

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

22-015

LABELING

Physician Sample – Not for Resale

<p>Drug Facts Active Ingredient (in each dose) Purpose Polyethylene Glycol 3350, 17 gLaxative</p>	<p>Drug Facts (continued) If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.</p>
<p>Use</p> <ul style="list-style-type: none"> relieves occasional constipation (irregularity) generally produces a bowel movement in 1 to 3 days 	<p>Directions</p> <ul style="list-style-type: none"> do not take more than directed unless advised by your doctor adults and children 17 years of age and older: <ul style="list-style-type: none"> stir and dissolve one packet of powder (17 g) in any 4 to 8 ounces of beverage (cold, hot or room temperature) then drink use once a day use no more than 7 days children 16 years of age or under: ask a doctor
<p>Warnings Allergy alert: Do not use if you are allergic to polyethylene glycol</p> <p>Do not use if you have kidney disease, except under the advice and supervision of a doctor</p>	<p>Other information</p> <ul style="list-style-type: none"> Store at 20° - 25°C(68° - 77°F) Tamper-Evident: Do not use if foil is open or broken
<p>Ask a doctor before use if you have</p> <ul style="list-style-type: none"> nausea, vomiting or abdominal pain a sudden change in bowel habits that lasts over 2 weeks irritable bowel syndrome 	<p>Inactive ingredients none</p>
<p>Ask a doctor or pharmacist before use if you are taking a prescription drug</p>	<p>Questions or comments? 1-800-XXX-YYYY</p>
<p>When using this product you may have loose, watery, more frequent stools</p> <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> you have rectal bleeding or your nausea, bloating, cramping or abdominal pain gets worse. These may be signs of a serious condition. you get diarrhea you need to use a laxative for longer than 1 week <p style="text-align: right;">➔</p>	

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www.website.com Lot and Expiration Date

<p>STANDARD FORMAT Helvetica Condensed Variable horizontal scale adheres to 39 characters per inch</p> <p>Drug Facts - 9 pt Helvetica Cnd. Bold Italic</p> <p>Drug Facts (continued) Drug Facts - 8 pt Helvetica Cnd. Bold Italic (continued) - 8 pt Helvetica Cnd.</p> <p>Headings - 8 pt Helvetica Cnd. Bold Italic</p> <p>Sub Heads - 6 pt Helvetica Cnd. Bold</p> <p>Text - 6 pt Helvetica Cnd, minimum leading 6.5</p> <p>Square Bullets - 5 pt Zaph Dingbals no compression</p> <p>Border - 1 pt rule, 3/64" gap all around</p> <p>Barline - 2.5 pt rule</p> <p>Hairline - .5 pt rule</p>
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Dissolves in Any Beverage

Drug Facts (continued)

If pregnant or breast-feeding, ask a health professional before use.
Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- Do not take more than directed unless advised by your doctor
- The bottle cap is a measuring cap marked to use for 17 years of children when filled to the top of the line (inside pocket in cap)
- Adults and children 17 years of age and older:
 - Fill to top of white section in cap which is marked to indicate the correct dose (17g)
 - Use and dissolve in any 4 to 8 ounces of beverage (cold, hot, or room temperature) then drink
 - Use once a day
 - Use no more than 7 days
- Children 16 years of age or under: ask a doctor

Other information

- Store at 20° - 25° (68° - 77°)
- Temperature sensitive: Do not use if the seal under cap is missing, open or broken

Inactive ingredients none

Questions or comments? 1-800-XXX-YYYY

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UCC 52768, 370-04

ORIGINAL
Rx
STRENGTH

MiraLAX
Polyethylene Glycol 3350
Powder for Solution, Laxative

ORIGINAL PRESCRIPTION STRENGTH

- Relieves Occasional Constipation
- Softens Stool

NET WT 8.3 OZ (238 g)

CONTAINS 14 ONCE-DAILY DOSES

MiraLAX increases frequency of bowel movements and softens the stool.

Drug Facts

Active ingredient (in each dose) Purpose
Polyethylene Glycol 3350, 17 g (cap filled to line) Laxative

Use

- relieves occasional constipation (e.g., laxative)
- generally provides a bowel movement in 1 to 3 days

Warnings

Allergy alert: Do not use if you're allergic to polyethylene glycol

- Do not use if you have kidney disease, except under the advice and supervision of a doctor
- Ask a doctor before use if you have
 - nausea, vomiting or abdominal pain
 - a sudden change in bowel habits that lasts over 2 weeks
 - or visible blood in stool
- Ask a doctor or pharmacist before use if you are taking a prescription drug

When using this product you may have loose, watery, more frequent stools

- Stop use and ask a doctor if
 - you have red blood or stool if
 - you have red blood or your nausea, bloating, cramping or abdominal pain gets worse. These may be signs of a serious condition.
 - you get diarrhea
 - you need to use a laxative for longer than 1 week

ATTACH LEGEND ON ALL DIGITAL MECHANICALS

STANDARD FORMAT

Helvetica Condensed
Variable horizontal scale adheres to 33 characters per inch

Drug Facts - 9 pt Helvetica Cond, Bold Italic

Drug Facts (continued):

Drug Facts - 8 pt Helvetica Cond, Bold Italic (continued) - 3 pt Helvetica Cond

Headings - 8 pt Helvetica Cond, Bold Italic

Sub-Headings - 8 pt Helvetica Cond, Bold

Text - 6 pt Helvetica Cond, minimum leading 5.5

Square Bullets - 5 pt Zapf Dingbats no compression

Border - 1 pt rule 3/16" gap all around

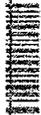
Baselines - 2.5 pt rule

Headlines - 5 pt rule

Certified by: _____

MiraLAX 17 gram single dose pouch





PDP



Drug Facts

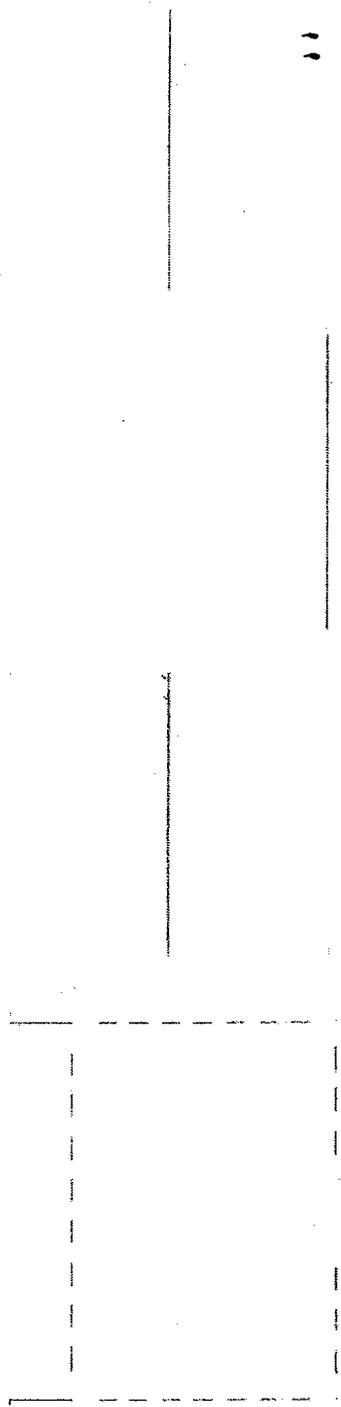


PDP

PDP

PDP

Contains xx single dose packets - Net Wt xx oz (xxx g)



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**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

Joyce Korvick
10/6/2006 03:44:14 PM

Andrea Segal
10/6/2006 03:52:20 PM