

PEN PREP - magnesium citrate powder, for solution

PEN Prep LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

OTC ACTIVE INGREDIENT SECTION

DRUG FACTS ACTIVE INGREDIENT (IN EACH DOSE) MAGNESIUM CITRATE 17 G

PURPOSE SECTION

SALINE LAXATIVE

KEEP OUT OF REACH OF CHILDREN SECTION

KEEP OUT OF REACH OF CHILDREN. IN CASE OF OVERDOSE, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER RIGHT AWAY.

INDICATIONS AND USES

RELIEVES OCCASIONAL CONSTIPATION (IRREGULARITY)

WARNINGS SECTION

WARNINGS: ALLERGY ALERT: DO NOT USE IF YOU ARE ALLERGIC TO MAGNESIUM CITRATE. DO NOT EXCEED MAXIMUM DOSE IN A 24 HOUR PERIOD. ASK A DOCTOR BEFORE USE IF YOU HAVE KIDNEY DISEASE NAUSEA, VOMITING OR ABDOMINAL PAIN A SUDDEN CHANGE OF BOWEL HABITS FOR OVER 2 WEEKS

ASK A DOCTOR OR PHARMACIST BEFORE USE IF YOU ARE TAKING A PRESCRIPTION DRUG. TAKE THIS PRODUCT TWO OR MORE HOURS BEFORE OR AFTER OTHER DRUGS. WHEN USING THIS PRODUCT YOU MAY HAVE LOOSE, WATERY, MORE FREQUENT STOOLS.

IF PREGNANT OR BREAST FEEDING, ASK A HEALTH PROFESSIONAL BEFORE USE.

DOSAGE AND ADMINISTRATION SECTION

FILL THIS BOTTLE TO THE TOP OF THE LABEL WITH COLD WATER OR OTHER LIQUIDS AND SHAKE THOROUGHLY. IF NEEDED, REFRIGERATE AFTER RECONSTITUTING, AND THEN SHAKE BEFORE USE. DO NOT USE AFTER 36 HOURS OF RECONSTITUTION. OR USE AS DIRECTED BY YOUR DOCTOR. CHILDREN UNDER 12, ASK YOUR DOCTOR.

INACTIVE INGREDIENT SECTION


SUCRALOSE, LEMON FLAVOR

PACKAGE LABEL PRINCIPAL DISPLAY PANEL

PEN PREP™ CITRATE OF MAGNESIUM 10 FL. OZ. AFTER RECONSTITUTION

OTHER INFORMATION: TAMPER EVIDENT: DO NOT USE IF TAMPER-PROOF CAP IS OPEN OR BROKEN.

QUESTIONS OR COMMENTS? 956-605-7590 PEN PREP L.L.C. MCALLEN, TEXAS 78504
WWW.PENRGV.COM

| <p>Drug Facts (continued)</p> <p>Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.</p> <p>Directions ■fill this bottle to the top of the label with cold water or other liquids and shake thoroughly. If needed, refrigerate after reconstituting, and then shake before use. Do not use after 36 hours of reconstitution. ■or use as directed by your doctor. ■children under 12, ask your doctor.</p> <p>Other information: tamper evident: do not use if tamper-proof cap is open or broken</p> <p>Inactive ingredients - sucralose, lemon flavor</p> <p>Questions or comments? 956-605-7590</p> <p>PEN Prep L.L.C. • McAllen, Texas 78504 www.PENrgv.com</p> | <p>PEN Prep™ Citrate of Magnesium</p>  <p>10 fl.oz. after reconstitution</p> | <p>Drug Facts</p> <table border="1"> <thead> <tr> <th>Active Ingredient (In each dose)</th> <th>Purpose</th> </tr> </thead> <tbody> <tr> <td>Magnesium Citrate 17g</td> <td>Saline laxative</td> </tr> </tbody> </table> <p>Uses ■relieves occasional constipation (irregularity)</p> <p>Warnings Allergy alert: Do not use if you are allergic to magnesium citrate Do not exceed maximum dosage in a 24 hour period Ask a doctor before use if you have ■kidney disease ■nausea, vomiting or abdominal pain ■a sudden change of bowel habits for over 2 weeks Ask a doctor or pharmacist before use if you are taking a prescription drug. Take this product two or more hours before or after other drugs. When using this product you may have loose, watery, more frequent stools. If pregnant or breast feeding, ask a health professional before use.</p> | Active Ingredient (In each dose) | Purpose | Magnesium Citrate 17g | Saline laxative |
|---|--|---|----------------------------------|---------|-----------------------|-----------------|
| Active Ingredient (In each dose) | Purpose | | | | | |
| Magnesium Citrate 17g | Saline laxative | | | | | |

PEN PREP

magnesium citrate powder, for solution

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:76334-001 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|---------------|
| MAGNESIUM CITRATE (UNII: RHO26O1T9V) (MAGNESIUM CATION - UNII:T6V3LHY838) | MAGNESIUM CITRATE | 17 g in 100 g |

Inactive Ingredients

| Ingredient Name | Strength |
|------------------------------|----------|
| SUCRALOSE (UNII: 96K6UQ3ZD4) | |

Product Characteristics

| | | | |
|-----------------|----------------------|---------------------|--|
| Color | | Score | |
| Shape | | Size | |
| Flavor | LEMON (LEMON FLAVOR) | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:76334-001-01 | 17 g in 1 BOTTLE | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part331 | 07/01/2010 | |

Labeler - PEN Prep LLC (968345434)**Registrant** - PEN Prep LLC (968345434)

Revised: 11/2011

PEN Prep LLC