

## **RU-21 HANGOVER RELIEF- aspirin, caffeine capsule**

### **RU-21**

*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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## **RU-21 HANGOVER RELIEF**

### **Drug Facts**

#### **Active ingredients (In each capsule)**

**Aspirin 250 mg (NSAID\*)**

**Caffeine 50 mg**

\*Nonsteroidal anti-inflammatory drug

#### **Purpose**

Pain Reliever

Alertness aid/Pain reliever aid

#### **Uses**

- for the temporary relief of minor aches and pains associated with a hangover
- helps restore mental alertness or wakefulness when experiencing fatigue or drowsiness associated with a hangover
- for temporary relief of headaches or body aches and pains

#### **Warnings**

**Reye's syndrome:** Children and teenagers who have or are recovering from chickenpox 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 • asthma (wheezing) • facial swelling • shock

#### **Do not use**

- if you have ever had an allergic reaction to aspirin or any other pain reliever/fever reducer
- in children under 12 years of age

#### **Stomach bleeding warning:**

This product contains a nonsteroidal anti-inflammatory drug (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

### **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 • you have a sodium-restricted diet

### **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 lasts for more than 10 days or gets worse
- new symptoms occur
- redness or swelling is present
- ringing in the ears or a loss of hearing occurs

### **When using this product**

- the recommended dose of this product contains caffeine. Limit the use of caffeine-containing medications, foods, or beverages because excess of caffeine may cause nervousness, irritability, irritability, sleeplessness, and occasionally rapid heartbeat.
- for occasional use only. 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 occur, consult a doctor.

### **Keep out of reach of children**

In case of overdose, get medical help or contact a Poison Control Center right away.

### **If pregnant or breastfeeding**

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.

### **Ask a doctor or pharmacist before use**

if you are taking a prescription drug for • diabetes • gout • arthritis

### **Directions**

upon waking, take 2 capsules with 8-12 oz. of water do not exceed recommended dosage

**Adults and children 12 years and over** (up to 60 years of age): 2-3 capsules every 6 hours, as needed, or as directed by a doctor. Do not exceed 8 capsules in 24 hours



# RU-21 HANGOVER RELIEF

aspirin, caffeine capsule

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:73156-010
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	250 mg
CAFFEINE (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)	CAFFEINE	50 mg

## Inactive Ingredients

Ingredient Name	Strength
SODIUM SUCCINATE HEXAHYDRATE (UNII: U16QOD6C4E)	
GELATIN (UNII: 2G86QN327L)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

## Product Characteristics

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	18mm
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73156-010-20	1 in 1 BOX	07/01/2019	
1		20 in 1 BLISTER PACK; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	07/01/2019	

**Labeler** - RU-21 (093475272)