

## **ACHE AND PAIN RELIEF TO GO- aspirin and caffeine powder Breakthrough 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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### **Ache and Pain Relief to Go™**

#### **Drug Facts**

<b>Active ingredients (per powder)</b>	<b>Purpose</b>
Aspirin 650mg (NSAID)*	Pain reliever
Caffeine 60mg	Pain reliever aid

\* nonsteroidal anti-inflammatory drug

#### **Uses**

Temporarily relieves:

- muscle pain
- minor arthritis pain
- headache
- pain of colds

#### **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
- facial swelling
- asthma (wheezing)
- shock

##### **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 longer than directed

**Do not use** if you are allergic to aspirin or any other pain reliever/fever reducer.

**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

- gout
- diabetes
- arthritis

**When using this product** limit use of caffeine-containing drugs, foods, or drinks, because too much caffeine may cause nervousness, irritability, sleeplessness, and occasionally rapid heartbeat

**Stop use and ask a doctor if**

- an allergic reaction occurs (seek medical help right away)
- pain gets worse or lasts more than 10 days
- redness or swelling is present
- fever lasts more than 3 days
- new symptoms occur
- ringing in the ears or a loss of hearing occurs
- 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

**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 right away.

**Directions**

**adults and children 12 years and over:**

- see instructions in red box for opening packet
- place 1 powder on the tongue and swallow with or without water
- repeat every 4-6 hours, while symptoms persist
- do not take more than 4 powders in 24 hours

**children under 12 years: ask a doctor**

**Inactive ingredients**

acesulfame potassium, citric acid, flavor, glucose, sucralose

**Questions?**

1-888-998-7436 (Mon-Fri 9AM-5PM MDT)

**Do not use if pouch  
is torn or open**

*distributed by*

**URGENT Rx®**

**Breakthrough Products, Inc.**

Denver, CO 80202

**PRINCIPAL DISPLAY PANEL - 1 Powder Packet**

*New!*

**NO  
WATER  
REQUIRED  
POUR DIRECTLY IN MOUTH**

**URGENT Rx®**

**FAST**

**POWDERS™**

□ SEE OPENING INSTRUCTIONS ON BACK PANEL □

**ACHE &**

**PAIN**

**URGENT Rx®**

**RELIEF**

**TO-GO™**

ASPIRIN (NSAID) + CAFFEINE /

PAIN RELIEVER + ADJUVANT

**lemon-lime**

distributed by UrgentRx

1 POWDER PACK

**New!**

**NO WATER REQUIRED**  
POUR DIRECTLY IN MOUTH

Do not use if pouch is torn or open

Ache & Pain Relief to Go™

**URGENT R<sup>®</sup>**  
distributed by

**Breakthrough Products, Inc.**  
Denver, CO 80202

Fold top and store in purse or wallet

US Pat. No 8,376,140

CCAP0714-A



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changes in behavior with nausea and vomiting occur, consult a doctor

because these symptoms could be an early sign of Reye's syndrome, a

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or bleeding problems • take a blood thinning (anticoagulant) or steroid

drug • take other drugs containing prescription or nonprescription

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alcoholic drinks every day while using this product • take more or for longer than directed. Do

**not use** if you are allergic to aspirin or any other pain reliever/fever reducer. **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**

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• vomit blood • have bloody or black stools • have stomach pain that does not get better if

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**TO OPEN**

- 1) ROLL ON LINE TO EXP-USE NOTCH
- 2) WHILE FOLDED, TEAR AT NOTCH (or use scissors)

URGENT Rx<sup>®</sup>  
**FAST**  
POWDERS™

◀SEE OPENING INSTRUCTIONS ON BACK PANEL▶

**ACHE &  
PAIN**



**RELIEF  
TO-GO™**

ASPIRIN (NSAID) + CAFFEINE/  
PAIN RELIEVER + ADJUVANT

lemon-lime

distributed by UrgentRx

1 POWDER PACK

## ACHE AND PAIN RELIEF TO GO

aspirin and caffeine powder

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG LABEL	<b>Item Code (Source)</b>	NDC:51596-008
<b>Route of Administration</b>	ORAL	<b>DEA Schedule</b>	

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
aspirin (aspirin)	aspirin	650 mg
caffeine (caffeine)	caffeine	60 mg

**Inactive Ingredients**

Ingredient Name	Strength
acesulfame potassium	
anhydrous citric acid	
dextrose	
sucralose	

**Product Characteristics**

Color	WHITE	Score	
Shape		Size	
Flavor	LEMON (Lemon-Lime)	Imprint Code	
Contains			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51596-008-05	5 in 1 BOX		
1	NDC:51596-008-01	1 in 1 POUCH; Combination Product Type = C112160		
2	NDC:51596-008-12	12 in 1 BOX		
2	NDC:51596-008-01	1 in 1 POUCH; Combination Product Type = C112160		
3	NDC:51596-008-24	24 in 1 BOX		
3	NDC:51596-008-01	1 in 1 POUCH; Combination Product Type = C112160		
4	NDC:51596-008-01	1 in 1 POUCH; Combination Product Type = C112160		
5	NDC:51596-008-10	10 in 1 BOX		
5		1 in 1 PACKET; Combination Product Type = C112160		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part343	10/01/2012	

**Labeler** - Breakthrough Products Inc. (962008251)

Revised: 10/2014

Breakthrough Products Inc.