100 grams of polyethylene glycol (PEG) 3350, NF, 7.5 grams of sodium sulfate, USP, 2.691 grams of sodium chloride, USP, and 1.015 grams of potassium chloride, USP, plus the following excipients: aspartame, NF (sweetener), acesulfame potassium, NF (sweetener), and lemon flavoring. Each pouch B contains 4.7 grams of ascorbic acid, USP and 5.9 grams of sodium ascorbate, USP. When 1 pouch A and 1 pouch B are dissolved together in water to a volume of 1 liter, MoviPrep (PEG-3350, sodium sulfate, sodium chloride, potassium chloride, sodium ascorbate, and ascorbic acid) is an oral solution having a lemon taste.

The entire, reconstituted, 2-liter MoviPrep colon preparation contains 200 grams of PEG-3350, 15 grams of sodium sulfate, 5.38 grams of sodium chloride, 2.03 grams of potassium chloride, 9.4 grams of ascorbic acid, and 11.8 grams of sodium ascorbate plus the following excipients: aspartame (sweetener), acesulfame potassium (sweetener), and lemon flavoring.

A container for reconstitution is enclosed.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

The primary mode of action is thought to be through the osmotic effect of polyethylene glycol 3350, sodium sulfate, sodium chloride, potassium chloride, sodium ascorbate, and ascorbic acid, which causes water to be retained in the colon and produces a watery stool.

12.3 Pharmacokinetics

The pharmacokinetics of MoviPrep have not been studied in patients with renal or hepatic insufficiency.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term studies in animals to evaluate the carcinogenic potential have not been performed with MoviPrep. Studies to evaluate potential for impairment of fertility or mutagenic potential have not been performed with MoviPrep.

14 CLINICAL STUDIES

The colon cleansing efficacy and safety of MoviPrep was evaluated in two randomized, actively-controlled, multi-center, investigator-blinded, phase 3 trials in patients scheduled to have an elective colonoscopy.

In the first study, patients were randomized to one of the following two colon preparation treatments: 1) 2 liters of MoviPrep with 1 additional liter of clear liquid split into two doses (during the evening before and the morning of the colonoscopy) and 2) 4 liters of polyethylene glycol plus electrolytes solution (4L PEG + E) split into two doses (during the evening before and the morning of the colonoscopy). Patients were allowed to have a morning breakfast, a light lunch, clear soup and/or plain yogurt for dinner. Dinner had to be completed at least one hour prior to initiation of the colon preparation administration.

The primary efficacy endpoint was the proportion of patients with effective colon cleansing as judged by blinded gastroenterologists on the basis of videotapes recorded during the colonoscopy.

The blinded gastroenterologists graded the colon cleansing twice (during introduction and withdrawal of the colonoscope) and the poorer of the two assessments was used in the primary efficacy analysis.

The efficacy analysis included 308 adult patients who had an elective colonoscopy. Patients ranged in age from 18 to 88 years old (mean age about 59 years old) with 52% female and 48% male patients. Table 3 displays the results.

Table 3: Effectiveness of Overall Colon Cleansing in the Study of MoviPrep vs 4 Liter Polyethylene Glycol plus Electrolytes Solution

	Responders A[2] or B[3] (%)	C[4] (%)	D[5] (%)
MoviPrep® (N=153)	88.9	9.8	1.3
4L PEG + E[1] (N=155)	94.8	4.5	0.6

[1] 4L PEG + E is 4 Liter Polyethylene Glycol plus Electrolytes Solution
[2] A: colon empty and clean or presence of clear liquid, but easily removed by suction
[3] B: brown liquid or semisolid remaining amounts of stool, fully removable by suction or displaceable, thus allowing a complete visualization of the gut mucosa
[4] C: semisolid amounts of stool, only partially removable with a risk of incomplete visualization of the gut mucosa
[5] D: semisolid or solid amounts of stool; consequently colonoscopy incomplete or needed to be terminated.
4 L PEG+E's responder rate was not significantly higher than MoviPrep's responder rate.

