

**GOODYS COOL ORANGE HEADACHE- acetaminophen and 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 Cool Orange Headache Powder

Drug Facts

Active ingredients (in each powder)

Purposes

Acetaminophen 325 mg.....	Pain reliever
Aspirin (NSAID*) 500 mg.....	Pain reliever
Caffeine 65 mg.....	Pain reliever aid

*nonsteroidal anti-inflammatory drug

Uses

Temporarily relieves minor aches and pains due to:

- headache
- backache
- toothache
- menstrual cramps
- muscular 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 a 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 4,000 mg of acetaminophen in 24 hours
- 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 nonprescription 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 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 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:** 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 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

PRINCIPAL DISPLAY PANEL

Goody's ®

COOL ORANGE POWDER

ACETAMINOPHEN/ASPIRIN (NSAID)/CAFFEINE

PAIN RELIEVER / PAIN RELIEVER AID



GOODYS COOL ORANGE HEADACHE

acetaminophen and aspirin and caffeine powder

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63029-663	
Route of Administration	ORAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)		ACETAMINOPHEN	325 mg	
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)		ASPIRIN	500 mg	
CAFFEINE (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)		CAFFEINE	65 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	ORANGE	Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63029-663-01	24 in 1 BOX; Type 0: Not a Combination Product	06/01/2012	
2	NDC:63029-663-04	4 in 1 BOX; Type 0: Not a Combination Product	06/01/2012	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC MONOGRAPH NOT FINAL	part343	06/01/2012		

Labeler - Medtech Products Inc. (122715688)

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Medtech Products Inc.