

# **SPLIZZ PAIN RELIEVER - GRAPEFRUIT-FLAVORED- acetaminophen, aspirin, and caffeine tablet, effervescent**

**Marga Labs, LLC**

*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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## **Splizz Pain Reliever - Grapefruit-flavored Tablets**

### ***Drug Facts***

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<b><i>Active ingredients (in each tablet)</i></b>	<b><i>Purpose</i></b>
Acetaminophen 250mg	Pain reliever
Aspirin 250mg (NSAID*)	Pain reliever
Caffeine 65mg	Pain reliever aid

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\* Nonsteroidal anti-inflammatory drug

### **Uses**

Temporarily relieves minor aches and pains due to:

- headache
- a cold
- arthritis
- backache
- muscular aches
- toothache
- premenstrual & 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**

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.

#### **Allergy alert**

Aspirin may cause a severe allergic reaction which may include:

- hives
- facial swelling
- asthma (wheezing)
- shock

## **Liver warning**

This product contains acetaminophen. Severe liver damage may occur if you take:

- more than 4000 mg 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.

## **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 heartbeat.

## **Do Not Use**

- if you ever had an allergic reaction to acetaminophen, 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
- you have a sodium-restricted diet

## **Ask a doctor or pharmacist before use if you are taking**

- a prescription drug for diabetes, gout, or arthritis
- any other drug, or are under a doctor's care for any serious condition

## **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
- ringing in the ears or loss of hearing occurs
- painful area is red or swollen
- pain gets worse or lasts for more than 10 days

- fever get worse or lasts for more than 3 days
- any new symptoms occur. These could be signs of a serious condition.

**If pregnant or breast-feeding**, ask a health care 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 right away.

### **Directions**

- **do not use more than directed**
- Fully dissolve 2 tablets in a glass of water and drink
- Adults and children 12 years and over: take 2 tablets every 6 hours; not more than 8 tablets in 24 hours.
- Children under 12 years: do not use.

### **Other information**

- **each tablet contains:** sodium 416 mg
- Phenylketonurics: contains phenylalanine 11 mg per tablet
- store at room temperature (59°-86°F)
- Read all product information before using.

### **Inactive ingredients**

acesulfame potassium, anhydrous citric acid, aspartame, D&C red # 28 aluminum lake, docusate sodium, FD&C red # 40, flavors, leucine, magnesium citrate, mannitol, povidone, sodium benzoate, sodium bicarbonate

### **Questions or comments?**

**Call 1-888-707-3713**

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CINCINNATI, OHIO 45241

### **PRINCIPAL DISPLAY PANEL - 20 Tablet Pouch Carton**

EXTRA STRENGTH

splizz

Fast Pain Reliever

Acetaminophen,  
Aspirin (NSAID) &  
Caffeine

Pain Reliever | Pain Reliever Aid

Red Grapefruit

20 Effervescent Tablets

**Drug Facts**

**Active ingredients**  
 Acetaminophen (325mg)  
 Aspirin (NSAID) 250mg  
 Pain reliever  
 Pain reliever  
 Hydrocodone bitartrate/acetaminophen

**Purpose**  
 Temporary relief of minor aches and pains due to:  
 headache  
 cold  
 flu  
 toothache  
 menstrual cramps

**Warnings**  
 Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, changes in behavior or symptoms could be an early sign of Reye's syndrome, a rare but serious illness.  
 Acetaminophen may cause severe skin reactions. Symptoms may include:  
 skin peeling or blisters  
 skin redness  
 blisters  
 rash  
 If a skin reaction occurs, stop use and seek medical help right away.  
 Allergy alert: Aspirin may cause a severe allergic reaction which may include:  
 facial swelling  
 asthma  
 hives  
 throat tightness  
 This product contains acetaminophen. Severe liver damage may occur if you take more than 4000 mg 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.

**Drug Facts (continued)**

**Do Not Use** if you ever had an allergic reaction to acetaminophen, 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, or are taking a blood thinner (warfarin).  
 Ask a doctor or pharmacist before use if you are taking a prescription drug for diabetes, gout, or arthritis.  
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20 Effervescent Tablets

100% Satisfaction Guaranteed!  
 If you're not completely satisfied, return any unused product for a full refund.

PN: 6152  
 REV: 09/20

Reddy, Splizz, Go.  
 Pain hurts. Sometimes it'll follow you around like a work, the gym or even at home with the kids. It just seems to keep you in its grip.  
 You need a multi-symptom pain reliever that's incredibly fast-acting and absolutely effective. That's Splizz, soothing effervescent tablets that dissolve quickly in a glass of water. Drink it and enjoy fast pain relief.  
 Splizz: Help Against Hurt.

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**Drug Facts (continued)**

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 right away.

**Directions** do not use more than directed. Fully dissolve 2 tablets in a glass of water and drink. Adults and children 12 years and over: take 2 tablets every 6 hours; not more than 8 tablets in 24 hours. Children under 12 years: do not use.

**Other information**  
 each tablet contains: sodium 416 mg  
 Phenylephrine: contains phenylephrine 11 mg per tablet. Store at room temperature (59°-85°F). Read all product information before using.

**Inactive ingredients** acetylsalicylic acid, anhydrous citric acid, aspartame, D&C red # 28 aluminum lake, docusate sodium, FD&C red # 40, flavors, leucine, magnesium citrate, mannitol, povidone, sodium benzoate, sodium bicarbonate

**Questions or comments?**  
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# SPLIZZ PAIN RELIEVER - GRAPEFRUIT-FLAVORED

acetaminophen, aspirin, and caffeine tablet, effervescent

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78612-100
Route of Administration	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Acetaminophen (UNII: 362O9ITL9D) (Acetaminophen - UNII:362O9ITL9D)	Acetaminophen	250 mg
Aspirin (UNII: R16CO5Y76E) (Aspirin - UNII:R16CO5Y76E)	Aspirin	250 mg
Caffeine (UNII: 3G6A5W338E) (Caffeine - UNII:3G6A5W338E)	Caffeine	65 mg

## Inactive Ingredients

Ingredient Name	Strength
Citric Acid Monohydrate (UNII: 2968PHW8QP)	
Sodium bicarbonate (UNII: 8MDF5V39QO)	
Mannitol (UNII: 3OWL53L36A)	
Povidone, Unspecified (UNII: FZ989GH94E)	
Acesulfame potassium (UNII: 23OV73Q5G9)	
Aspartame (UNII: Z0H242BBR1)	

## Product Characteristics

Color	PINK (Light pink)	Score	no score
Shape	ROUND (Round pressed tablet)	Size	25mm
Flavor	GRAPEFRUIT	Imprint Code	S
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78612-100-20	10 in 1 CARTON	01/21/2021	
1		2 in 1 POUCH; 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	01/21/2021	

Labeler - Marga Labs, LLC (105847280)

