

PAIN STOPPERS EX- acetaminophen, caffeine, aspirin tablet, coated
PAIN STOPPERS EXTRA- acetaminophen, caffeine, aspirin tablet, coated
Honeywell Safety Products USA, 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.

Pain Stoppers EX

Active Ingredients (in each tablet)

Acetaminophen 250 mg

Aspirin 250 mg

Caffeine 65 mg

Purpose

Pain reliever/fever reducer

Pain reliever/fever reducer

Diuretic

Uses

for the temporary relief of minor aches and pain with a headache

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: Aspirin may cause a severe allergic reaction which may include:

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

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.

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

- more than 8 tablets 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 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 NSAIDs (aspirin, ibuprofen, naproxen, or others).
- 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, food or beverages, while taking this product because too much caffeine may cause nervousness, sleeplessness, irritability, occasionally, rapid heartbeat

Do not use

- if you have 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.
- for more than 10 days for pain unless directed by a doctor
- for more than 3 days for fever unless directed by a doctor

Ask a doctor before use if

- stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you are taking a diuretic
- you have high blood pressure, heart disease, liver cirrhosis, or kidney disease
- you have asthma

Ask a doctor or pharmacist before use if you are

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

Stop use and ask a doctor if

- symptoms do not improve
- new symptoms occur
- pain or fever persists or gets worse
- 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 ringing in the ears or a loss of hearing occurs, consult a doctor before taking any more of this product.

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

Keep out of reach of children.

Overdose warning: In case of accidental overdose, get medical help or contact a Poison Control

Center immediately. Prompt 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**
- drink a full glass of water with each dose
- adults and children 12 years of age and older: take 2 tablets every 6 hours not more than 8 tablets in 24 hours
- children under 12 years of age: consult a doctor

Other Information

- store at room temperature 15 °-30 ° C (59 °-86 ° F)
- TAMPER EVIDENT - DO NOT USE IF OPEN OR TORN

Inactive Ingredients

hypromellose, maltodextrin, microcrystalline cellulose, povidone, sodium starch glycolate, starch, stearic acid, titanium dioxide

Questions or Comments?

1-800-430-5490

Pain Stoppers EX 100CT

ORTH

NORTH

PAIN STOPPERS EXTRA STRENGTH

Maximum Strength Pain Reliever

PAIN STOPPERS EXTRA STRENGTH

Maximum Strength Pain Reliever

Aspirin 250mg.

Acetaminophen 250mg.

Caffeine 65mg.

