HEADACHE RELIEF TO GO- acetaminophen 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.

HEADACHE RELIEF TO-GOTM

Drug Facts

Active ingredients (per powder)	Purpose
Acetaminophen 650 mg	Pain reliever
Caffeine 50 mg	Pain reliever aid

Uses

Temporarily relieves minor aches and pains due to:

- headache
- muscular aches

Warnings

Liver warning

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

- more than 6 powders 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

Do not use

- if you are allergic to acetaminophen
- 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

Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin

When using this product limit the 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

- pain gets worse or lasts for more than 10 days
- fever gets worse or lasts for more than 3 days
- new symptoms occur
- redness or swelling is present

These could be signs of a serious condition.

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children.

Overdose warning

Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

- do not take more than directed (see overdose warning)
- adults and children 12 years and over
- see instructions above for opening packet
- place 1 powder on the tongue and swallow with or without water
- repeat every 4-6 hours, wile symptoms persist
- do not take more than 6 pouches in 24 hours
- children under 12 years: ask a doctor

Inactive ingredients

acesulfame potassium, citric acid, ethylcellulose, flavor, sodium chloride, sucralose, sucrose

Questions?

1-888-99-URGENT (1-888-998-7436) (Mon-Fri 9AM-5PM MDT)

Do not use if pouch is torn or open

distributed by UrgentRx®
Breakthrough Products, Inc. Denver, CO 80202

PRINCIPAL DISPLAY PANEL - Pouch Label

New

Formula!

Now with

Acetaminophen

FAST POWDERSTM

No Liquid Required

Pour Directly in Mouth

SEE OPENING INSTRUCTIONS ON BACK PANEL

HEADACHE

URGENTRx

RELIEF

TO-GO

ACETAMINOPHEN + CAFFEINE/PAIN RELEIVER + ADJUVANT

sweet orange

distributed by UrgentRx

1 powder pack





www.urgentRx.com

Do not use if pouch is torn or open



Headache Relief to Go[™] Contains No Aspirin

distributed by URGENT Ry®

Breakthrough Products, Inc. Denver, CO 80202

Fold Top and Store in Purse or Wallet



Drug Facts

1) FOLD ON LINE TO EXPOSE NOTCH
2) WHILE FOLDED, TEAR AT NOTCH
(or use scissors)
ing drugs, food

or pharmacist before use if you are taking the blood thirning drug warfarin. When using this product limit the 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 • pain gets worse or lasts more than 10 days • fever gets worse or lasts more than 3 days • new symptoms occur • redness or swelling is present. These could be signs of a serious condition. If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. Overdose warning: Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms. Directions • do not take more than directed (see overdose warning) • adults and children 12 years of age and older • see instructions above 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 6 powders in 24 hours • children under 12 years of age, ask doctor Inactive ingredients accsulfame potassium, citric acid, ethylcellulose, flavor, sodium chloride, sucralose, sucrose

Questions? 1-888-99-URGENT (Mon-Fri 9AM-5PM MDT)

HEADACHE RELIEF TO GO

acetaminophen and caffeine powder

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:51596-010

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
acetaminophen (UNII: 362O9ITL9D) (acetaminophen - UNII:362O9ITL9D)	a ceta mino phen	650 mg
caffeine (UNII: 3G6 A5W338E) (caffeine - UNII:3G6 A5W338E)	caffeine	50 mg

Inactive Ingredients			
Ingredient Name	Strength		
acesulfame potassium (UNII: 23OV73Q5G9)			
citric acid monohydrate (UNII: 2968 PHW8 QP)			
ethylcelluloses (UNII: 7Z8S9VYZ4B)			
sodium chloride (UNII: 451W47IQ8X)			
sucralose (UNII: 96K6UQ3ZD4)			
sucrose (UNII: C151H8M554)			

Product Characteristics			
Color	WHITE	Score	
Shape		Size	
Flavor	ORANGE	Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51596-010-01	1 in 1 POUCH		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part343	07/15/2014	

Labeler - Breakthrough Products Inc. (962008251)

Revised: 6/2014 Breakthrough Products Inc.