PLUSPHARMA EXTRA STRENGTH PAIN RELIEVER,FEVER REDUCER 500 MG- acetaminophen tablet
Gemini Pharmaceuticals, Inc. dba Plus Pharma

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

Purposes

Pain reliever/fever reducer

Uses

- for the temporary relief of minor aches and pains due to:

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

Warnings

Liver warning: This product contains acetaminophen. The maximum daily dose of this product is 6 tablets (3,000 mg) in 24 hours. 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

Do not use

- with any other drug containing acetaminophen (prescription or non prescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- if you are allergic to acetaminophen or any of the inactive ingredients in this product

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: Taking more than the recommended dose (overdose) may cause liver damage. In the 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:

- take 2 tablets every 6 hours while symptoms last
- do not take more than 6 tablets in 24 hours unless directed by a doctor
- do not take for more than 10 days unless directed by a doctor.

Children under 12 years: ask a doctor.

Other information

- **Do not use if imprinted safety seal under cap is broken or missing**
- Store at room temperature

Inactive ingredients

Povidone, Pregelatinized Starch, Sodium Starch Glycolate, Stearic Acid.

Questions?

If you have any questions or comments, or to report an adverse event, please contact (800) 795-9775.

Principal Display Panel

PlusPHARMA

See New Warnings Information and Directions

Extra Strength

ACETAMINOPHEN 500 mg

PAIN RELIEVER FEVER REDUCER

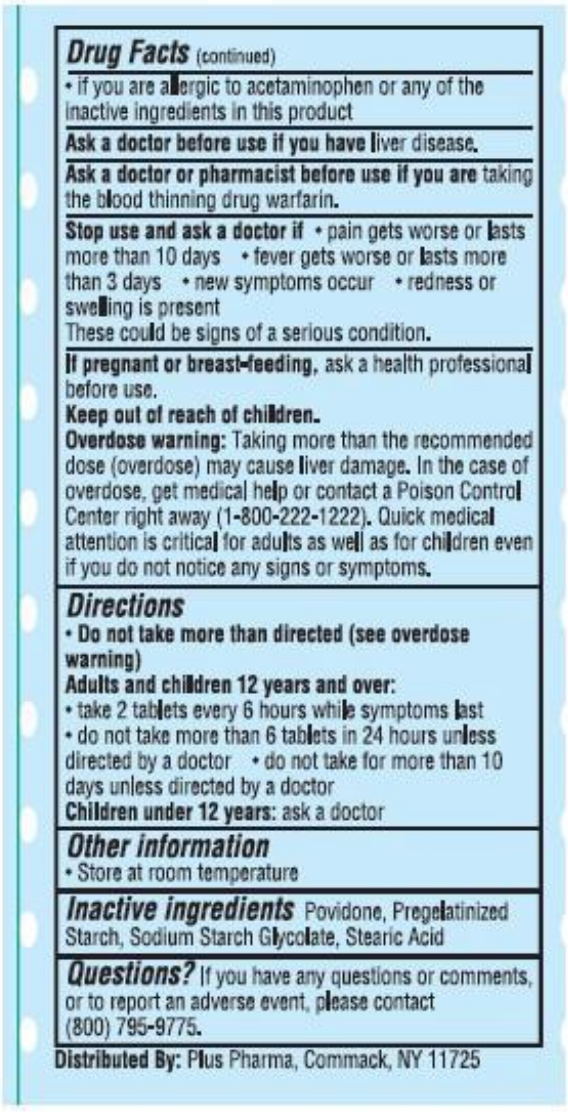
CONTAINS NO ASPIRIN

Compare to the Active Ingredient in Extra Strength Tylenol®

This product is not manufactured or distributed by McNeil Consumer Healthcare, owner of the

registered trademark Extra Strength Tylenol®

100 TABLETS 500 mg each



Drug Facts (continued)

• if you are allergic to acetaminophen or any of the inactive ingredients in this product

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: Taking more than the recommended dose (overdose) may cause liver damage. In the 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.

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Other information

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Inactive ingredients Povidone, Pregelatinized Starch, Sodium Starch Glycolate, Stearic Acid

Questions? If you have any questions or comments, or to report an adverse event, please contact (800) 795-9775.

Distributed By: Plus Pharma, Commack, NY 11725

PlusPHARMA

See New Warnings Information and Directions

Extra Strength

ACETAMINOPHEN 500 mg

PAIN RELIEVER FEVER REDUCER

CONTAINS NO ASPIRIN

Compare to the Active Ingredient in Extra Strength Tylenol®

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1000 TABLETS 500 mg each

PLUSPHARMA EXTRA STRENGTH PAIN RELIEVER,FEVER REDUCER 500 MG

acetaminophen tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:51645-706
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**
POVIDONE (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics			
Color	white	**Score**	2 pieces
Shape	ROUND (round flat faced beveled edge)	**Size**	12mm
Flavor		**Imprint Code**	GPI;A5
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51645-706-01	100 in 1 BOTTLE, PLASTIC		
2	NDC:51645-706-10	1000 in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	03/27/2006	

Labeler - Gemini Pharmaceuticals, Inc. dba Plus Pharma (055942270)

Registrant - Gemini Pharmaceuticals, Inc. dba Plus Pharma (055942270)

Establishment

Name	Address	ID/FEI	Business Operations
Gemini Pharmaceuticals, Inc. dba Plus Pharma		055942270	manufacture(51645-706)

Revised: 3/2006 Gemini Pharmaceuticals, Inc. dba Plus Pharma