

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

*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 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- use by expiration date on package

***Inactive ingredients***

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

**www.medline.com** Manufactured in the USA with US and foreign components by:  
Medline Industries, Inc., Northfield, IL 60093 RE18HND **1-800-MEDLINE**

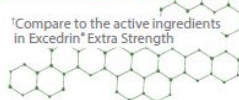
†This product is not manufactured or distributed by Novartis Consumer Health, Inc., owner of the registered trademark Excedrin® Extra Strength.

**Package Label**



NDC: 53329-988-30

Compare to the active ingredients in Excedrin® Extra Strength



# Extra Strength Pain Relief

Acetaminophen, 250mg  
Aspirin, 250mg and Caffeine, 65 mg

Pain reliever aid

100 Tablets

**TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.**

### Drug Facts

#### Active ingredient (in each tablet)

Acetaminophen 250 mg ..... Pain reliever  
Aspirin 250 mg (NSAID) ..... Pain reliever  
Caffeine 65 mg ..... Pain reliever aid  
\*nonsteroidal anti-inflammatory drug**Uses** temporarily relieves minor aches and pains due to: ■ headache  
■ sinusitis ■ cold ■ arthritis ■ muscular aches ■ toothache ■ premenstrual  
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 redness ■ 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  
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■ with other drugs containing acetaminophen**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 problemswww.medline.com Manufactured in the USA with US and foreign components by:  
Medline Industries, Inc., Northfield, IL 60053 RE18HND 1-800-MEDLINE  
[SEE] 010M00013

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This product is not  
manufactured or  
distributed by Horst  
Chamberlain, Inc.,  
or its regional  
representatives for  
Extra Strength.

PEEL HERE

### Drug Facts (continued)

■ 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  
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■ 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  
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■ you have high blood pressure, heart disease, liver or kidney disease  
■ you are taking a diuretic ■ have asthma ■ 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  
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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  
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tablets in 24 hours ■ children under 12 years: do not use unless directed by a doctor

#### Other information

■ store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)  
■ use by expiration date on package**Inactive ingredients** carmelum wax, colloidal silicon dioxide, hypromellose,  
microcrystalline cellulose, mineral oil, polydioxane, pregelatinized starch, sodium starch  
glycolate, stearic acid, titanium dioxide

## EXTRA PAIN RELIEF ACETAMINOPHEN, ASPIRIN (NSAID) AND CAFFEINE

acetaminophen, salicylic acid, caffeine tablet, film coated

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53329-988
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	250 mg
SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SALICYLIC ACID	250 mg
CAFFEINE (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)	CAFFEINE	65 mg

### Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
CARNAUBA WAX (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 (025460908)

**Establishment**

Name	Address	ID/FEI	Business Operations
Time Cap Labs		037052099	manufacture(53329-988)

**Establishment**

Name	Address	ID/FEI	Business Operations
Medline Industries		079800021	repack(53329-988)

Revised: 12/2019

Medline Industries