# PAIN RELIEVER EXTRA STRENGTH- acetaminophen tablet Amerisource Bergen

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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#### **DRUG FACTS**

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

Acetaminophen 500 mg

# **Purpose**

#### Pain reliever/ fever reducer

#### Uses

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

# Warnings

**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 ever day while using this product

#### 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.

# 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. 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:
  - take 2 tablets every 4 to 6 hours while symptoms last.
  - do not take more than 8 tablets in 24 hours
  - o do not take for more than 10 days unless directed by a doctor
- children under 12 years: do not use

#### Other information

store at controlled room temperature 15°-30°C (59°-86°F)

# **Inactive ingredients**

povidone, pregelatinized starch, sodium starch glycolate\*, stearic acid \*may contain this ingredient

#### **Questions or comments?**

Call 1-877-753-3935 Monday- Friday 9AM- 5PM EST

# **Principal Display Panel**

Compare to TYLENOL® Extra Strength active ingredient  $\dagger$ 

Extra Strength

PAIN RELIEVER

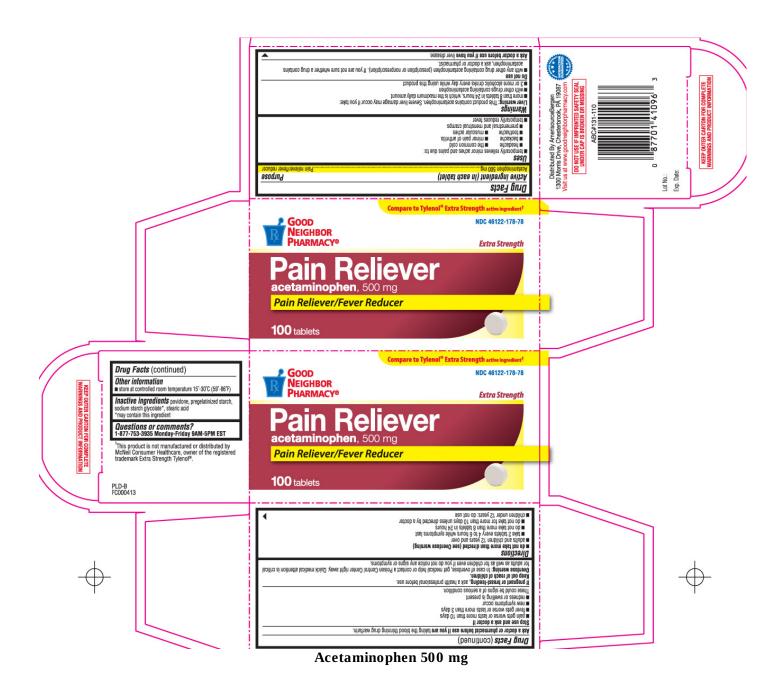
# **ACETAMINOPHEN 500 mg**

pain reliever/ fever reducer

# KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

†This product is not manufactured or distributed by McNeil Consumer Healthcare, owner of the registered trademark Extra Strength Tylenol®

#### **Product Label**



# PAIN RELIEVER EXTRA STRENGTH

acetaminophen tablet

Product Information				
Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:46122-178	
Route of Administration	ORAL	DEA Schedule		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINO PHEN (ACETAMINO PHEN)	ACETAMINOPHEN	500 mg	

Inactive	Ingredients
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Ingredient Name	Strength
POVIDONES	
STARCH, CORN	
SODIUM STARCH GLYCOLATE TYPE A CORN	
STEARIC ACID	

Product Characteristics			
Color	WHITE	Score	no score
Shape	ROUND	Size	12mm
Flavor		Imprint Code	TCL252
Contains			

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:46122-178-72	1 in 1 BOX			
1		60 in 1 BOTTLE			
2	NDC:46122-178-78	1 in 1 BOX			
2		100 in 1 BOTTLE, PLASTIC			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part343	11/08/2011	

# Labeler - Amerisource Bergen (007914906)

 $\pmb{Registrant -} \ \ P \ \ and \ \ L \ \ Development \ of \ \ New \ \ York \ \ Corporation \ (800014821)$ 

Revised: 12/2012 Amerisource Bergen