

GOODYS EXTRA STRENGTH HEADACHE MIXED FRUIT BLAST- 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.

Goodys Extra Strength Headache Powder - Mixed Fruit Blast

Drug Facts

Active ingredients

(in each powder):

Acetaminophen 325 mg

Aspirin (NSAID*) 500 mg

Caffeine 65 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
- muscular aches
- colds
- backache
- toothache
- menstrual cramps

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 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.

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 Poison Control Center (1-800-222-1222) right away. Quick medical attention is critical for adults as well as 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

- store below 25°C (77°F)

Inactive ingredients

colloidal silicon dioxide, flavors, guar gum, mannitol, microcrystalline cellulose, sucralose

Questions?

1-866-255-5197 goodypowder.com

PRINCIPAL DISPLAY PANEL

Goody's Mixed Fruit Blast
Acetaminophen/ Aspirin (NSAID)/ Caffeine
Pain reliever/ Pain Reliever Aid



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acetaminophen, aspirin, and caffeine powder

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63029-664
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAFFEINE (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)	CAFFEINE	65 mg
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	500 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
GUAR GUM (UNII: E89I1637KE)	
MANNITOL (UNII: 3OWL53L36A)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	FRUIT (Mixed Fruit)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63029-664-04	4 in 1 CARTON; Type 0: Not a Combination Product	08/01/2015	
2	NDC:63029-664-24	24 in 1 CARTON; Type 0: Not a Combination Product	08/01/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part343	08/01/2015	

Labeler - Medtech Products Inc. (122715688)