In the second study, patients were randomized to one of the following two colon preparation treatments: 1) 2 liters of MoviPrep with 1 additional liter of clear liquid in the evening prior to the colonoscopy and 2) 90 mL of oral sodium phosphate solution (90 mL OSPS) with at least 2 liters of additional clear liquid during the day and evening prior to the colonoscopy. Patients randomized to MoviPrep therapy were allowed to have a morning breakfast; a light lunch; and clear soup and/or plain yogurt for dinner. Dinner had to be completed at least one hour prior to initiation of the colon preparation administration.

The primary efficacy endpoint was the proportion of patients with effective colon cleansing as judged by the colonoscopist and one blinded gastroenterologist (on the basis of videotapes recorded during the colonoscopy). In case of a discrepancy between the colonoscopist and the blinded gastroenterologist, a second blinded gastroenterologist made the final efficacy determination.

The efficacy analysis included 280 adult patients who had an elective colonoscopy. Patients ranged in age from 21 to 76 years old (mean age about 53 years old) with 47% female and 53% male patients. Table 4 displays the results.

Table 4: Effectiveness of Overall Colon Cleansing in the Study of MoviPrep vs 90mL Oral Sodium Phosphate Solution

	Responders A[2] or B[3] (%)	C[4] (%)	D[5] (%)
MoviPrep® (N=137)	73.0	23.4	3.6
90 mL OSPS[1] (N=143)	64.4	29.4	6.3

[1] OSPS is Oral Sodium Phosphate Solution
[2] A: empty and clean or clear liquid (transparent, yellow, or green)
[3] B: brown liquid or semisolid remaining small amounts of stool, fully removable by suction or displaceable allowing a complete visualization of the underlying mucosa
[4] C: semi solid only partially removable/displaceable stools; risk of incomplete examination of the underlying mucosa
[5] D: heavy and hard stool making the segment examination uninterpretable and, consequently, the colonoscopy needed to be terminated
MoviPrep's responder rate was not significantly higher than OSPS's responder rate.

16 HOW SUPPLIED/STORAGE AND HANDLING

MoviPrep is supplied as a white to yellow powder. MoviPrep is administered as an oral solution after reconstitution.

NDC 65649-201-75, MoviPrep, single use carton.
NDC 65649-201-76, MoviPrep, professional sample carton.

Each carton contains a disposable container for reconstitution of MoviPrep and 4 pouches (2 of pouch A and 2 of pouch B).

STORAGE

Store carton/container at 25°C (77°F); excursions permitted to 15-30°C (59-86°F). When reconstituted, store upright and keep solution refrigerated. Use within 24 hours.

17 PATIENT COUNSELING INFORMATION

- Advise patients who require a diet low in phenylalanine that MoviPrep contains aspartame – a maximum of 233 mg per treatment. This sweetener, after hydrolysis in the body, provides 131 mg of phenylalanine to the patient.
- Ask patients to inform you if they have trouble swallowing or are prone to regurgitation or aspiration.
- Instruct patients that each pouch needs to be diluted in water before ingestion and that they need to drink additional clear liquid (e.g., water, clear soup, fruit juice without pulp, soft drinks, tea and/or coffee without milk) according to instructions.
- Inform patients that oral medications may not be absorbed properly if they are taken within one hour of starting each dose of MoviPrep.
- Tell patients not to take other laxatives while they are taking MoviPrep.
- Tell patients that MoviPrep produces a watery stool (diarrhea) which cleanses the colon before colonoscopy. Advise patients receiving MoviPrep to adequately hydrate before, during, and after the use of MoviPrep. Patients may have clear soup and/or plain yogurt for dinner, finishing the evening meal at least one hour prior to the start of MoviPrep treatment. No solid food should be taken from the start of MoviPrep treatment until after the colonoscopy.
- Tell patients that the first bowel movement may occur approximately 1 hour after the start of MoviPrep administration. Abdominal bloating and distention may occur before the first bowel movement. If severe abdominal discomfort or distention occurs, stop drinking MoviPrep temporarily or drink each portion at longer intervals until these symptoms diminish. If severe symptoms persist, notify your health provider.

Manufactured by:
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For:
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