

Sample - Not for Sale		<ul style="list-style-type: none"> • Sugar Free • Dissolves in any Beverage 																																																	
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In case of overdose, get medical help or contact a Poison Control Center right away. </td> </tr> <tr> <th colspan="2" style="text-align: left; padding: 2px;">Directions</th> </tr> <tr> <td colspan="2" style="padding: 2px;"> <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 </td> </tr> <tr> <th colspan="2" style="text-align: left; padding: 2px;">Other information</th> </tr> <tr> <td colspan="2" style="padding: 2px;"> <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 </td> </tr> <tr> <th colspan="2" style="text-align: left; padding: 2px;">Inactive ingredients</th> </tr> <tr> <td colspan="2" style="padding: 2px;">none</td> </tr> <tr> <th colspan="2" style="text-align: left; padding: 2px;">Questions or comments?</th> </tr> <tr> <td colspan="2" style="padding: 2px;"> 1-800-MiraLAX (1-800-647-2529) or www.MiraLAX.com </td> </tr> <tr> <td colspan="2" style="padding: 2px;"> Bayer, the Bayer Cross, and MiraLAX are registered trademarks of Bayer. © 2015 Bayer. Dist by: Bayer HealthCare LLC, Whippany, NJ 07981 </td> </tr> <tr> <td colspan="2" style="text-align: center; padding: 2px;"> XXXXX-XX </td> </tr> </table>	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.		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The image shows a purple and white sachet of MiraLAX NeatPAX. The sachet features the MiraLAX logo in purple and white, with 'NeatPAX Travel Size' in pink and white. It also includes a 'UNFLAVORED POWDER GRIT FREE' seal, a Bayer logo, and the text '1 DOSE' and 'NET WT 0.5 OZ (17 g)'. A dashed line with an arrow indicates where to fold the sachet.

ATTACH LEGEND ON ALL DIGITAL MECHANICALS

STANDARD FORMAT
 Helvetica Condensed
 Variable horizontal scale adheres to 39 characters per inch

Drug Facts - 9 pt Helvetica Cnd, Bold Italic

Drug Facts (continued)
Drug Facts - 8 pt Helvetica Cnd, Bold Italic (continued) - 8 pt Helvetica Cnd.

Headings - 8 pt Helvetica Cnd, Bold Italic

Sub Heads - 6 pt Helvetica Cnd, Bold

Text - 6 pt Helvetica Cnd, minimum leading 6,5

Square Bullets - 3,5 pt Zaph Dingbats no compression

Border - 1 pt rule, 3/64" gap all around

Barline - 1 pt rule _____

Hairline - .5 pt rule _____

Certified by: dw

FDA Submission: 03.25.15

Not For Individual Sale		<ul style="list-style-type: none"> • Sugar Free • Dissolves in any Beverage 				
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		XXXXXX-XX				



MiraLAX
 Polyethylene Glycol 3350, Powder for Solution, Osmotic Laxative

UNFLAVORED
 POWDER
 GRIT FREE

NeatPAX Travel Size

- Relieves Occasional Constipation/Irregularity
- Softens Stool

1 DOSE NET WT 0.5 OZ (17 g)

FOLD AT LINE
 TEAR AT ARROW

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Text - 6 pt Helvetica Cnd, minimum leading 6,5

Square Bullets - 3,5 pt Zaph Dingbats no compression

Border - 1 pt rule, 3/64" gap all around

Barline - 1 pt rule _____

Hairline - .5 pt rule _____

Certified by: dw

FDA Submission: 03.25.15

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Bayer		XXXXX-XX				



MiraLAX
 Polyethylene Glycol 3350, Powder for Solution, Osmotic Laxative

UNFLAVORED
 POWDER
 GRIT FREE

NeatPAX Travel Size

- Relieves Occasional Constipation/Irregularity
- Softens Stool

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Border - 1 pt rule, 3/64" gap all around

