

**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.*

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**Goodys Cool Orange Headache Powder**

***Drug Facts***

***Active ingredients (in each powder)***

Acetaminophen 325 mg

***Active ingredients (in each powder)***

Aspirin (NSAID\*) 500 mg

\*nonsteroidal anti-inflammatory drug

***Purpose***

Pain reliever/fever reducer

***Active ingredient (in each powder)***

Caffeine 65 mg

***Purpose***

Pain reliever aid

***Uses***

- temporarily relieves minor aches and pains due to:
  - headache
  - menstrual cramps
  - backache
  - muscular aches
  - toothache
  - 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 a 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 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

**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, foods, 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 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 or comments?***

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

**TAMPER EVIDENT FEATURE: DO NOT USE IF PACKET IS DAMAGED OR OPEN.**

**PRINCIPAL DISPLAY PANEL**

Goody's COOL ORANGE EXTRA STRENGTH HEADACHE POWDERS  
24 SEALED POWDER PACKS



## GOODYS COOL ORANGE HEADACHE

acetaminophen and aspirin and caffeine powder

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:63029-663	
<b>Route of Administration</b>	ORAL			
<b>Active Ingredient/Active Moiety</b>				
<b>Ingredient Name</b>		<b>Basis of Strength</b>	<b>Strength</b>	
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	
<b>Inactive Ingredients</b>				
<b>Ingredient Name</b>			<b>Strength</b>	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
GUAR GUM (UNII: E89I1637KE)				
MANNITOL (UNII: 3OWL53L36A)				
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)				
SUCRALOSE (UNII: 96K6UQ3ZD4)				
<b>Product Characteristics</b>				
<b>Color</b>		<b>Score</b>		
<b>Shape</b>		<b>Size</b>		
<b>Flavor</b>	ORANGE	<b>Imprint Code</b>		
<b>Contains</b>				
<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
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	
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
OTC MONOGRAPH NOT FINAL	part343	06/01/2012		

**Labeler** - Medtech Products Inc. (122715688)