# GOOD SENSE PAIN RELIEF EXTRA STRENGTH- acetaminophen tablet, coated L. Perrigo Company

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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# **Perrigo Pain Relief Drug Facts**

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

Acetaminophen 500 mg

# Purpose

Pain reliever/fever reducer

#### Uses

- temporarily relieves minor aches and pains due to:
- the common cold
- headache
- backache
- minor pain of arthritis
- toothache
- muscular aches
- premenstrual and menstrual cramps
- temporarily reduces fever

#### **Warnings**

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

- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away.

#### Do not use

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- if you have ever had an allergic reaction to this product or any of its ingredients

#### Ask a doctor before use if you have

liver disease

# Ask a doctor or pharmacist before use if you are

taking the blood thinning drug warfarin

#### Stop use and ask a doctor if

- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- new symptoms occur
- redness or swelling is present

These could be signs of a serious condition.

# If pregnant or breast-feeding,

ask a health professional before use.

#### Keep out of reach of children.

**Overdose warning:** In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

#### **Directions**

do not take more than directed (see overdose warning)

adults and children 12 years and over	<ul> <li>take 2 tablets every 6 hours while symptoms last</li> <li>do not take more than 6 tablets in 24 hours, unless directed by a doctor</li> <li>do not use for more than 10 days unless directed by a doctor</li> </ul>
children under 12 years	ask a doctor

## **Inactive ingredients**

corn starch\*, FD&C red #40 aluminum lake, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, sodium starch glycolate\*, stearic acid, sucralose, talc, titanium dioxide \*may contain these ingredients

#### Questions or comments?

1-800-719-9260

#### **Principal Display Panel**

Extra Strength

Pain Relief

Pain Reliever/Fever Reducer

**TABLETS** 

Actual Size

Acetaminophen

Easy To Swallow

For Adults • Sweet Coated

Compare to active ingredient of Extra Strength Tylenol®

100% SATISFACTION GUARANTEED

50 Tablets – 500 mg Each



#### GOOD SENSE PAIN RELIEF EXTRA STRENGTH

acetaminophen tablet, coated

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0113-0227	
Route of Administration	ORAL			

l	Active Ingredient/Active Moiety			
l	Ingredient Name	Basis of Strength	Strength	
l	ACETAMINO PHEN (UNII: 36209 ITL9 D) (ACETAMINO PHEN - UNII: 36209 ITL9 D)	ACETAMINOPHEN	500 mg	

Inactive Ingredients		
Ingredient Name	Strength	
STARCH, CORN (UNII: O8232NY3SJ)		
FD&C RED NO. 40 (UNII: WZB9127XOA)		
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)		
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)		
PO VIDO NE, UNSPECIFIED (UNII: FZ989GH94E)		
STEARIC ACID (UNII: 4ELV7Z65AP)		
SUCRALOSE (UNII: 96K6UQ3ZD4)		
TALC (UNII: 7SEV7J4R1U)		
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)		

Product Characteristics				
Color	RED	Score	no score	
Shape	ROUND (convex)	Size	10 mm	
Flavor		Imprint Code	L227	
Contains				

Packaging			
# Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1 NDC:0113-0227-71	1 in 1 CARTON	02/13/2006	
1	50 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	02/13/2006	

# Labeler - L. Perrigo Company (006013346)

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