2 Tablets Per Packet

Quantity 100 Tablets

NORTH

Pain Soppers EX 250CT

NORTH

PAIN STOPPERS EXTRA STRENGTH

Maximum Strength Pain Reliever

Maximum Strength Pain Reliever

Acetaminophen 250 mg

Pain reliever / fever reducer

Aspirin 250 mg NSAID

Pain reliever / fever reducer

Caffeine stimulant 65mg

See New Warnings Information

2 Tablets Per Packet

Quantity 250 Tablets

PainStoppers EX 500ct

NORTH

by Honeywell

PAIN STOPPERS EXTRA STRENGTH

*Maximum Strength
Pain Reliever*

Maximum Strength Pain Reliever

Acetaminophen 250 mg

Pain reliever / fever reducer

Aspirin 250 mg NSAID

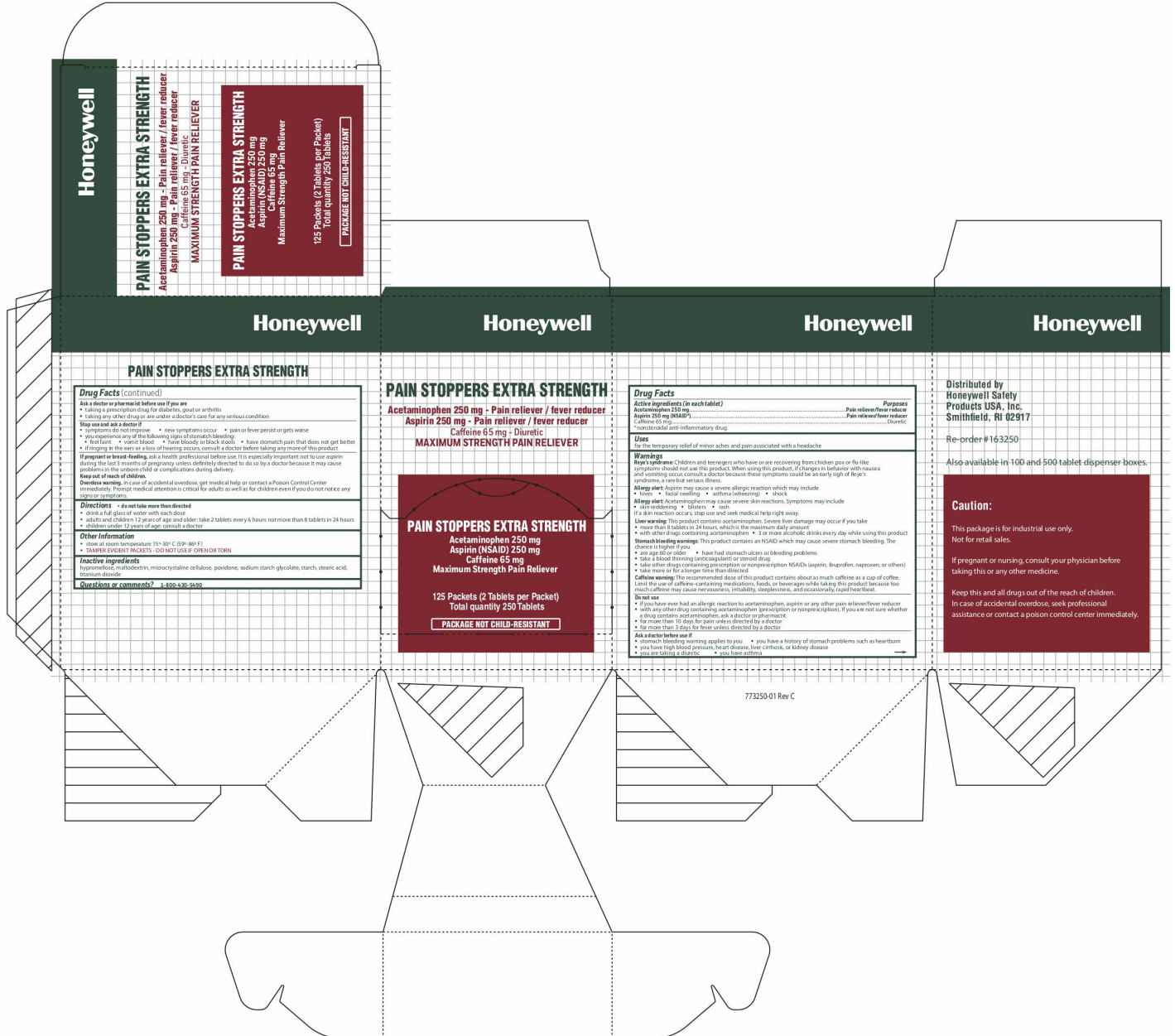
Pain reliever / fever reducer

Caffeine stimulant 65 mg

See New Warnings information

2 Tablets Per Packet
Quantity 500 Tablets

Pain Stoppers Extra



PAIN STOPPERS EX
acetaminophen, caffeine, aspirin tablet, coated

773250-01 Rev C

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0498-2521
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	250 mg
CAFFEINE (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)	CAFFEINE	65 mg
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	250 mg

Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
POVIDONE K30 (UNII: U725QWY32X)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	

Product Characteristics

Color	white	Score	no score
Shape	ROUND	Size	11mm
Flavor		Imprint Code	FR;9
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-2521-10	100 in 1 BOX	01/02/2017	
1	NDC:0498-2521-01	2 in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:0498-2521-25	250 in 1 BOX	01/02/2017	
2	NDC:0498-2521-01	2 in 1 PACKET; Type 0: Not a Combination Product		
3	NDC:0498-2521-50	500 in 1 BOX	01/02/2017	
3	NDC:0498-2521-01	2 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	01/02/2017	

PAIN STOPPERS EXTRA

acetaminophen, caffeine, aspirin tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0498-2520
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAFFEINE (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)	CAFFEINE	65 mg
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	250 mg
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	250 mg

Inactive Ingredients

Ingredient Name	Strength
STEARIC ACID (UNII: 4ELV7Z65AP)	
POVIDONE K30 (UNII: U725QWY32X)	
STARCH, CORN (UNII: O8232NY3SJ)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

Product Characteristics

Color	white (SNOW WHITE)	Score	no score
Shape	ROUND	Size	11mm
Flavor		Imprint Code	FR;9
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-2520-50	250 in 1 CARTON	03/07/2012	01/01/2017
1	NDC:0498-2520-25	125 in 1 CARTON		
1	NDC:0498-2520-10	50 in 1 CARTON		
1	NDC:0498-2520-01	2 in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:0498-2520-23	100 in 1 BOX	01/02/2017	01/03/2017
2	NDC:0498-2520-02	2 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	03/07/2012	01/04/2017

Labeler - Honeywell Safety Products USA, Inc (079287321)**Registrant** - Honeywell Safety Products USA, Inc (079287321)

Establishment

Name	Address	ID/FEI	Business Operations
Honeywell Safety Products USA, Inc		079287321	repack(0498-2520, 0498-2521)

Revised: 1/2020

Honeywell Safety Products USA, Inc