## GOODYS EXTRA STRENGTH- acetaminophen, aspirin, and caffeine powder Medtech Products Inc.

-----

#### Goodys Extra Strength Headache Powders

FAST PAIN RELIEF Goody's ® EXTRA STRENGTH HEADACHE POWDERS

## ACETAMINOPHEN • ASPIRIN (NSAID) / CAFFEINE PAIN RELIEVER / PAIN RELIEVER AID 24 ENVELOPES CONTAINING 6 POWDERS EACH

#### **Drug Facts**

#### Active ingredients

(in each powder):
Acetaminophen 260 mg
Aspirin (NSAID\*) 520 mg
Caffeine 32.5 mg
\*nonsteroidal anti-inflammatory drug

#### **Purposes**

Pain reliever/fever reducer Pain reliever/fever reducer Pain reliever aid

#### Uses

- temporarily relieves minor aches and pains due to:
- headache
- muscle aches
- minor arthritis pain
- colds
- temporarily reduces fever

#### Warnings:

**Reye's syndrome:** Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.

**Allergy Alert:** Aspirin may cause severe allergic reaction which may include:

• hives • facial swelling • shock • asthma (wheezing).

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

- more than 4 powders in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

**Stomach bleeding warning**: This product contains a NSAID, which may cause severe stomach

bleeding. The chance is higher if you

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or non-prescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed.

#### Do not use

- if you have ever had an allergic reaction to aspirin or any other pain reliever/fever reducer
- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

#### Ask a doctor before use if

- you have liver disease
- stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, or kidney disease
- you are taking a diuretic
- you have asthma

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

taking a prescription drug for diabetes, gout, or arthritis

## When using this product

limit the use of caffeine-containing drugs, food, or drinks because too much caffeine may cause nervousness, irritability, sleeplessness, and, occasionally, rapid heart beat. The recommended dose of this product contains about as much caffeine as a cup of coffee.

#### Stop use and ask a doctor if

- an allergic reaction occurs. Seek medical help right away.
- you experience any of the following sights of stomach bleeding:
  - feel faint

- vomit blood
- have bloody or black stools
- have stomach pain that does not get better
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- any new symptoms appear
- ringing in the ears or a loss of hearing occurs These could be signs of a serious condition.

#### If pregnant or breast-feeding,

ask a health professional before use. It is especially important not to use aspirin during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

#### 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.

#### Directions:

- do not take more than directed (see overdose warning)
- adults and children 12 years and over: place 1 powder on tongue every 6 hours, while symptoms persist. Drink a full glass of water with each dose, or stir powder into a glass of water or other liquid.
- do not take more than 4 powders in 24 hours unless directed by a doctor.
- children under 12 years of age: ask a doctor.

#### Other information

- each powder contains: potassium 60 mg
- store below 25°C (77°F)

## **Inactive ingredients**

lactose monohydrate, potassium chloride

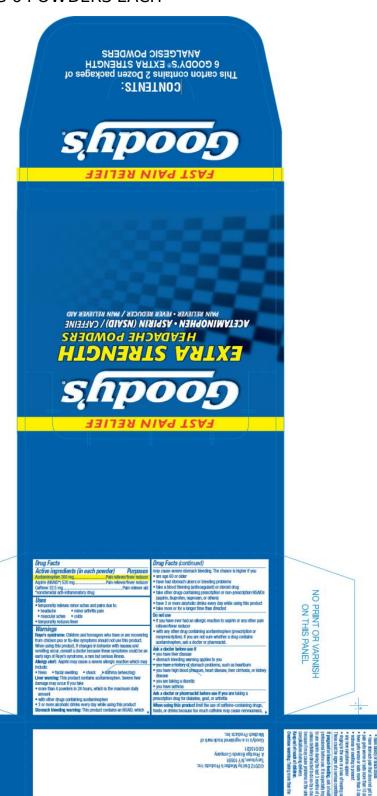
#### Questions or comments?

