PLUS PHARMA PAIN RELIEVER,FEVER REDUCER- 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.

Acetaminophen 325 mg Tablets

DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

Drug Facts

Active ingredient (in each tablet)

Acetaminophen 325 mg

Purposes

Pain reliever/fever reducer

Uses

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

Warnings

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

- adult takes more than 4,000 mg of acetaminophen in 24 hours
- child takes more than 5 doses in 24 hours
- taken with other drugs containing acetaminophen
- adult has 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 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 the user has liver disease.

Ask a doctor or pharmacist before use if the user is taking the blood thinning drug warfarin.

Stop use and ask a doctor if
- pain gets worse or lasts more than 10 days in adults
- pain gets worse or lasts more than 5 days in children under 12 years
- 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 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 4 to 6 hours while symptoms last • do not take more than 10 tablets in 24 hours, unless directed by a doctor • do not use for more than 10 days unless directed by a doctor
children 6 years to under 12 years	• take 1 tablet every 4 to 6 hours, while symptoms last • do not take more than 5 tablets in 24 hours • do not use for more than 5 days unless directed by a doctor
children under 6 years	ask a doctor

Other information
- store at room temperature in a dry place

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

Manufactured in a GMP facility in the USA

PlusPHARMA®

NDC 51645-703-01

See New Warnings Information & Directions

Regular Strength

ACETAMINOPHEN 325 mg

PAIN RELIEVER • FEVER REDUCER

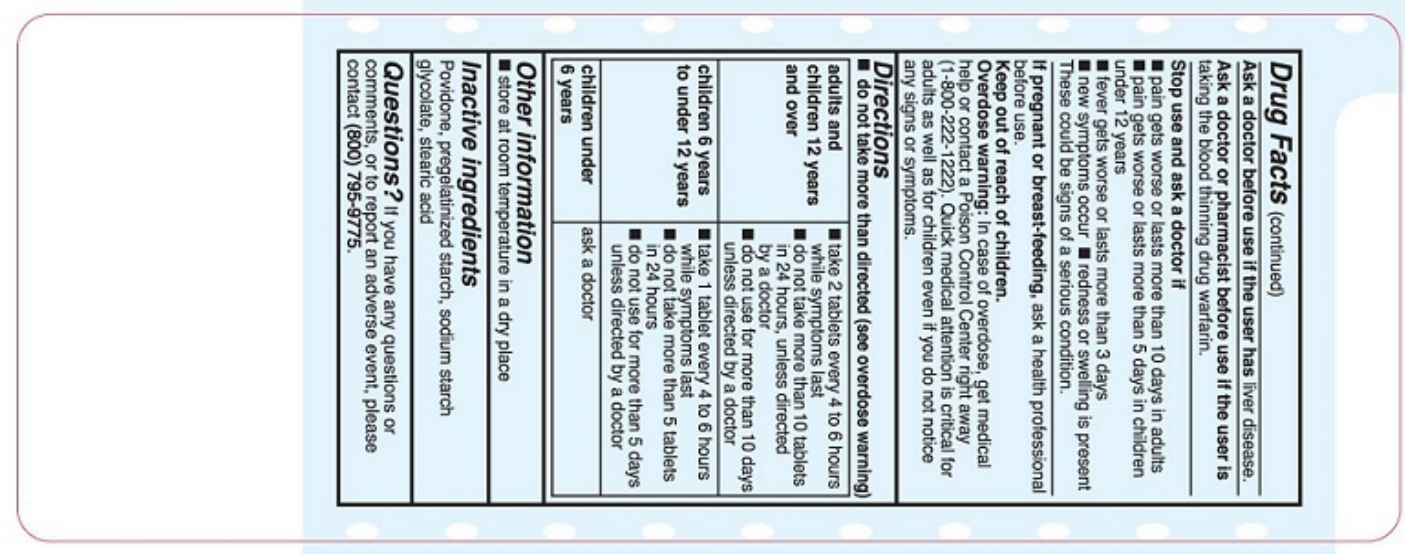
CONTAINS NO ASPIRIN

Contains no ingredient from a gluten-containing grain (wheat, barley, or rye).

*Compare to the Active Ingredient in Regular Strength Tylenol®

*Plus Pharma is not affiliated with the owner of the registered trademark Tylenol®.

100 TABLETS 325 mg each



PLUS PHARMA PAIN RELIEVER,FEVER REDUCER

acetaminophen tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:51645-703
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 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 (round)	**Score**	no score
Shape	ROUND (flat faced beveled edge)	**Size**	10mm
Flavor		**Imprint Code**	GPI;A325
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:51645-703-01	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/27/2006	12/31/2023
2	NDC:51645-703-10	1000 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/27/2006	12/31/2023
3	NDC:51645-703-05	50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/27/2006	11/30/2017

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	03/27/2006	12/31/2023

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

Establishment

Name	Address	ID/FEI	Business Operations
Gemini Pharmaceuticals, Inc. dba Plus Pharma		055942270	manufacture(51645-703)