

## **PEN PREP PLUS - 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.*

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## **OTC ACTIVE INGREDIENT SECTION**

DRUG FACTS ACTIVE INGREDIENT (IN EACH DOSE) MAGNESIUM CITRATE 17 G  
SIMETHICONE 80 MG

## **INACTIVE INGREDIENT SECTION**

SUCRALOSE, LEMON FLAVOR

## **INDICATIONS AND USES**

RELIEVES OCCASIONAL CONSTIPATION (IRREGULARITY)

## **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.

## **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.

## **WARNINGS SECTION**

WARNINGS: ALLERGY ALERT: DO NOT USE IF YOU ARE ALLERGIC TO MAGNESIUM CITRATE OR SIMETHICONE. 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.

## **PREGNANCY OR BREAST FEEDING SECTION**

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

## **PURPOSE SECTION**


SALINE LAXATIVE REDUCTION OF INTESTINAL GAS

## PACKAGE LABEL PRINCIPAL DISPLAY PANEL

PEN PREP™ CITRATE OF MAGNESIUM PLUS 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

<b>Drug Facts</b> (continued) <b>Keep out of reach of children.</b> In case of overdose, get medical help or contact a Poison Control Center right away. <b>Directions</b> ■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. <b>Other information:</b> tamper evident: do not use if tamper-proof cap is open or broken <b>Inactive ingredients</b> - sucralose, lemon flavor <b>Questions or comments? 956-605-7590</b> <b>PEN Prep L.L.C. • McAllen, Texas 78504</b> <b>www.PENrgv.com</b>	<b>PEN Prep™</b> <b>Citrate of Magnesium Plus</b>  <b>10 fl.oz. after reconstitution</b>	<b>Drug Facts</b> <table border="1"><tr><th>Active Ingredient (In each dose)</th><th>Purpose</th></tr><tr><td>Magnesium Citrate 17g</td><td>Saline laxative</td></tr><tr><td>Simethicone 80mg</td><td>Reduction of intestinal gas</td></tr></table> <b>Uses</b> ■relieves occasional constipation (irregularity) <b>Warnings</b> <b>Allergy alert:</b> Do not use if you are allergic to magnesium citrate or simethicone <b>Do not exceed</b> maximum dosage in a 24 hour period <b>Ask a doctor before use if you have</b> ■kidney disease ■nausea, vomiting or abdominal pain ■a sudden change of bowel habits for over 2 weeks <b>Ask a doctor or pharmacist before use if you are</b> taking a prescription drug. Take this product two or more hours before or after other drugs. <b>When using this product</b> you may have loose, watery, more frequent stools. <b>If pregnant or breast feeding,</b> ask a health professional before use.	Active Ingredient (In each dose)	Purpose	Magnesium Citrate 17g	Saline laxative	Simethicone 80mg	Reduction of intestinal gas
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## PEN PREP PLUS

magnesium citrate powder, for solution

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76334-002
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
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	.08 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
SUCRALOSE (UNII: 96K6UQ3ZD4)	

### Product Characteristics

Color		Score	
Shape		Size	

<b>Flavor</b>	LEMON (LEMON FLAVOR)			<b>Imprint Code</b>	
<b>Contains</b>					
<b>Packaging</b>					
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
1	NDC:76334-002-02	17 g in 1 BOTTLE			
<b>Marketing Information</b>					
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>		<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
OTC monograph final	part331		07/01/2010		

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

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