PHARBETOL REGULAR STRENGTH- acetaminophen tablet Pharbest Pharmaceuticals, Inc.

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 4,000 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 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 the 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	 take 2 tablets, every 4 to 6 hours while symptoms last do not take more than 10 tablets in 24 hours, unless directe by a doctor do not use for more than 10 days unless directed by a doctor
children 6 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

• Tamper Evident: do not use if imprinted safety seal under cap is broken or

missing

store between 20-25°C (68-77°F)

Inactive ingredients

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

Questions?

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

PHARBEST

NDC 16103-353-11

Manufactured in the USA

Regular Strength

*COMPARE TO the active ingredients in TYLENOL® REGULAR STRENGTH TABLETS

Contains no Aspirin

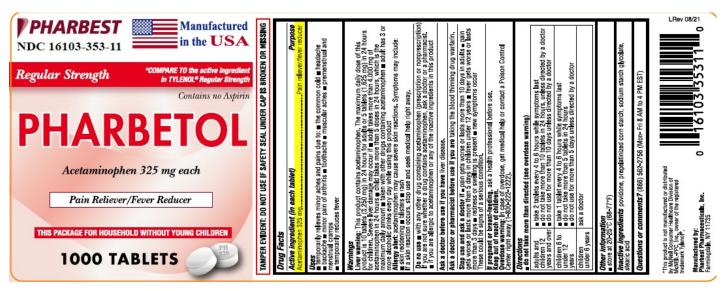
PHARBETOL®

Acetaminophen 325mg each

Pain Reliever • Fever Reducer

THIS PACKAGE FOR HOUSEHOLD WITHOUT YOUNG CHILDREN

1000 TABETS



PHARBETOL REGULAR STRENGTH acetaminophen tablet Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:16103-353

Route of Administration

ORAL

Active Ingredient/Active Moiety

	Ingredient Name	Basis of Strength	Strength
l	ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII: 36209ITL9D)	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	10mm	
Flavor		Imprint Code	PH020	
Contains				

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:16103- 353-07	1 in 1 CARTON	01/09/2007	
1		60 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:16103- 353-08	1 in 1 CARTON	01/09/2007	
2		100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
3	NDC:16103- 353-11	1000 in 1 BOTTLE; Type 0: Not a Combination Product	01/09/2007	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	01/09/2007	

Labeler - Pharbest Pharmaceuticals, Inc. (557054835)

Registrant - Pharbest Pharmaceuticals, Inc. (557054835)

Establishment			
Name	Address	ID/FEI	Business Operations
Pharbest Pharmaceuticals, Inc.		557054835	analysis(16103-353), manufacture(16103-353), pack(16103-353), label(16103-353)

Revised: 12/2024 Pharbest Pharmaceuticals, Inc.