## REGULOID- psyllium powder, for solution Preferred Pharmaceuticals Inc.

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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2688 - Rugby

#### **Drug Facts**

#### Active ingredient (in each rounded TEASPOON)

Psyllium Husks, approximately 3.4 g

#### Purpose

**Bulk-forming Laxative** 

#### Uses

relieves occasional constipation generally produces 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.

**Allergy alert:** This product may cause an allergic reaction in people sensitive to inhaled or ingested psyllium

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

- a sudden change in bowel habits persisting for 2 weeks
- abdominal pain, nausea, or vomiting

#### Ask a doctor or pharmacist before use if you are

taking any other drug. Take this product two or more hours before or after other drugs. Laxatives may affect how other drugs work.

#### Stop use and ask a doctor if

- constipation lasts more than 7 days
- rectal bleeding occurs

These may 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**

• put one dose into an empty glass

- mix this product (child or adult dose) with at least 8 ounces (oz) (a full glass) of water or other fluid. Taking this product without enough liquid may cause choking. See choking warning.
- stir briskly and drink promptly. If mixture thickens, add more liquid and stir.

adults & children 12 years & over	1 rounded TEASPOON in 8 oz of liquid,	
	up to 3 times daily	
children 6 to under 12 years	1/2 adult dose in 8 oz of liquid, up to 3 times daily	
children under 6 years	ask a doctor	

**New Users**: Start with one dose per day, gradually increase to 3 doses per day as necessary.

As your body adjusts to increased fiber intake, you may experience changes in bowel habits or minor bloating.

#### Other information

each teaspoon contains: potassium 30 mg, sodium 5 mg

#### **Inactive ingredient**

sucrose

#### Questions or comments?

1-800-645-2158

#### **DIETARY FIBER SUPPLEMENT**

Diets low in saturated fat and cholesterol that include 7 grams of soluble fiber per day from psyllium husk, as in Reguloid, may reduce the risk of heart disease by lowering cholesterol. One adult dose of Reguloid has 2.4 grams of this soluble fiber. Consult a doctor if you are considering use of this product as part of a cholesterol-lowering program.

#### SEE WARNINGS & DIRECTIONS IN LAXATIVE SECTION.

**Dosage: Adults and children 12 years and over:** 1 rounded teaspoon in 8 ounces of liquid, 3 times daily. **Children under 12 years:** ask a doctor.

Supplement Facts		
Serving Size 1 rounded teaspoon (7g)		
Servings per container 77		
Amount Per Serving %DV**		
Calories 25		
Total Carbohydrates 7 g	2%	
Dietary Fiber 3 g	12%	
Soluble Fiber 2 g	*	
Sugars 3 g	*	
Iron 0.4 mg	2%	
Sodium 5 mg	<1%	
Potassium 30 mg	<1%	
**% Daily Value (DV) is based on a 2,000 calorie diet.		

**INGREDIENTS:** Sucrose, Psyllium Husk

TAMPER EVIDENT: DO NOT USE IF IMPRINTED

INNER FOIL SEAL IS BROKEN OR MISSING

Store below 30°C (86°F). Protect contents from humidity. Keep tightly closed.

#### Distributed by:

**Rugby Laboratories** 

17177 N Laurel Park Drive

Suite 233

Livonia, MI 48152

www.rugbylaboratories.com

Re-order No. 370160

Rev. 08/17 R-29

6879-08-17

Relabeled By: Preferred Pharmaceuticals Inc.

**Rugby**®

NDC 68788-7129-3

**REGULAR FLAVOR** 

**Reguloid®** 

# NATURAL VEGETABLE BULK-FORMING LAXATIVE POWDER & DIETARY FIBER SUPPLEMENT

#### **PSYLLIUM HUSK**

- Gentle, Effective Relief From Constipation
- Daily Fiber Source
- No Chemical Stimulants, Not Addictive

Net Wt. 19 oz

(540 g)

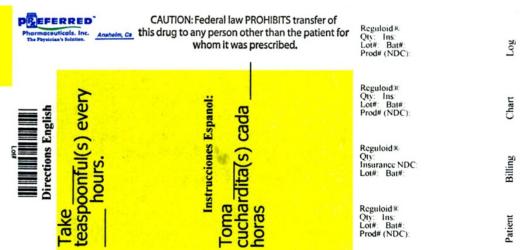
Relabeled By: Preferred Pharmaceuticals Inc.



Pkg Size: Exp Date: Lot#: Batch#: Ins:

Mfg: Rugby Laboratories; Livonia, MI Prod#:

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#### **REGULOID**

psyllium powder, for solution

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:68788-7129(NDC:0536-4444)

Route of Administration ORAL

#### **Active Ingredient/Active Moiety**

Ingredient NameBasis of StrengthStrengthPSYLLIUM HUSK (UNII: 0 SHO53407G) (PSYLLIUM HUSK - UNII:0 SHO53407G)PSYLLIUM HUSK3.4 g in 7 g

#### **Inactive Ingredients**

Ingredient Name Strength
SUCROSE (UNII: C151H8 M554)

#### **Product Characteristics**

Color	BROWN	Score	no score	
Shape		Size		
Flavor		Imprint Code		
Contains				

#### **Packaging**

l	#	# Item Code Package Description		<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ı	1	NDC:68788-7129-3	369 g in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2018	

#### **Marketing Information**

Marketing Category Application Number or Monograph Citation Marketing Start Date Marketing End Date

OTC monograph not final	part334	03/30/2018	

## Labeler - Preferred Pharmaceuticals Inc. (791119022)

### Registrant - Preferred Pharmaceuticals Inc. (791119022)

Establishment				
Name	Address	ID/FEI	Business Operations	
Preferred Pharmaceuticals Inc.		791119022	RELABEL(68788-7129)	

Revised: 3/2018 Preferred Pharmaceuticals Inc.