

**CITRUCEL- methylcellulose powder, for solution**  
**GlaxoSmithKline Consumer Healthcare Holdings (US) 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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**Drug Facts**

**Active ingredient CITRUCEL Orange**  
**(in each heaping tablespoon)**

Methylcellulose (a non-allergenic fiber) 2g

**Active ingredient CITRUCEL Sugar Free**  
**(in each rounded tablespoon)**

Methylcellulose (a non-allergenic fiber) 2g

**Purpose**

Bulk-forming fiber laxative

**Uses**

- relieves occasional constipation (irregularity)
- generally produces a bowel movement in 12-72 hours

**Warnings**

**Choking: taking this product without adequate fluid may cause it to swell and block your throat or esophagus and may cause choking. Do not take this product if you have difficulty in swallowing. If you experience chest pain, vomiting, or difficulty in swallowing or breathing after taking this product, seek immediate medical attention.**

**Ask a doctor before use if you have**

- a sudden change in bowel habits that persists for two weeks
- abdominal pain, nausea or vomiting

**Stop use and ask a doctor if**

- constipation lasts more than 7 days
- you have rectal bleeding

These could be signs of a serious condition.

**Keep out of reach of children.**

In case of overdose, get medical help or contact a Poison Control Center right away.

**Directions**

- **MIX THIS PRODUCT (CHILD OR ADULT DOSE) WITH AT LEAST 8 OUNCES (A FULL GLASS) OF WATER OR OTHER FLUID. TAKING THIS PRODUCT WITHOUT ENOUGH LIQUID MAY CAUSE CHOKING. SEE CHOKING WARNING**
- use product at the first sign of constipation or irregularity
- put one dose in a full glass of cold water
- stir briskly and drink promptly
- drinking another glass of water is helpful

**CITRUCEL Orange**

<b>Age</b>	<b>Dose</b>
adults & children 12 years of age and over	start with 1 heaping <b>tablespoon</b> . Increase as needed, 1 heaping <b>tablespoon</b> at a time, up to 3 times per day.
children 6 - 11 years of age	start with 2.5 level <b>teaspoons</b> . Increase as needed, 2.5 level <b>teaspoons</b> at a time, up to 3 times per day.
children under 6 years of age	consult a physician

**CITRUCEL Sugar Free**

<b>Age</b>	<b>Dose</b>
adults & children 12 years of age and over	start with 1 rounded <b>tablespoon</b> . Increase as needed, 1 rounded <b>tablespoon</b> at a time, up to 3 times per day.
children 6 - 11 years of age	start with 2 level <b>teaspoons</b> . Increase as needed, 2 level <b>teaspoons</b> at a time, up to 3 times per day.
children under 6 years of age	consult a physician

**Other information (Citrucel Orange)**

- **each heaping tablespoon contains:** calcium 80 mg and potassium 105mg
- each heaping tablespoon contributes 60 calories from sucrose and maltodextrin
- store below 77°F (25°C)
- protect contents from humidity
- keep tightly closed

### ***Other information (Citrucel Sugar Free)***

- **each rounded tablespoon contains:** calcium 80 mg and potassium 115 mg
- each rounded tablespoon contributes 24 calories from maltodextrin
- store below 77°F (25°C)
- protect contents from humidity
- keep tightly closed
- **Phenylketonurics: CONTAINS PHENYLALANINE** 52mg per adult dose

### ***Inactive ingredients (Citrucel Orange)***

citric acid, dibasic calcium phosphate, FD&C yellow #6 lake, maltodextrin, orange flavors (natural and artificial), potassium citrate, riboflavin, sucrose, titanium dioxide, tricalcium phosphate

### ***Inactive ingredients (Citrucel Sugar Free)***

aspartame, dibasic calcium phosphate, FD&C yellow #6 lake, malic acid, maltodextrin, orange flavors (natural and artificial), potassium citrate, riboflavin

### ***Questions or comments? (Citrucel Orange)***

call toll-free **1-800-897-6081**

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**Warren, NJ 07059**

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### **DIRECTIONS FOR USE (NO SCOOP DOSING):**



1. Fill glass with at least 8 oz. of cold water.



2. Measure heaping tablespoon of product (one dose) and stir product into water. Stir briskly and drink promptly.

**Questions or comments? (Citrucel Sugar Free)**

call toll-free **1-800-897-6081**

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**DIRECTIONS FOR USE (NO SCOOP DOSING):**



1. Fill glass with at least 8 oz. of cold water.



2. Measure rounded tablespoon of product (one dose) and stir product into water. Stir briskly and drink promptly.

**Principal Display Panel**

**NDC 0135-0089-69**

**Great Taste**

## **CITRUCEL**

### **METHYLCELLULOSE FIBER THERAPY FOR IRREGULARITY**

- Gentle and clinically proven effective\*
- Gives you additional fiber to help relieve occasional constipation
- Fiber for irregularity that won't cause excess gas\*\*

**orange** FLAVOR

NET WT 16 OZ (454 GRAMS)

**Great Tasting**

### **CITRUCEL Orange**

Citrucel offers these great benefits:

- **Gentle and clinically proven effective** to help relieve occasional constipation\*
- **Fiber that won't ferment** to cause excess gas \*\*
- **100% Soluble, gluten-free, non-allergenic fiber**

\*When Used As Directed.

