

**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 constipation (irregularity)
- helps to restore and maintain regularity
- for constipation associated with other bowel disorders like IBS when recommended by a doctor
- 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

Age	Dose
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

Age	Dose
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 80mg and potassium 110mg
- 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 85mg and potassium 125mg
- 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?***

**call toll-free 1-800-897-6081** (English/Spanish) weekdays

Citrucel® is a registered trademark of the Sanofi group of companies and licensed by the GlaxoSmithKline group of companies.

For more information on Citrucel®, visit [citrucel.com](http://citrucel.com).

Distributed by:

**GlaxoSmithKline** Consumer Healthcare, L.P.

Moon Township, PA 15108

**CITRUCEL® Orange**

**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.

\*\*We are as concerned about the environment as you are so we have removed the scoop from our Citrucel powder products. Doing so helps save energy, reduce the amount of plastic produced and improve environmental footprints.

## CITRUCEL® Sugar Free

### 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.

\*\*We are as concerned about the environment as you are so we have removed the scoop from our Citrucel powder products. Doing so helps save energy, reduce the amount of plastic produced and improve environmental footprints.

### Principal Display Panel

NDC 0135-0089-69

CITRUCEL®

**METHYLCELLULOSE FIBER THERAPY FOR REGULARITY**

Great Taste

- Gentle and clinically proven effective
- Gives you additional fiber to help balance your diet
- The ONLY fiber for regularity that won't cause excess gas\*

**orange** FLAVOR

NET WT 16 OZ (454 GRAMS)

**Great-Tasting**

CITRUCEL® **Orange**

Citrucel's unique because it is:

- **Gentle and clinically proven effective** to help restore and maintain regularity.

- **The ONLY fiber that won't ferment** to cause excess gas like other fiber products.\*
- **100% soluble, non-allergenic and gluten-free.**

\*Based on laboratory testing. Individual results may vary.

5E643 SB F4

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**Principal Display Panel**

**NDC 0135-0090-74**

**CITRUCEL®**

**METHYLCELLULOSE FIBER THERAPY FOR REGULARITY**

Great Taste

- Gentle and clinically proven effective
- Gives you additional fiber to help balance your diet
- The ONLY fiber for regularity that won't cause excess gas\*

**sugar free** ORANGE FLAVOR

NET WT 32 OZ (907 GRAMS)

**Great-Tasting Orange Flavor**

**CITRUCEL<sup>®</sup> Sugar Free**

Citrucel's unique because it is:

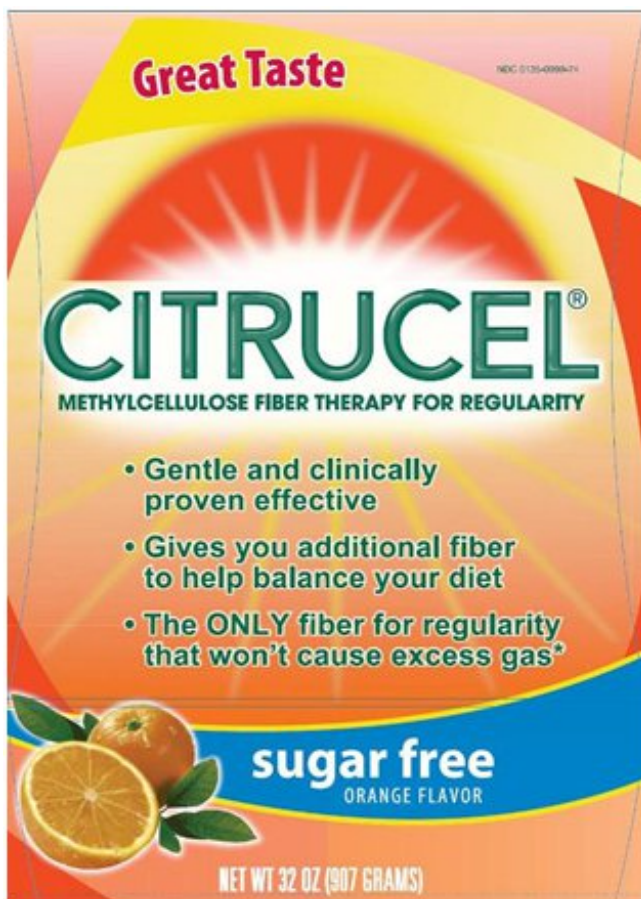
- **Gentle and clinically proven effective** to help restore and maintain regularity.
- **The ONLY fiber that won't ferment** to cause excess gas like other fiber products.\*
- **100% soluble, non-allergenic and gluten-free.**

\*Based on laboratory testing. Individual results may vary.

5M245 SB F4

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62056XG



**CITRUCEL**

methylcellulose powder, for solution

**Product Information**

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

**Active Ingredient/Active Moiety**

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

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
MALTO DEXTRIN (UNII: 7CVR7L4A2D)	
POTASSIUM CITRATE (UNII: EE90ONI6FF)	
RIBOFLAVIN (UNII: TLM2976OFR)	
SUCROSE (UNII: C151H8M554)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRICALCIUM PHOSPHATE (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>	
METHYLCELLULOSE (4000 MPA.S) (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>	
ASPARTAME (UNII: Z0H242BBR1)				
ANHYDRO US DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)				
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)				
MALIC ACID (UNII: 817L1N4CKP)				
MALTODEXTRIN (UNII: 7CVR7L4A2D)				
POTASSIUM CITRATE (UNII: EE90ONI6FF)				
RIBOFLAVIN (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>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
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>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
OTC monograph not final	part334	09/16/2010		

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