

GOODYS EXTRA STRENGTH- acetaminophen, aspirin, and caffeine 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.

Goody's Extra Strength

PDP

Goody's®

EXTRA STRENGTH HEADACHE POWDERS

ACETAMINOPHEN • ASPIRIN (NSAID) / CAFFEINE PAIN RELIEVER / PAIN RELIEVER AID

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

Pain reliever

Pain reliever aid

Uses

Temporarily relieves minor aches and pains due to:

- headache • minor arthritis pain
- muscle aches • colds

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).

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.

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 an 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.

Caffeine warning: This product contains caffeine. Limit the use of caffeine-containing medications, foods, or beverages because too much caffeine may cause nervousness, irritability, sleeplessness, and, occasionally, rapid heart beat.

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
- the blood thinning drug warfarin

Stop use and ask a doctor if

- an allergic reaction occurs. Seek medical help right away
- you experience any of the following signs of stomach bleeding
 - feel faint • vomit blood • have bloody or black stool
 - 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 may 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 51 mg**
- store below 25°C (77°F)

Inactive ingredient

lactose monohydrate, potassium chloride

Questions?

1-866-255-5197 weekdays or goodyspowder.com

Principal Display Panel

Goody's
EXTRA STRENGTH
HEADACH POWDERS
FAST PAIN RELIEF
ACETAMINOPHEN
ASPIRIN (NSAID) / CAFFEINE
PAIN RELIEVER/PAIN RELIEVER AID
2 POWDER STICK PACKS

NEW!
ON-THE-GO
STICK PACKS
Same Fast Formula!

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See attached leaflet for full information
Do not buy if leaflet is missing or torn.



0 42037 11095 6

Tamper Evident:
Do not use if packet is damaged or open.

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30033-MVA-YY

Drug Facts	
Active ingredients (in each powder)	Purposes
Acetaminophen 250 mg	Pain reliever
Aspirin (NSAID)* 520 mg	Pain reliever
Caffeine 32.5 mg	Pain reliever aid
*nonsteroidal anti-inflammatory drug	
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.	
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ACETAMINOPHEN
ASPIRIN (NSAID) / CAFFEINE
PAIN RELIEVER/PAIN RELIEVER AID
18 PACKS



GOODYS EXTRA STRENGTH

acetaminophen, aspirin, and caffeine powder

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:63029-625

Route of Administration		ORAL		
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)		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	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)				
POTASSIUM CHLORIDE (UNII: 660YQ98I10)				
Product Characteristics				
Color	WHITE	Score		
Shape		Size		
Flavor		Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63029-625-02	2 in 1 PACKAGE; Type 0: Not a Combination Product	11/01/2013	
2	NDC:63029-625-06	6 in 1 CARTON; Type 0: Not a Combination Product	11/01/2013	
3	NDC:63029-625-18	18 in 1 CARTON; Type 0: Not a Combination Product	11/01/2013	
4	NDC:63029-625-24	24 in 1 CARTON; Type 0: Not a Combination Product	11/01/2013	
5	NDC:63029-625-50	50 in 1 CARTON; 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 NOT FINAL	part343	11/01/2013		

Labeler - Medtech Products Inc. (122715688)