

**EXTRA PAIN RELIEF ACETAMINOPHEN, ASPIRIN (NSAID) AND CAFFEINE-  
acetaminophen, salicylic acid, caffeine tablet, film coated  
Medline Industries, LP**

*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.*

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**988 Extra Pain Relief Acetaminophen, Aspirin (NSAID) and Caffeine**

***Active ingredient (in each tablet)***

Acetaminophen 250 mg

Aspirin 250 mg (NSAID)\*

Caffeine 65 mg

\*nonsteroidal anti-inflammatory drug

***Purpose***

Pain reliever

Pain reliever

Pain reliever aid

***Uses***

- temporarily relieves minor aches and pains due to:
- headache
- sinusitis
- cold
- arthritis
- muscular aches
- toothache
- premenstual and menstrual cramps

***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 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 severe 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 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 which while taking this product because too much caffeine may cause nervousness, irritability, sleeplessness and 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 doctor before use if**

- 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
- you have liver disease

### **Stop using and ask a doctor if**

- an allergic reaction occurs. Seek medical help right away.
- painful area is red or swollen

- symptoms do not improve
- any new symptoms appear
- 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
- fever gets worse or lasts for more than 3 days
- pain gets worse or lasts for more than 10 days

**If pregnant or breast-feeding,**

ask a health 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.**

In case of accidental 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.

***Directions***

- do not use more than directed
- drink a full glass of water with each dose
- adults and children 12 years and over: take 2 tablets every 6 hours; not more than 8 tablets in 24 hours
- children under 12 years: do not use unless directed by a doctor

***Other information***

- store at 20°-25°C (68°-77°F)

***Inactive ingredients***

carnauba wax, colloidal silicon dioxide, hypromellose, microcrystalline cellulose, mineral oil, povidone, pregelatinized starch, sodium starch glycolate, stearic acid, titanium dioxide

**Manufacturing Information**

Manufactured for:  
Medline Industries, LP  
Three Lakes Drive, Northfield, IL 60093 USA  
Made in USA with domestic and foreign materials  
[www.medline.com](http://www.medline.com)

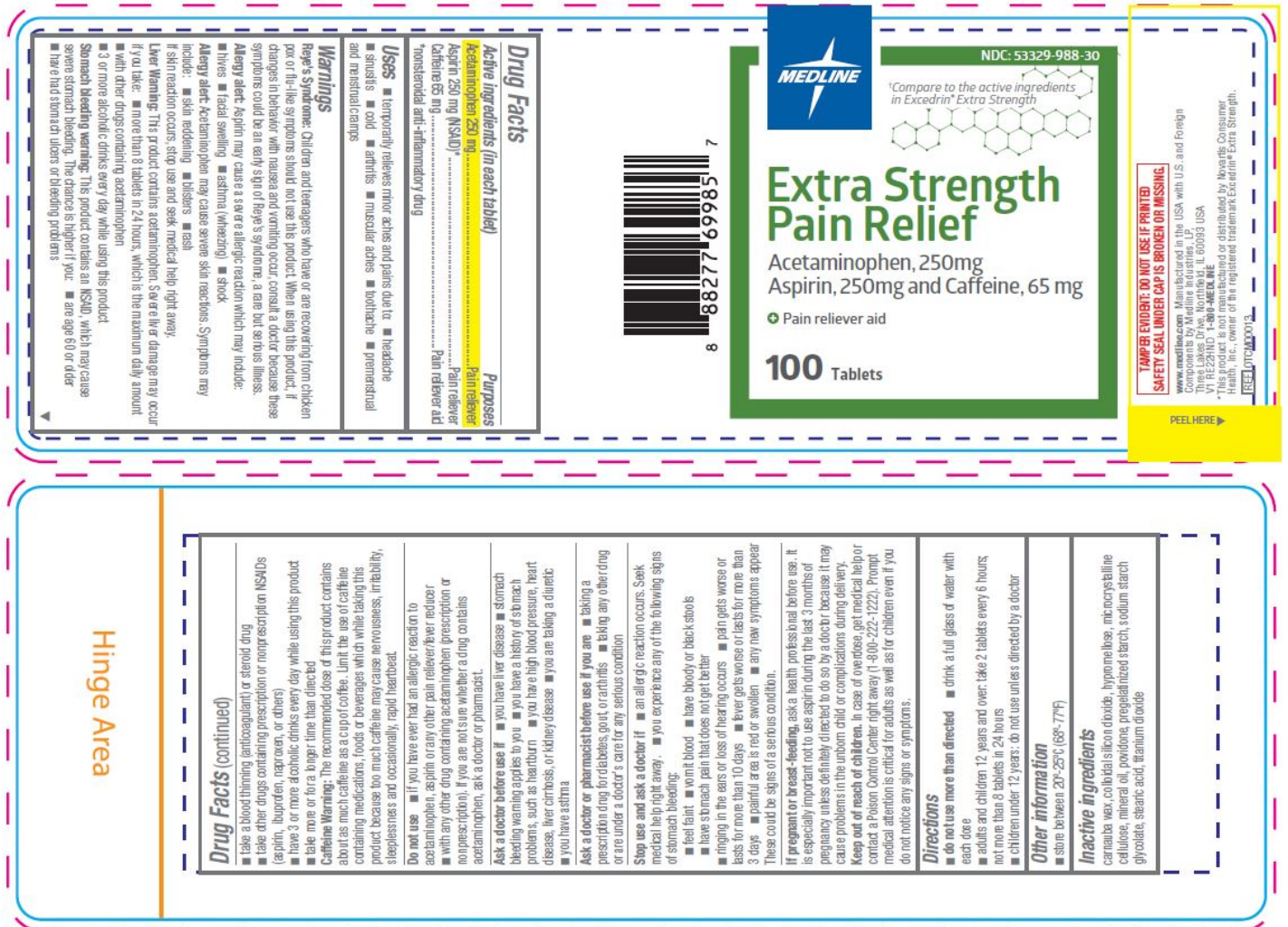
1-800-MEDLINE (633-5463)

REF: OTCM00013

V1 RE22HND

†This product is not manufactured or distributed by Novartis Consumer Health, Inc., owner of the registered trademark Excedrin® Extra Strength.

**Package Label**



<b>EXTRA PAIN RELIEF ACETAMINOPHEN, ASPIRIN (NSAID) AND CAFFEINE</b>			
acetaminophen, salicylic acid, caffeine tablet, film coated			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:53329-988
<b>Route of Administration</b>	ORAL		
<b>Active Ingredient/Active Moiety</b>			
<b>Ingredient Name</b>		<b>Basis of Strength</b>	<b>Strength</b>

<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	250 mg
<b>SALICYLIC ACID</b> (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SALICYLIC ACID	250 mg
<b>CAFFEINE</b> (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)	CAFFEINE	65 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>STARCH, PREGELATINIZED CORN</b> (UNII: O8232NY3SJ)	
<b>SODIUM STARCH GLYCOLATE TYPE A CORN</b> (UNII: AG9B65PV6B)	
<b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>MINERAL OIL</b> (UNII: T5L8T28FGP)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	

### Product Characteristics

<b>Color</b>	white	<b>Score</b>	score with uneven pieces
<b>Shape</b>	CAPSULE (capsule shaped tablet)	<b>Size</b>	18mm
<b>Flavor</b>		<b>Imprint Code</b>	TCL370
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53329-988-30	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/04/2018	



### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	06/04/2018	

**Labeler** - Medline Industries, LP (025460908)

**Registrant** - Medline Industries, LP (025460908)

Revised: 12/2022

Medline Industries, LP