CRITICAL CARE ASPIRIN TO GO- aspirin 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.

Critical Care Aspirin to Go™

Drug Facts

Active ingredient (per powder)

Aspirin 325mg (NSAID)[1]

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[1] nonsteroidal anti-inflammatory drug

Purpose

Pain reliever

Uses

Temporarily relieves:
- headache
- toothache
- pain of colds
- muscle pain
- menstrual pain
- minor pain of arthritis

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 for:
- gout
- diabetes
- arthritis

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 1-2 powders on the tongue and swallow with or without water
- repeat every 4-6 hours, while symptoms persist
- do not take more than 8 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 - 325 mg Pouch Label

New!

Be prepared.
Discover the
life saving
benefits of
aspirin.

Ask your doctor.

NO
WATER
REQUIRED
POUR DIRECTLY IN MOUTH

SEE OPENING INSTRUCTIONS ON BACK PANEL

CRITICAL
CARE
325
mg

URGENT Rx®

ASPIRIN
TO-GO™

ASPIRIN (NSAID) /
PAIN RELIEVER

lemon-lime

distributed by UrgentRx
1 POWDER PACK

[redacted]

Drug Facts

Active ingredient (per powder) — **Purpose**

Aspirin 325mg (NSAID)* ..... Pain reliever

*nonsteroidal anti-inflammatory drug

Uses temporarily relieves • headache • toothache • pain of colds • muscle pain • menstrual pain • minor pain of arthritis **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 for: • gout • diabetes • arthritis **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 Center right away **Directions adults and children 12 years and over:** • see instructions in red box for opening packet • place 1-2 powders on the tongue and swallow with or without water • repeat every 4-6 hours, while symptoms persist • do not take more than 8 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 SIDE SLITS)

Do not use if pouch is torn or open

Critical Care Aspirin to Go™

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

US Pat. No 8,376,140

CCCC0714-A

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Fold top and store in purse or wallet

New!

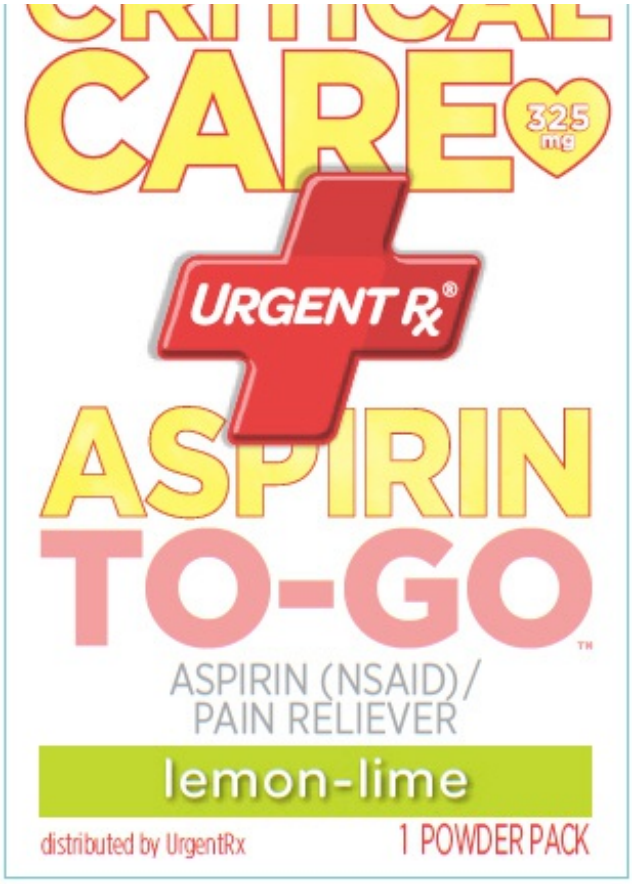
Be prepared. Discover the life saving benefits of aspirin.

Ask your doctor.

NO WATER REQUIRED
POUR DIRECTLY IN MOUTH

◄SEE OPENING INSTRUCTIONS ON BACK PANEL►

CRITICAL



CRITICAL CARE ASPIRIN TO GO

aspirin powder

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:51596-006
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
aspirin (UNII: R16CO5Y76E) (aspirin - UNII:R16CO5Y76E)	aspirin	325 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:51596-006-05	5 in 1 BOX		
1		1 in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:51596-006-12	12 in 1 BOX		
2		1 in 1 POUCH; Type 0: Not a Combination Product		
3	NDC:51596-006-24	24 in 1 BOX		
3		1 in 1 POUCH; Type 0: Not a Combination Product		
4	NDC:51596-006-01	1 in 1 POUCH; Type 0: Not a Combination Product		
5	NDC:51596-006-10	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.