

PAIN STOPPERS EXTRA - acetaminophen, caffeine, 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 drugs (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 directed
Caffeine 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

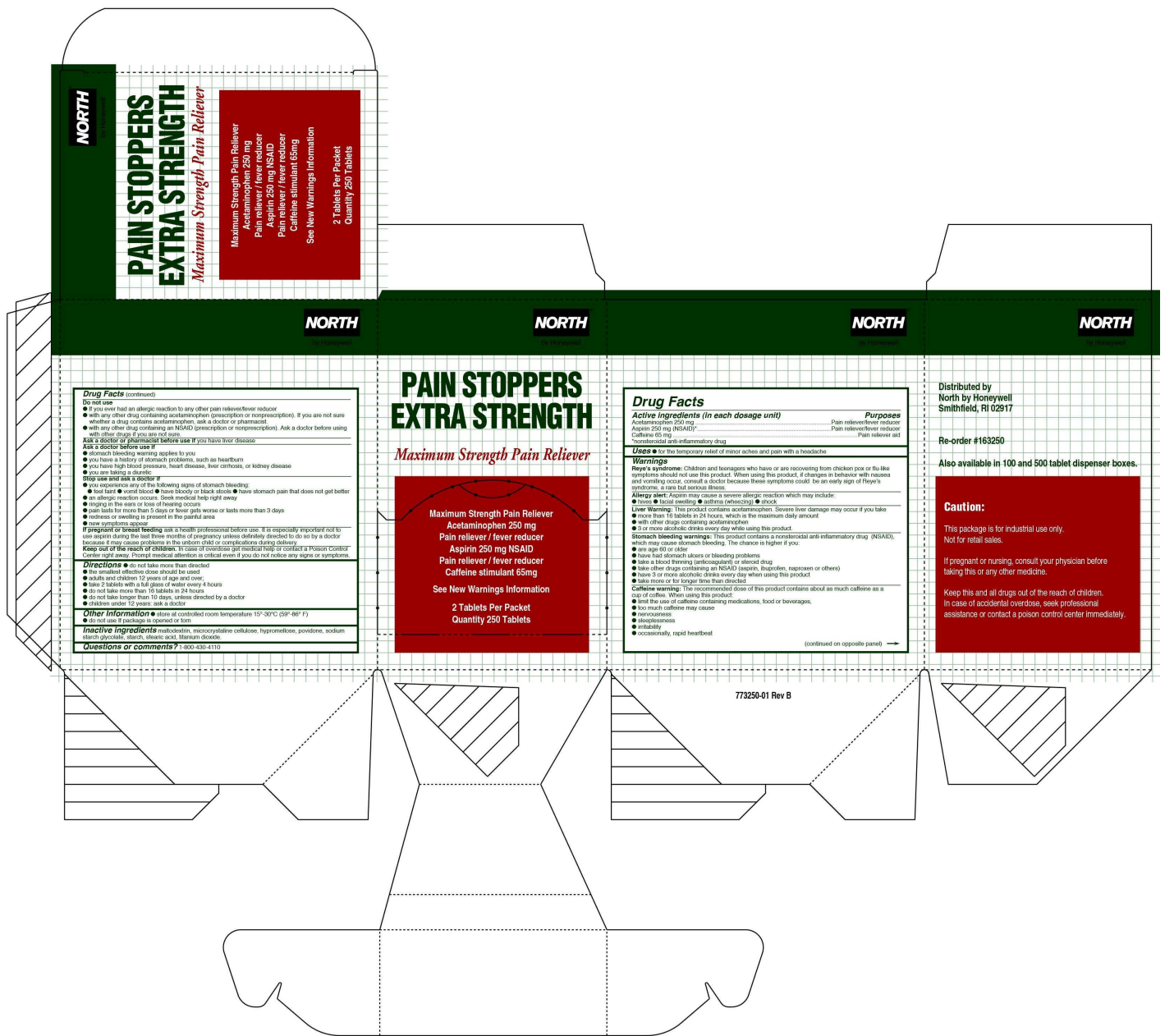
MONTHS OF PREGNANCY UNLESS SPECIFICALLY DIRECTED TO DO SO BY A DOCTOR BECAUSE IT MAY CAUSE PROBLEMS IN THE UNBORN CHILD OR COMPLICATIONS DURING DELIVERY. KEEP OUT OF REACH OF CHILDREN.

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.

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.

Inactive Ingredients: maltodextrin, microcrystalline 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 | Item Code (Source) | NDC:0498-2520 |
| Route of Administration | ORAL | | |

| Active Ingredient/Active Moiety | | | |
|--|-------------------|----------|--|
| Ingredient Name | Basis of Strength | Strength | |
| CAFFEINE (UNII: 3G6A5W338 E) (CAFFEINE - UNII:3G6A5W338 E) | 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 | | |
| 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) |