Barline - 1 pt rule

Hairline - .5 pt rule

Certified by: dw

FDA Submission: 03.25.15

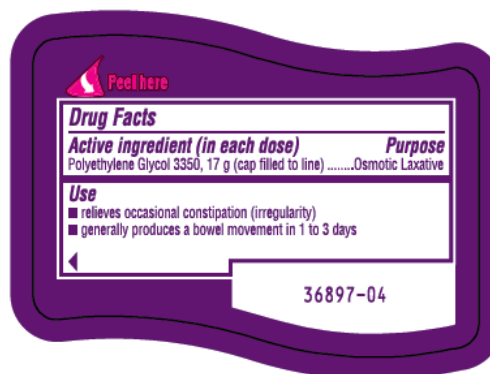


FDA Submission: 03.26.15

**ATTACH LEGEND ON ALL
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STANDARD FORMAT Helvetica Condensed Variable horizontal scale adheres to 39 characters per inch Drug Facts - 9 pt Helvetica Cnd. Bold Italic Drug Facts (continued) Drug Facts - 8 pt Helvetica Cnd. Bold Italic (continued) - 8 pt Helvetica Cnd. Headings - 8 pt Helvetica Cnd. Bold Italic Sub Heads - 6 pt Helvetica Cnd. Bold Text - 6 pt Helvetica Cnd, minimum leading 6.5 Square Bullets - 5 pt Zaph Dingbats no compression Border - 1.5 pt rule, 3/64" gap all around Barline - 2.5 pt rule _____ Hairline - .5 pt rule _____

Certified by: eb
FDA Submission
APO #: 2015-2715
10.02.15 dw

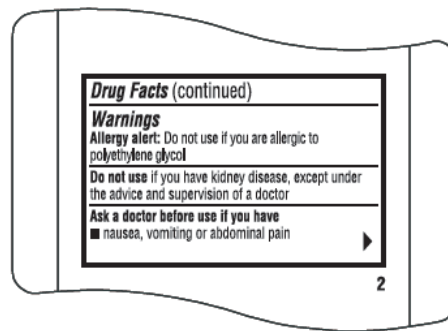


Top Panel

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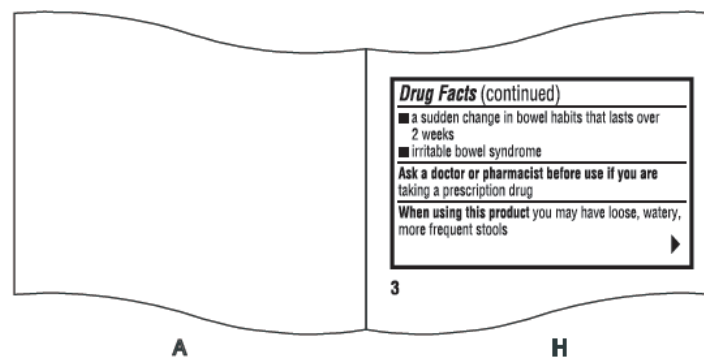


Base

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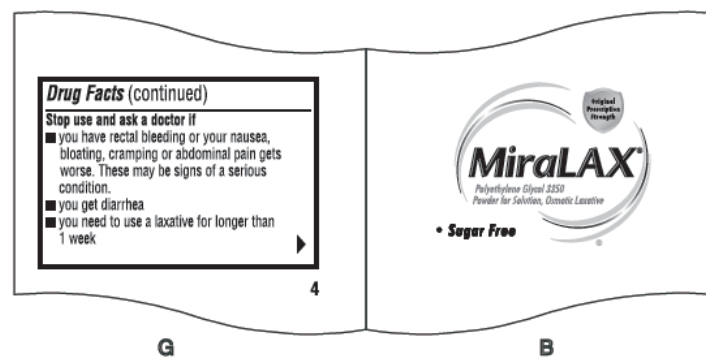
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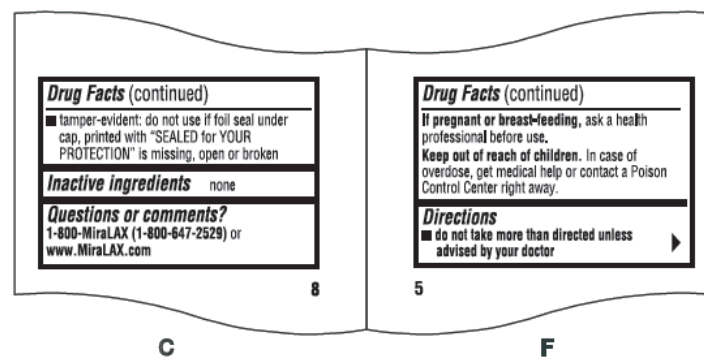
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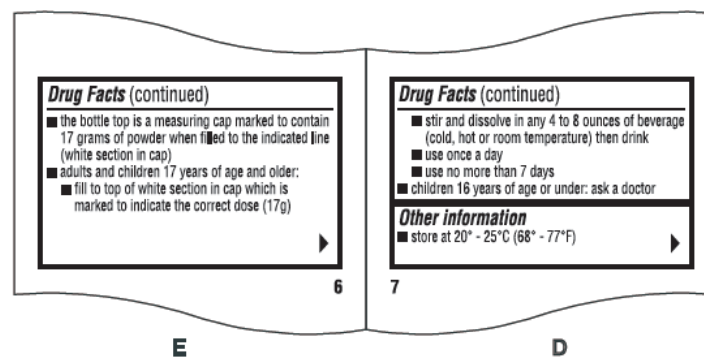
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Certified by: eb
FDA Submission
APO #: 2015-2715
10.02.15 dw



