ACETAMINOPHEN- acetaminophen 325mg tablet America's Pharmacy Source LLC

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 325mg

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. The maximum daily dose of this product is 10 tablets (3,250 mg) in 24 hours for adults or 5 tablets (1,625 mg) in 24 hours for children. Severe liver damage may occur if

- adult takes more than 4000 mg of acetaminophen in 24 hours, which is the maximum daily amount
- child takes more than 5 doses in 24 hours, which is the maximum daily amount
- 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 nonprescription). 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 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:

In the case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

Directions

• do not take more than directed (see overdose warning).

take 2 tablets, every 4 to 6 hours while symptoms lastdo not take more than 10 tablets in 24 hours, unless directed by
a doctor
o do not take for more than 10 days unless directed by a doctor
 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
ask a doctor

Other information

• store between 20-25°C (68-77°F)

Inactive ingredients

povidone, pregelatinized starch, sodium starch glycolate, stearic acid

Questions?

Adverse drug event call: (866) 562-2756 (Mon - Fri 8 AM to 4 PM EST)

COMPARE TO ACTIVE

INGREDIENT IN

TYLENOL® REGULAR STRENGTH

AMERICA'S

PHARMACY SOURCE

REGULAR STRENGTH

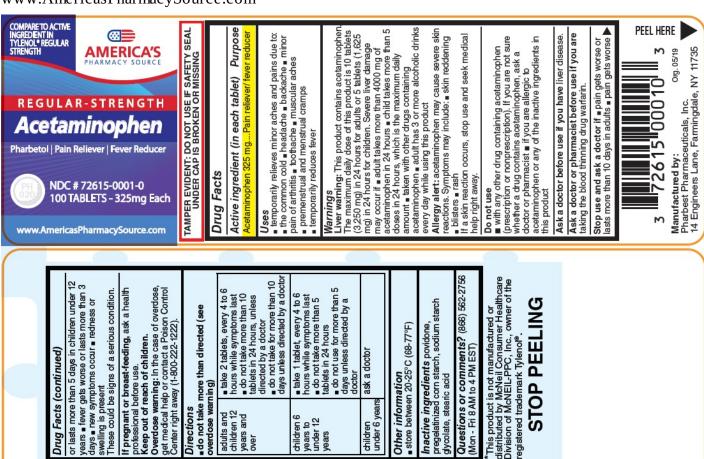
Acetaminophen

Pharbetol l Pain Reliever l Fever Reducer

NDC# 72615-0001-0

100 TABLETS - 325mg Each

www.AmericasPharmacySource.com



directed by a doctor

children 6 years to under 12 years

overdose warning)

adults and children 12

ACETAMINOPHEN

Drug Facts (continued)

Keep out of reach of children.

essional before use.

acetaminophen 325mg tablet

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72615-0001	
Route of Administration	ORAL			

Other information store between 20-25°C (68-77°F)

alvoolate, stearic acid

ask a doctor

under 6 years

egistered trademark Tylenol

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINO PHEN (UNII: 36209 ITL9 D) (ACETAMINO PHEN - UNII: 36209 ITL9 D)	ACETAMINOPHEN	325 mg	

Inactive Ingredients			
Ingredient Name	Strength		
PO VIDO NE (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	10 mm
Flavor		Imprint Code	PH0 20
Contains			

ı	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:72615-0001- 0	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/02/2019	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	10/02/2019	

Labeler - America's Pharmacy Source LLC (116701866)

Registrant - America's Pharmacy Source LLC (116701866)

Establishment			
Name	Address	ID/FEI	Business Operations
Pharbest Pharmaceuticals, Inc.		557054835	manufacture(72615-0001), analysis(72615-0001), repack(72615-0001), relabel(72615-0001)

Revised: 11/2019 America's Pharmacy Source LLC