# GOODYS HANGOVER- as pirin 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 Hangover**

# **Drug Facts**

# Active ingredients (in each powder)

# **Purposes**

# Uses

Temporarily relieves minor aches and pains due to:

- hangover
- headache
- muscle aches

Helps restore mental alertness when experiencing fatigue or drowsiness associated with a hangover

#### **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).

**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:**

The recommended dose of this product contains about as much caffeine as a cup of coffee. Limit the use of caffeine-containing medications, foods, or beverages while taking this product because too much caffeine may cause nervousness, irritability, sleeplessness, and, occasionally, rapid heart beat.

#### Do not use

- for more than 2 days for a hangover unless directed by a doctor. Not intended for use as a substitute for sleep. If fatigue or drowsiness persists or continues to recur, consult a doctor.
- if you have ever had an allergic reaction to aspirin or any other pain reliever/fever reducer
- in children under 12 years of age

## Ask a doctor before use if

- 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 • arthritis

# 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
- 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.

In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

#### Directions

- •Adults and children 12 years and over: place 1 powder on tongue every 6 hours, while symptoms persist. Drink a full 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: ask a doctor.

# Other information

Store below 25°C (77°F)

# **Inactive ingredients**

colloidal silicon dioxide, flavor, guar gum, mannitol, microcrystalline cellulose, sucralose, xylitol.

## Questions?

**1-866-255-5197** goodyspowder.com

## PRINCIPAL DISPLAY PANEL

Goody's® Hangover

Berry Citrus Boost

ASPIRIN (NSAID) / PAIN RELIEVER, CAFFEINE /ALERTNESS AID

16 powder stick packs



# TAMPER EVIDENT: DO NOT USE IF PACK IS DAMAGED OR OPEN.

#### TO OPEN CHILD-RESISTANT PACKAGE







Pinch and tear at either arrow or use scissors.

# **Drug Facts**

# Active ingredients Purposes (in each powder) Aspirin (NSAID\*) 1000 mg Pain reliever Caffeine 150 mg Alertness aid "nonsteroidal anti-inflammatory drug

Uses Temporarily relieves minor aches and pains due to:

hangover headache muscle aches. Helps restore
mental alertness when experiencing fatigue or drowsiness
associated with a hangover.

### Warnings

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#### Drug Facts (continued)

containing prescription or non-prescription NSAIDs (espirin, ibuprofen, neproxen, or others) = have 3 or more alcoholic drinks every day while using this product = take more or for a longer time than directed

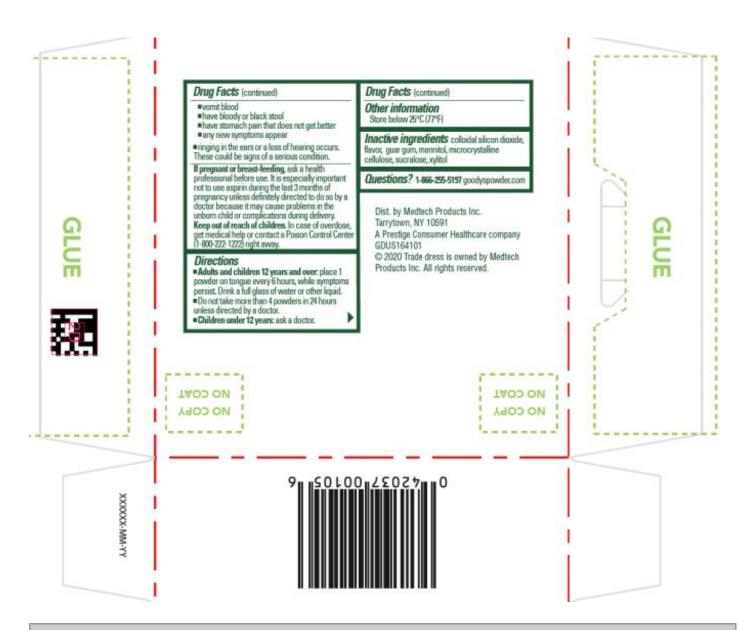
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Ask a doctor before use if stomach bleeding warning applies to you syou have a history of stomach problems, such as heartburn you have high blood pressure, heart disease, liver cirrhosis, or kidney disease you are taking a diuretic you have asthma

Ask a doctor or pharmacist before use if you are taking a prescription drug for \*diabetes \*gout \*arthritis

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: afeel faint



# **GOODYS HANGOVER**

aspirin and caffeine powder

Duadust Information

Product information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63029-665

Route of Administration ORAL

# Active Ingredient/Active Moiety Ingredient Name Basis of Strength CAFFEINE (UNII: 3G6 A5W338E) (CAFFEINE - UNII:3G6 A5W338E) CAFFEINE (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E) ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E) ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)

Inactive Ingredients		
Ingredient Name	Strength	
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)		
<b>GUAR GUM</b> (UNII: E8911637KE)		

MANNITOL (UNII: 3OWL53L36A)	
MICRO CRYSTALLINE CELLULO SE (UNII: OP1R32D61U)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XYLITOL (UNII: VCQ006KQ1E)	

Product Characteristics			
Color	WHITE	Score	
Shape		Size	
Flavor	BERRY (Berry Citrus)	Imprint Code	
Contains			

F	Packaging			
#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:63029-665-04	4 in 1 CARTON; Type 0: Not a Combination Product	11/15/20 19	
2	NDC:63029-665-16	16 in 1 CARTON; Type 0: Not a Combination Product	11/15/2019	
3	NDC:63029-665-24	24 in 1 CARTON; Type 0: Not a Combination Product	11/15/20 19	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part343	11/15/20 19	

# Labeler - Medtech Products Inc. (122715688)

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