1-866-255-5197 (English/Spanish) weekdays

#### PRINCIPAL DISPLAY PANEL

FAST PAIN RELIEF
Goody's ®
EXTRA STRENGTH
HEADACHE POWDERS
ACETAMINOPHEN • ASPIRIN (NSAID) / CAFFEINE
PAIN RELIEVER / PAIN RELIEVER AID
24 ENVELOPES CONTAINING 6 POWDERS EACH

NO PRINT OR VARNISH ON THIS PANEL





#### PRINCIPAL DISPLAY PANEL

FAST PAIN RELIEF
Goody's®
EXTRA STRENGTH
HEADACHE POWDERS
ACETAMINOPHEN • ASPIRIN (NSAID) / CAFFEINE
PAIN RELIEVER / PAIN RELIEVER AID
18 Powders



#### PRINCIPAL DISPLAY PANEL

FAST PAIN RELIEF Goody's ® EXTRA STRENGTH



FAST PAIN RELIEF
Goody's ®
EXTRA STRENGTH
HEADACHE POWDERS
ACETAMINOPHEN • ASPIRIN (NSAID) / CAFFEINE
PAIN RELIEVER / PAIN RELIEVER AID
50 Powders



#### **GOODYS EXTRA STRENGTH**

acetaminophen, aspirin, and caffeine powder

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63029-6

Route of Administration ORAL

# Active Ingredient/Active Moiety Ingredient Name Basis of Strength ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII: 36209ITL9D) ASPIRIN (UNII: R16C05Y76E) (ASPIRIN - UNII: R16C05Y76E) ASPIRIN (UNII: R16C05Y76E) (ASPIRIN - UNII: R16C05Y76E) ASPIRIN (UNII: R16C05Y76E) (ASPIRIN - UNII: R16C05Y76E)

		_
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	520 mg
CAFFEINE (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)	CAFFEINE	32.5 mg

Inactive Ingredients	
Ingredient Name	Strength

POTASSIUM (UNII: RWP5GA015D)

LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)

Product Characteristics			
Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging					
	# Item Code Package Description		Marketing Start Date	Marketing End Date	
		NDC:63029-662- 01	6 in 1 BOX; Type 0: Not a Combination Product	11/01/2013	11/30/2023

Marketing Information				
Marketing Application Number or Monograph Category Citation		Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M013	11/01/2013	11/30/2023	

## **GOODYS EXTRA STRENGTH**

acetaminophen, aspirin, and caffeine powder

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63029-655
Route of Administration	ORAL		

Active Ingredient/Active Moiety				
Ingredient Name	<b>Basis of Strength</b>	Strength		
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	260 mg		
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	520 mg		
CAFFEINE (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)	CAFFEINE	32.5 mg		

Inactive Ingredients			
Ingredient Name Strength			
POTASSIUM (UNII: RWP5GA015D)			
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)			

Product Characteristics			
Color	white	Score	

Shape	Size
Flavor	Imprint Code
Contains	

Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
1 NDC:63029-655- 01	18 in 1 BOX; Type 0: Not a Combination Product	11/01/2013	11/30/2023	

Marketing Information					
MarketingApplication Number or MonographMarketing StartMarketing EndCategoryCitationDateDate					
OTC Monograph Drug	M013	11/01/2013	11/30/2023		

## **GOODYS EXTRA STRENGTH**

acetaminophen, aspirin, and caffeine powder

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63029-633	
Route of Administration	ORAL			

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	Strength	
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	260 mg	
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	520 mg	
CAFFEINE (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)	CAFFEINE	32.5 mg	

Inactive Ingredients				
Ingredient Name	Strength			
POTASSIUM (UNII: RWP5GA015D)				
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)				

Product Characteristics				
Color	white	Score		
Shape		Size		
Flavor		Imprint Code		
Contains				

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:63029-633- 01	24 in 1 BOX; Type 0: Not a Combination Product	11/01/2013	11/30/2023

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M013	11/01/2013	11/30/2023	

## **GOODYS EXTRA STRENGTH**

acetaminophen, aspirin, and caffeine powder

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63029-644	
Route of Administration	ORAL			

Active Ingredient/Active Moiety				
Ingredient Name	<b>Basis of Strength</b>	Strength		
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	260 mg		
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	520 mg		
CAFFEINE (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)	CAFFEINE	32.5 mg		

Inactive Ingredients				
Ingredient Name	Strength			
POTASSIUM (UNII: RWP5GA015D)				
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)				

Product Characteristics			
Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:63029-644- 01	50 in 1 BOX; Type 0: Not a Combination Product	11/01/2013		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	11/01/2013	

## Labeler - Medtech Products Inc. (122715688)

Revised: 10/2024 Medtech Products Inc.