PAIN STOPPERS EXTRA - caffeine, acetaminophen and aspirin tablet, coated North Safety Products LLC

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.

DRUG FACTS

Active Ingredients (In Each Tablet)

Acetaminophen 250 mg

Aspirin 250 mg

Caffeine 65 mg

Enter section text here.

Pain reliever/Fever reducer

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

Do not take more than directed

the smallest effective dose should be used

adults and children 12 years of age and over; take 2 tablets with a full glass of water every 4 hours

do not take more than 16 tablets in 24 hours

do not take longer than 10 days, unless directed by a doctor

children under 12 years: ask a doctor

Warnings:

Reye's syndrome: Children and teenagers should not use this medicine for chicken pox or flu symptoms before a doctor is consulted about Reye's syndrome, a rare but serious illness reported to be associated with aspirin.

Allergy Alert-Do not use:

- if you are allergic to aspirin or any other salicylate
- if you have ever had an allergic reaction to any other pain

reliever/fever reducer

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

- more than 8 tablets in 24 hours
- with other drugs containing acetaminophen (prescription or nonprescription). Ask a doctor or pharmacist before using with other drugs if you are not sure.
- 3 or more alcoholic drinks every day while using this product

Stomach Bleeding Warning:This product contains nonsteroidal anti-inflammatory dugs (NSAIDs), 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 an NSAID (aspirin, ibuprofen, naproxen, or others.
- Take more or for a longer time than directedCaffeine warning: The recommended dose of this product contains about as much caffeine as a

cup of coffee.

When using this product:

limit the use of caffeine containing medications, food or beverages, too much caffeine may cause nervousness, sleeplessness, irritability, occasionally, rapid heartbeat

Do not use:

If you ever had an allergic reaction to any other pain reliever/fever reducer

- with any other pain reliever/fever reducer
- for pain for more than 10 days or for fever for more than 3

days unless directed by a doctor

with any other product containing acetaminophen If you are not sure

whether a drug contains acetaminophen, ask a doctor or pharmacist

Ask doctor before using if you have:

- upset stomach or stomach pain
- ulcers
- bleeding problems
- high blood pressure
- heart or kidney disease
- taken a diuretic
- reached age 60 or older

with any other drug containing an NSAID (prescription or nonprescription). Ask a doctor before using

with other drugs if you are not sure

taking a blood thinning (anticoagulant) or steroid drug

When using this product do not exceed recommended dose

Stop use and ask a doctor if:

- ringing in the ears or loss of hearing occurs
- pain or fever persists or gets worse
- new symptoms occur
- redness or swelling is present
- · you feel faint, vomit blood, or have bloody or black stools. These are signs of stomach bleeding

If pregnant or breast-feeding baby, ask a health professional

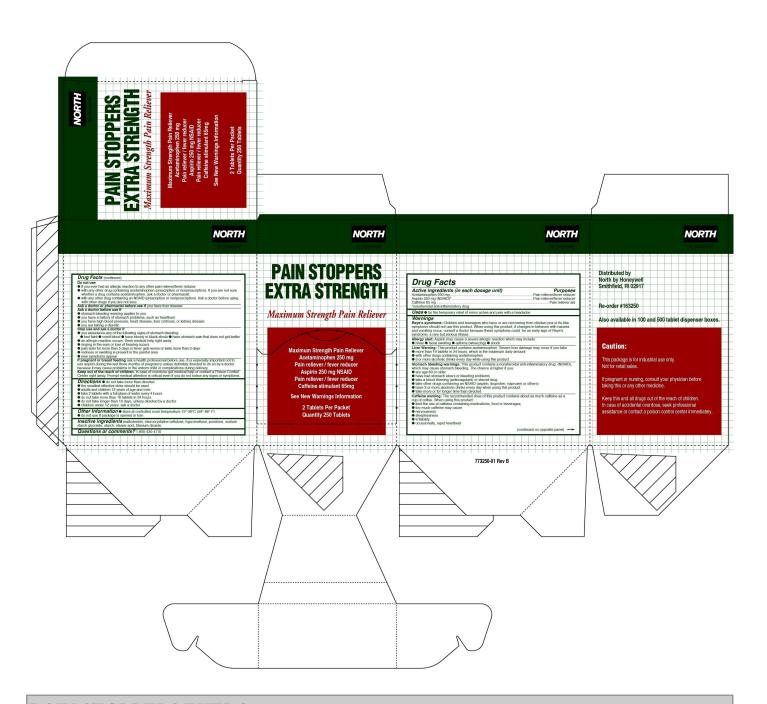
before use. IT IS ESPECIALLY IMPORTANT NOT TO USE ASPIRIN DURING THE LAST 3

MONTHS OF PREGNANCY UNLESS SPECIFICALLY 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. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

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Inactive Ingredients: maltodextrin, microcrystaline cellulose, hypromellose, povidone, sodium starch glycolate, starch, stearic acid, titanium dioxide MM1



PAIN STOPPERS EXTRA

acetaminophen, caffeine, aspirin tablet, coated

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

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
CAFFEINE (CAFFEINE)	CAFFEINE	65 mg	
ACETAMINO PHEN (ACETAMINO PHEN)	ACETAMINOPHEN	250 mg	
ASPIRIN (ASPIRIN)	ASPIRIN	250 mg	

Inactive Ingredients	
Ingredient Name	Strength
STEARIC ACID	
PO VIDONE K30	
STARCH, CORN	
CELLULO SE, MICRO CRYSTALLINE	
SODIUM STARCH GLYCOLATE TYPE A POTATO	

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

Pa	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:0498-2520-50	250 in 1 CARTON			
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			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	03/07/2012	

Labeler - North Safety Products LLC (019777263)

Registrant - North Safety Products LLC (019777263)

Establishment			
Name	Address	ID/FEI	Business Operations
ULTRAtab Laboratories, Inc.		151051757	manufacture(0498-2520)

Establishment			
Name	Address	ID/FEI	Business Operations
Ultra Seal Corporation		085752004	repack(0498-2520)

Revised: 4/2013 North Safety Products LLC