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Drug Facts

Active ingredient (in each dose) Polyethylene Glycol 3350, 17 g	Purpose Osmotic Laxative
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Use

- relieves occasional constipation (irregularity)
- generally produces a bowel movement in 1 to 3 days

Warnings

Allergy alert: Do not use if you are 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
- irritable bowel syndrome

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 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

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
- adults and children 17 years of age and older:
 - 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

Other information

- store at 20° - 25°C (68° - 77°F)
- tamper-evident: do not use if foil is open or broken

Inactive ingredients none

Questions or comments?
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Polyethylene Glycol 3350, Powder for Solution, Osmotic Laxative



NeatPAX

- Dissolves in Any Beverage
- Sugar Free





Polyethylene Glycol 3350, Powder for Solution, Osmotic Laxative



NeatPAX

- Relieves Occasional Constipation/Irregularity
- Softens Stool



10 ONCE-DAILY DOSES

10 PACKETS
NET WT 0.5 OZ (17g) EACH



Polyethylene Glycol 3350, Powder for Solution, Osmotic Laxative



NeatPAX



Travel Size

10
PRE-MEASURED,
SINGLE DOSES

00000000

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Text - 6 pt Helvetica Cnd, minimum leading 6.5

Square Bullets - 5 pt Zaph Dingbats no compression

Border - 2.5 pt rule, 3/64" gap all around

Barline - 2.5 pt rule

Hairline - .5 pt rule

Certified by: eb

APD #: 2015-XXXX
05.14.13 dw

FDA Submission: 83-25-175
Reference ID: 3839775



FDA Submission: 03.25.15



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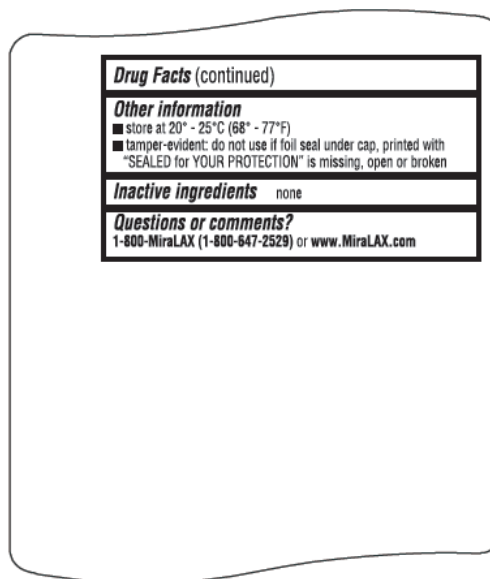
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- the bottle top is a measuring cap marked to contain 17 grams of powder when filled to the indicated line (white section in cap)
- adults and children 17 years of age and older:
 - fill to top of white section in cap which is marked to indicate the correct dose (17g)
 - stir 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

**ATTACH LEGEND ON ALL
DIGITAL MECHANICALS**

STANDARD FORMAT Helvetica Condensed Variable horizontal scale adheres to 39 characters per inch Drug Facts - 9 pt Helvetica Cnd, Bold Italic Drug Facts (continued) Drug Facts - 8 pt Helvetica Cnd, Bold Italic (continued) - 8 pt Helvetica Cnd. Headings - 8 pt Helvetica Cnd, Bold Italic Sub Heads - 6 pt Helvetica Cnd, Bold Text - 6 pt Helvetica Cnd, minimum leading 6,5 Square Bullets - 5 pt Zaph Dingbats no compression Border - 1.5 pt rule, 3/64" gap all around Barline - 2.5 pt rule  Hairline - .5 pt rule 

Certified by: eb
FDA Submission
APO #: 2015-2715
10.02.15 dw









MiraLAX® increases frequency of bowel movements and softens the stool.