\*\*Based On Laboratory Testing. Individual Results May Vary.

### **TAMPER EVIDENT PACKAGE**

DO NOT USE IF FOIL SEAL IS MISSING OR BROKEN.

5E643

NDC 0135-0089-69

**Great Taste**



**CITRUCEL**

**METHYLCELLULOSE FIBER THERAPY FOR IRREGULARITY**

- **Gentle and clinically proven effective\***
- **Gives you additional fiber to help relieve occasional constipation**
- **Fiber for irregularity that won't cause excess gas\*\***



**orange**  
FLAVOR

NET WT 16 OZ (454 GRAMS)

## Principal Display Panel

**NDC 0135-0090-74**

**Great Taste**

**CITRUCEL**

**METHYLCELLULOSE FIBER THERAPY FOR IRREGULARITY**

- Gentle and clinically proven effective\*
- Gives you additional fiber to help relieve occasional constipation
- Fiber for irregularity that won't cause excess gas\*\*

**sugar free ORANGE FLAVOR**

NET WT 32 OZ (907 GRAMS)

**Great Tasting Orange Flavor**

**CITRUCEL Sugar Free**

Citrucel offers these great benefits:

- **Gentle and clinically proven effective** to help relieve occasional constipation\*

- **Fiber that won't ferment** to cause excess gas\*\*
- **100% Soluble, gluten-free, and non-allergenic fiber**  
\*When Used As Directed.  
\*\*Based On Laboratory Testing. Individual Results May Vary.

**TAMPER EVIDENT PACKAGE**

DO NOT USE IF FOIL SEAL IS MISSING OR BROKEN.

5M245



**CITRUCEL**

methylcellulose powder, for solution

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0135-0089
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Route of Administration ORAL

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>METHYLCELLULOSE (4000 MPA.S)</b> (UNII: MRJ667KA5E) (METHYLCELLULOSE (4000 MPA.S) - UNII:MRJ667KA5E)	METHYLCELLULOSE (4000 MPA.S)	2 g in 19 g

### Inactive Ingredients

Ingredient Name	Strength
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>ANHYDROUS DIBASIC CALCIUM PHOSPHATE</b> (UNII: L11K75P92J)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>MALTODEXTRIN</b> (UNII: 7CVR7L4A2D)	
<b>POTASSIUM CITRATE</b> (UNII: EE90ONI6FF)	
<b>RIBOFLAVIN</b> (UNII: TLM2976OFR)	
<b>SUCROSE</b> (UNII: C151H8M554)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>TRICALCIUM PHOSPHATE</b> (UNII: K4C08XP666)	

### Product Characteristics

<b>Color</b>	ORANGE	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	ORANGE	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0135-0089-69	454 g in 1 BOTTLE; Type 0: Not a Combination Product	09/16/2010	
2	NDC:0135-0089-71	850 g in 1 BOTTLE; Type 0: Not a Combination Product	09/16/2010	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	09/16/2010	

## CITRUCEL

methylcellulose powder, for solution

### Product Information



<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0135-0090
<b>Route of Administration</b>	ORAL		

<b>Active Ingredient/Active Moiety</b>		
<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>METHYLCELLULOSE (4000 MPA.S)</b> (UNII: MRJ667KA5E) (METHYLCELLULOSE (4000 MPA.S) - UNII:MRJ667KA5E)	METHYLCELLULOSE (4000 MPA.S)	2 g in 10.2 g

<b>Inactive Ingredients</b>	
<b>Ingredient Name</b>	<b>Strength</b>
<b>ASPARTAME</b> (UNII: Z0H242BBR1)	
<b>ANHYDROUS DIBASIC CALCIUM PHOSPHATE</b> (UNII: L11K75P92J)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>MALIC ACID</b> (UNII: 817L1N4CKP)	
<b>MALTODEXTRIN</b> (UNII: 7CVR7L4A2D)	
<b>POTASSIUM CITRATE</b> (UNII: EE90ONI6FF)	
<b>RIBOFLAVIN</b> (UNII: TLM2976OFR)	

<b>Product Characteristics</b>			
<b>Color</b>	ORANGE	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	ORANGE	<b>Imprint Code</b>	
<b>Contains</b>			

<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0135-0090-70	479 g in 1 BOTTLE; Type 0: Not a Combination Product	09/16/2010	
2	NDC:0135-0090-74	907 g in 1 BOTTLE; Type 0: Not a Combination Product	09/16/2010	
3	NDC:0135-0090-75	1191 g in 1 BOTTLE; Type 0: Not a Combination Product	09/16/2010	

<b>Marketing Information</b>			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	09/16/2010	

**Labeler** - GlaxoSmithKline Consumer Healthcare Holdings (US) LLC (079944263)

