

# **XPECT PAIN AWAY- pain reliever tablet**

## **Cintas Corporation**

-----

### **Xpect Pain Away**

#### **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

**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 severe stomach bleeding. The chance is higher if you

- 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 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, foods, or beverages while taking this product because too much caffeine may cause nervousness, irritability, sleeplessness, and, occasionally, rapid heart beat.

**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.

**Ask a doctor before use if:**

- you have liver disease
- 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:**

- any other drug containing an NSAID (prescription or nonprescription)

- a blood thinning (anticoagulant) or steroid drug
- a prescription drug for diabetes, gout, or arthritis
- any other drug or are under a doctor's care for any serious condition

Stop use and ask a doctor if:

- an allergic reaction occurs. Seek medical help right away.
- 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 • ringing in the ears or loss of hearing occurs
- painful area is red or swollen • pain gets worse or lasts for more than 10 days
- fever gets worse or lasts for more than 3 days • any new symptoms appear

If pregnant or breast-feeding, ask a health professional before use. It is especially important to not 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. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Temporarily relieves minor aches and pains due to:

- headache
- a cold
- arthritis
- muscular aches
- sinusitis
- toothache
- premenstrual & menstrual cramps

Keep out of reach of children.

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.

## Purposes

Active ingredients (in each tablet)

Acetaminophen 250 mg.....Pain reliever  
 Aspirin 250 mg (NSAID)\*.....Pain reliever  
 Caffeine 65 mg.....Pain reliever aid

## Directions

- do not use more than directed
- drink a full glass of water with each dose
- adults and children 12 years and over: take two tablets every 6 hours; not more than 8 tablets in 24 hours

- children under 12 years: ask a doctor

Acetaminophen 250 mg.....Pain reliever  
 Aspirin 250 mg (NSAID)\*.....Pain reliever  
 Caffeine 65 mg.....Pain reliever aid  
 \*nonsteroidal anti-inflammatory drug

hydroxypropyl methylcellulose, maltodextrin, microcrystalline cellulose, polyethylene glycol, povidone, sodium starch glycolate, starch, stearic acid, titanium dioxide

### Other Information

- store at controlled room temperature 20-25C (68-77F)
- read all product information before using. Keep this box for important information.



## XPECT PAIN AWAY

pain reliever tablet

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:42961-202
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

Ingredient Name	Strength
<b>HYDROXYPROPYL METHACRYLATE</b> (UNII: UKW89XAX2X)	
<b>MALTODEXTRIN</b> (UNII: 7CVR7L4A2D)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	

<b>POLYETHYLENE GLYCOL 250</b> (UNII: 5246R0812J)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>SODIUM STARCH GLYCOLATE TYPE A CORN</b> (UNII: AG9B65PV6B)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

### Product Characteristics

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	11mm
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42961-202-02	100 in 1 BOX	02/27/2021	
1	NDC:42961-202-01	2 in 1 PACKET; Type 1: Convenience Kit of Co-Package		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA075794	02/27/2021	

**Labeler** - Cintas Corporation (056481716)

**Registrant** - Cintas Corporation (056481716)

### Establishment

Name	Address	ID/FEI	Business Operations
UltraTab Laboratories		151051757	manufacture(42961-202)

Revised: 3/2021

Cintas Corporation