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.

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
  - 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
  - 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 †

Extra Strength

PAIN RELIEVER

ACETAMINOPHEN 500 mg

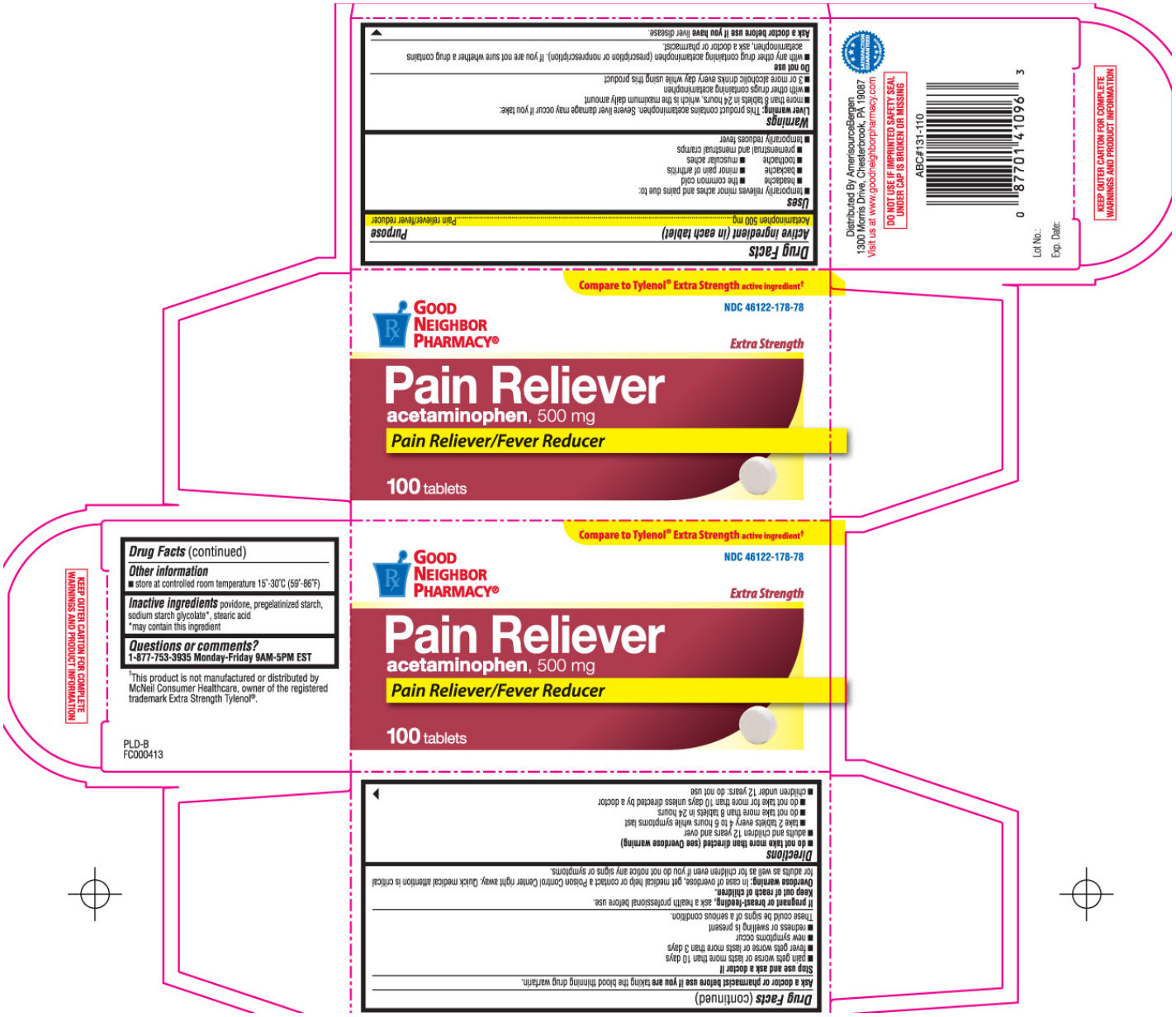
pain reliever/ fever reducer

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



Acetaminophen 500 mg

PAIN RELIEVER EXTRA STRENGTH

acetaminophen tablet

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

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg

Inactive Ingredients

Ingredient Name	Strength
POVIDONES (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

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

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)

Registrant - P and L Development of New York Corporation (800014821)

Revised: 12/2012 Amerisource Bergen