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ATTACH LEGEND ON ALL DIGITAL MECHANICALS

STANDARD FORMAT Helvetica Condensed Variable horizontal scale adheres to 39 characters per inch
Drug Facts - 9 pt Helvetica Cnd. Bold Italic
Drug Facts (continued) Drug Facts - 8 pt Helvetica Cnd. Bold Italic (continued) - 8 pt Helvetica Cnd.
Headings - 8 pt Helvetica Cnd. Bold Italic
Sub Heads - 6 pt Helvetica Cnd. Bold
Text - 6 pt Helvetica Cnd, minimum leading 6.5
Square Bullets - 5 pt Zaph Dingbats no compression
Border - 1.5 pt rule, 3/64" gap all around
Barline - 2.5 pt rule 
Hairline - .5 pt rule 

Certified by: eb
 FDA Submission
 APO #: 2015-2715
 10.01.15 dw

<p>Drug Facts</p> <p>Active ingredient (in each dose) Purpose Polyethylene Glycol 3350, 17 g (cap filled to line)..... Osmotic Laxative</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>Warnings</p> <p>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>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>Ask a doctor or pharmacist before use if you are taking a prescription drug</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>Drug Facts (continued)</p> <p>If pregnant or breast-feeding, ask a health professional before use.</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</p> <ul style="list-style-type: none"> do not take more than directed unless advised by your doctor the bottle top is a measuring cap marked to contain 17 grams of powder when filled to the indicated line (white section in cap) adults and children 17 years of age and older: <ul style="list-style-type: none"> fill to top of white section in cap which is marked to indicate the correct dose (17g) stir 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 <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 seal under cap, printed with "SEALED for YOUR PROTECTION" is missing, open or broken <p>Inactive ingredients none</p> <p>Questions or comments? 1-800-MiraLAX (1-800-647-2529) or www.MiraLAX.com</p>
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• Sugar Free 36889-04

20% MORE FREE! Easy to Pour Bottle

MiraLAX[®]
Polyethylene Glycol 3350, Powder for Solution, Osmotic Laxative

- Dissolves in Any Beverage
- Relieves Occasional Constipation/Irregularity
- Softens Stool

MiraLAX[®] increases frequency of bowel movements and softens the stool.

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Lot Expiry Area

UNFLAVORED
POWDER
GRIT FREE

BAYER

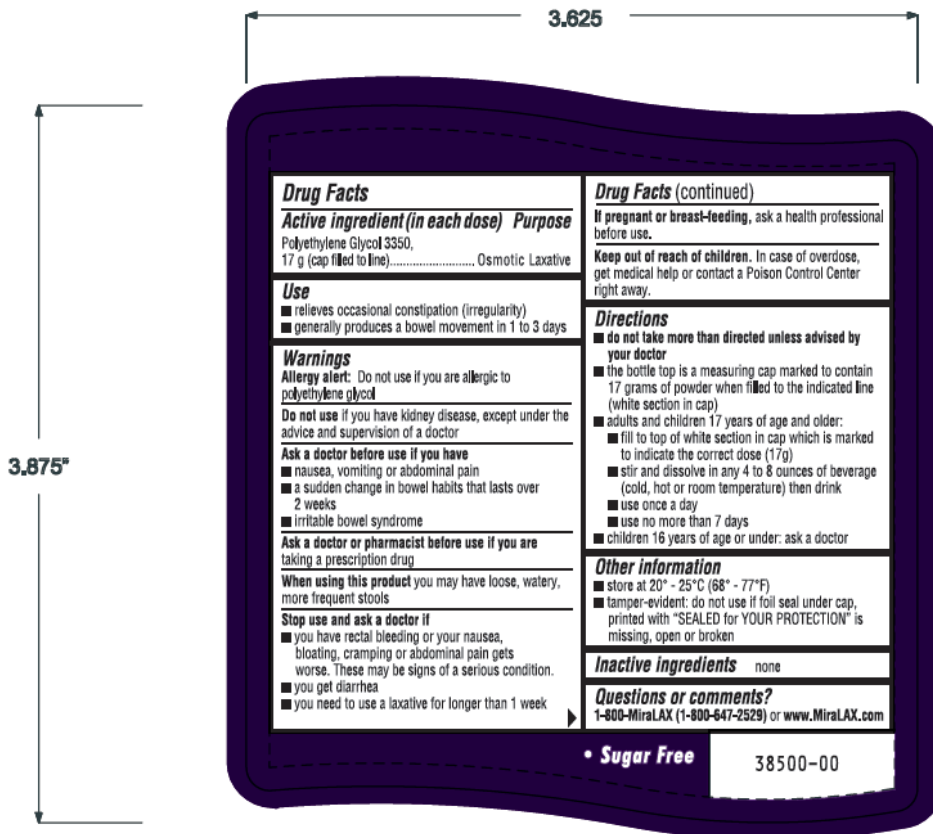
36 ~~30~~ ONCE-DAILY DOSES NET WT 21.5 OZ (612 g)

