# GOODYS PM- acetaminophen and diphenhydramine citrate powder Medtech Products 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.

-----

### Goodys PM

### **Drug Facts**

### Active ingredients

### (in each powder)

Acetaminophen 500 mg Diphenhydramine Citrate 38 mg

### **Purposes**

Pain reliever Nighttime sleep-aid

#### Uses

• temporary relief of occasional headaches and minor aches and pains with accompanying sleeplessness

### **Warnings**

**Liver warning:** This product contains acetaminophen. Severe liver damage may occur if you take

- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

**Allergy Alert:** Acetaminophen may cause severe skin reactions. Symptoms may include:

• skin reddening • blisters • rash. If a skin reaction occurs, stop use and seek medical help right away.

#### Do not use

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- in children under 12 years of age
- with any other product containing diphenhydramine, even one used on skin

### Ask a doctor before use if you have

- liver disease
- glaucoma
- a breathing problem such as emphysema or chronic bronchitis
- trouble urinating due to an enlarged prostate gland

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

- the blood thinning drug warfarin
- sedatives or tranquilizers

### When using this product

- drowsiness will occur
- avoid alcoholic drinks
- be careful when driving a motor vehicle or operating machinery

### Stop use and ask a doctor if

- sleeplessness persists continuously for more than 2 weeks. Insomnia may be a symptom of a serious underlying medical illness.
- pain gets worse or lasts more than 10 days
- redness or swelling is present
- any new symptoms appear

These could be signs of a serious condition.

### If pregnant or breast-feeding,

ask a health professional before use.

### Keep out of reach of children.

### Overdose warning:

Taking more than the recommended dose can cause serious health problems. In case of overdose, get medical help or contact Poison Control Center (1-800-222-1222) right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

### Directions

- do not take more than directed (see overdose warning)
- adults and children 12 years of age and over: take 2 powders at bedtime, if needed, or as directed by a doctor. Drink a full glass of water with each dose, or may stir powder into a glass of water or other liquid.
- do not give to children under 12 years of age

### **Other Information**

- each powder contains: **potassium 42 mg**
- store below 25°C (77°F)

### **Inactive ingredients**

citric acid, docusate sodium, fumaric acid, glycine, lactose monohydrate, magnesium stearate, potassium chloride, silica gel, sodium benzoate, sodium citrate dihydrate

### Questions or comments?

1-866-255-5197

### **Principal Display Panel**

Goody's PM **Acetaminophen** • Diphenhydramine Citrate
Pain Reliever/ Nighttime sleep-aid
FOR PAIN WITH SLEEPLESSNESS



# Drug Facts (continued)

# Ask a doctor or pharmacist before use if you

■ the blood thinning drug warfarin ■ sedatives or tranquilizers

## When using this product

- drowsiness will occur avoid alcoholic drinks
- be careful when driving a motor vehicle or operating machinery

### Stop use and ask a doctor if

- sleeplessness persists continuously for more than 2 weeks. Insomnia may be a symptom of a serious underlying medical illness.
- pain gets worse or lasts more than 10 days
- redness or swelling is present
- any new symptoms appear. These could be signs \*\*\* Inactive ingredients citric acid, of a serious condition.

If pregnant or breast-feeding, ask a health professional before use.

### Keep out of reach of children.

Overdose warning: Taking more than the recommended dose can cause serious health problems. In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

## Drug Facts (continued)

### Directions

- do not take more than directed (see overdose warning)
- adults and children 12 years and over, take 2 powders at bedtime, if needed, or as directed by a doctor. Drink a full glass of water with each dose, or stir powder into a glass of water or other liquid.
- do not give to children under 12 years

## Other information

- each powder contains: potassium 42 mg
- store below 25°C (77°F)

Adocusate sodium, fumaric acid, glycine, lactose Pmonohydrate, magnesium stearate, potassium chloride, silica gel, sodium benzoate, sodium citrate dihydrate

Questions? 1-866-255-5197 goodyspowder.com

Keep carton for future reference.



Dist. by Medtech Products Irc. Tarrytown, NY 10591 A Prestige Consumer Health are company GDUS008102 ©2019 Trade dress is owned by Medtech Products Inc. All rights reserved.









# TO OPEN CHILD-RESISTANT PACKAGE



Shake pack so powder settles on bottom.



**Purposes** 

Pinch and tear at either arrow or use scissors.



Tilt head back and pour powder onto tongue.

# **Drug Facts**

# Active ingredients (in each powder)

Acetaminophen 500 mg......Pain reliever

Diphenhydramine

Citrate 38 mg.....Nighttime sleep-aid

**Uses** Temporary relief of occasional headaches and minor aches and pains with accompanying sleeplessness.

## Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take

- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

# Drug Facts (continued)

Allergy Alert: Acetam inophen may cause severe skin reactions. Symptoms may include:

■ skin reddening ■ blisters ■ rash.

If a skin reaction occurs, stop use and seek medical help right a (a).

### Do not use

- with any other drug containing acetaminophen (prescription or non-prescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- in children under 12 years of age
- with any other product containing diphenhydramine, even one used on skin

## Ask a doctor before use if you have

- liver disease glaudoma
- a breathing problem such as emphysema or chronic bronchitis
- trouble urinating due to an enlarged prostate gland

TAMPER EVIDENT: DO NOT USE IF PACK IS DAMAGED OR OPEN.

### **GOODYS PM**

acetaminophen and diphenhydramine citrate powder

### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:63029-656

Route of Administration ORAL

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

Ingredient Name Basis of Strength Strength

ACETAMINO PHEN (UNII: 36209 ITL9 D) (ACETAMINO PHEN - UNII: 36209 ITL9 D)	ACETAMINOPHEN	500 mg
<b>DIPHENHYDRAMINE CITRATE</b> (UNII: 4OD433S209) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE CITRATE	38 mg

Inactive Ingredients		
Ingredient Name	Strength	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)		
DO CUSATE SO DIUM (UNII: F05Q2T2JA0)		
FUMARIC ACID (UNII: 88 XHZ13131)		
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		
POTASSIUM CHLORIDE (UNII: 660 YQ98 I10)		
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)		
SODIUM BENZOATE (UNII: OJ245FE5EU)		
TRISO DIUM CITRATE DIHYDRATE (UNII: B22547B95K)		
GLYCINE (UNII: TE7660 XO1C)		

Product Characteristics			
Color	WHITE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

P	Packaging			
#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:63029-656-06	6 in 1 CARTON; Type 0: Not a Combination Product	09/01/2013	
2	NDC:63029-656-16	16 in 1 CARTON; Type 0: Not a Combination Product	09/01/2013	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC MONOGRAPH FINAL	part341	09/01/2013		

# Labeler - Medtech Products Inc. (122715688)

Revised: 4/2020 Medtech Products Inc.