

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).**

adults and children 12 years and over	<ul style="list-style-type: none">◦ 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 take for more than 10 days unless directed by a doctor
children 6 to 11 years	<ul style="list-style-type: none">◦ take 1 tablet, every 4 to 6 hours while symptoms last◦ do not take more than 5 tablets in 24 hours
children under 6 years	<ul style="list-style-type: none">◦ 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 1 Pain Reliever 1 Fever Reducer
 NDC# 72615-0001-0
 100 TABLETS - 325mg Each
 www.AmericasPharmacySource.com

COMPARE TO ACTIVE INGREDIENT IN
 TYLENOL® REGULAR STRENGTH

REGULAR-STRENGTH

Acetaminophen

Pharbetol | Pain Reliever | Fever Reducer

NDC # 72615-0001-0
 100 TABLETS - 325mg Each

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TAMPER EVIDENT: DO NOT USE IF SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

Drug Facts

Active ingredient (in each tablet) Purpose
 Acetaminophen 325 mg... 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 ■ 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

PEEL HERE

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Orig. 05/19

Manufactured by:
 Pharbest Pharmaceuticals, Inc.
 14 Engineers Lane, Farmingdale, NY 11735

Drug Facts (continued)

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)

adults and children 12 years and over	<ul style="list-style-type: none"> ■ 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 take for more than 10 days unless directed by a doctor
children 6 years to under 12 years	<ul style="list-style-type: none"> ■ 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 between 20-25°C (68-77°F)

Inactive ingredients povidone, pregelatinized corn starch, sodium starch glycolate, stearic acid

Questions or comments? (866) 562-2756 (Mon - Fri 8 AM to 4 PM EST)

*This product is not manufactured or distributed by McNeil Consumer Healthcare Division of McNEIL-PPC, Inc., owner of the registered trademark Tylenol®.

STOP PEELING

ACETAMINOPHEN		
acetaminophen 325mg tablet		
Product Information		
Product Type	HUMAN OTC DRUG	Item Code (Source) NDC:72615-0001
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	Score	no score
Shape	ROUND	Size	10 mm
Flavor		Imprint Code	PH020
Contains			

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