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Whippany, NJ 07981

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FDA Submission: 03.25.15



ATTACH LEGEND ON ALL DIGITAL MECHANICALS

STANDARD FORMAT
Helvetica Condensed
Variable horizontal scale adheres to 39 characters per inch
Drug Facts - 9 pt Helvetica Cnd, Bold Italic
Drug Facts (continued)
Drug Facts - 8 pt Helvetica Cnd, Bold Italic (continued) - 8 pt Helvetica Cnd.
Headings - 8 pt Helvetica Cnd, Bold Italic
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Square Bullets - 5 pt Zaph Dingbats no compression
Border - 1.5 pt rule, 3/64" gap all around
Barline - 2.5 pt rule
Hairline - .5 pt rule



Certified by: **eb**

APO #: 2011-92929
01.31.12
PTI-UNWIND 3



FDA Submission: 03.25.15

**ATTACH LEGEND ON ALL
 DIGITAL MECHANICALS**

STANDARD FORMAT
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Variable horizontal scale adheres to 39 characters per inch
Drug Facts - 9 pt Helvetica Cnd. Bold Italic
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Barline - 2.5 pt rule 
Hairline - .5 pt rule 

Certified by: eb
 APO #: 2013-95247
 07.30.13 - ju
 FDA Submission: 03.25.15

• Sugar Free

<p>Drug Facts</p> <p>Active ingredient (in each dose)..... Purpose Polyethylene Glycol 3350, 17 g (cap filled to line) Osmotic Laxative</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>Warnings</p> <p>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>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>Ask a doctor or pharmacist before use if you are taking a prescription drug</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>Drug Facts (continued)</p> <p>If pregnant or breast-feeding, ask a health professional before use.</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</p> <ul style="list-style-type: none"> ■ do not take more than directed unless advised by your doctor ■ the bottle top is a measuring cap marked to contain 17 grams of powder when filled to the indicated line (white section in cap) ■ adults and children 17 years of age and older: <ul style="list-style-type: none"> ■ fill to top of white section in cap which is marked to indicate the correct dose (17g) ■ stir 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 <p>Other information ■ store at 20° - 25°C (68° - 77°F)</p> <ul style="list-style-type: none"> ■ tamper-evident: do not use if foil seal under cap, printed with "SEALED for YOUR PROTECTION" is missing, open or broken <p>Inactive ingredients none</p> <p>Questions or comments? 1-800-MiraLAX (1-800-647-2529) or www.MiraLAX.com</p>
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This label may not be the latest approved by FDA.
For current labeling information, please visit <https://www.fda.gov/drugsatfda>





Peel here

Drug Facts

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

Use

- relieves occasional constipation (irregularity)
- generally produces a bowel movement in 1 to 3 days

Warnings

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

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Ask a doctor before use if you have

- nausea, vomiting or abdominal pain
- a sudden change in bowel habits that lasts over 2 weeks
- irritable bowel syndrome

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

• Sugar Free

36893-04



• Sugar Free

Drug Facts	Drug Facts (continued)
Active ingredient (in each dose)..... Purpose Polyethylene Glycol 3350, 17 g (cap filled to line) Osmotic Laxative	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.
Use ■ relieves occasional constipation (irregularity) ■ generally produces a bowel movement in 1 to 3 days	Directions ■ do not take more than directed unless advised by your doctor ■ the bottle top is a measuring cap marked to contain 17 grams of powder when filled to the indicated line (white section 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) ■ stir 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
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Drug Facts (continued)

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/s/

KAREN M MAHONEY
10/29/2015