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.

Ache and Pain Relief to Go™

Drug Facts

Active ingredients (per powder)	Purpose
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)

distributed by
URGENT Rx®
Breakthrough Products, Inc.
Denver, CO 80202

PRINCIPAL DISPLAY PANEL - 1 Powder Packet

New!

**NO
WATER
REQUIRED
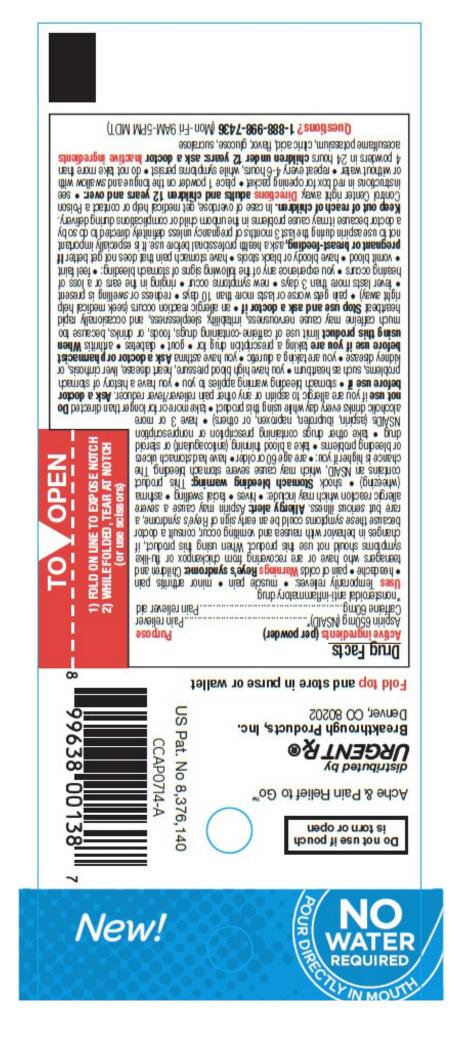POUR DIRECTLY IN MOUTH**

**URGENT Rx®
FAST
POWDERSᴛᴍ**
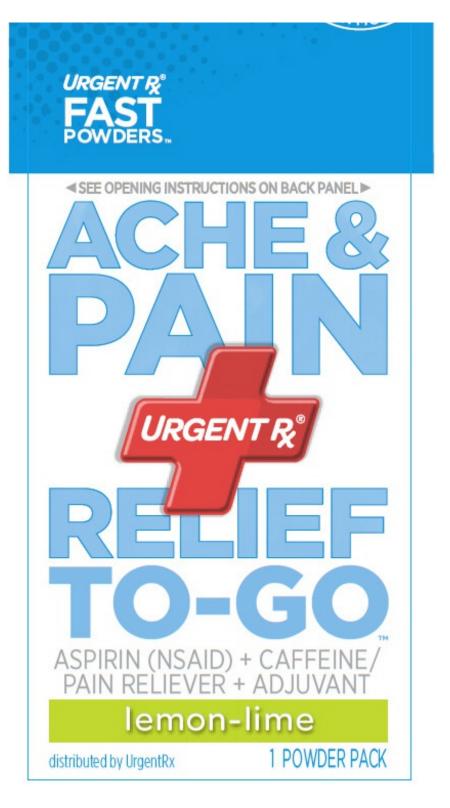
☐ SEE OPENING INSTRUCTIONS ON BACK PANEL ☐

**ACHE &
PAIN
URGENT Rx®
RELIEF
TO-GOᴛᴍ**

ASPIRIN (NSAID) + CAFFEINE /
PAIN RELIEVER + ADJUVANT

lemon-lime

distributed by UrgentRx
1 POWDER PACK

Ache & Pain Relief to Go™

distributed by
URGENT Rx®
Breakthrough Products, Inc.
Denver, CO 80202

US Pat. No 8,376,140

CCAP0714-A

Do not use if pouch is torn or open

Fold top and store in purse or wallet

Drug Facts

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

*nonsteroidal anti-inflammatory drug

Uses Temporarily relieves • minor arthritis pain • muscle pain • muscle ache • 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)

TO ✓ OPEN
1) FOLD ON LINE TO EXPOSE NOTCH
2) WHILE FOLDED, TEAR AT NOTCH
(or use scissors)

ACHE AND PAIN RELIEF TO GO

aspirin and caffeine powder

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:51596-008
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
aspirin (UNII: R16CO5Y76E) (aspirin - UNII:R16CO5Y76E)	aspirin	650 mg
caffeine (UNII: 3G6A5W338E) (caffeine - UNII:3G6A5W338E)	caffeine	60 mg

Inactive Ingredients

Ingredient Name	Strength
acesulfame potassium (UNII: 23OV73Q5G9)	
anhydrous citric acid (UNII: XF417D3PSL)	
dextrose (UNII: IY9XDZ35W2)	
sucralose (UNII: 96K6UQ3ZD4)	

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; Type 0: Not a Combination Product		
2	NDC:51596-008-12	12 in 1 BOX		
2	NDC:51596-008-01	1 in 1 POUCH; Type 0: Not a Combination Product		
3	NDC:51596-008-24	24 in 1 BOX		
3	NDC:51596-008-01	1 in 1 POUCH; Type 0: Not a Combination Product		
4	NDC:51596-008-01	1 in 1 POUCH; Type 0: Not a Combination Product		
5	NDC:51596-008-10	10 in 1 BOX		
5		1 in 1 PACKET; 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	10/01/2012	

Labeler - Breakthrough Products Inc. (962008251)

Revised: 10/2014

Breakthrough Products Inc.