PHARBETOL REGULAR STRENGTH- acetaminophen tablet Pharbest Pharmaceuticals, Inc.

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 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

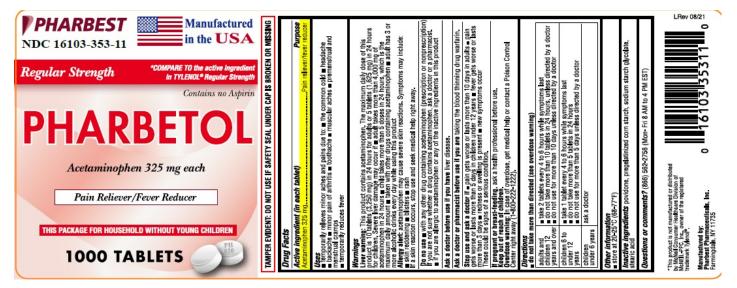
PHARBETOL[®]

Acetaminophen 325mg each

Pain Reliever • Fever Reducer

THIS PACKAGE FOR HOUSEHOLD WITHOUT YOUNG CHILDREN

1000 TABETS



PHARBETOL REGULAR STRENGTH

acetaminophen tablet

-										
Ρ	roduct Info	rmation								
Product Type			HUMAN OTC	HUMAN OTC DRUG		ode (So	urce)	NDC:161	03-353	
Route of Administration			ORAL	ORAL						
A	ctive Ingred		-							
			ngredient Nam				Basis of S	-	Strength 325 mg	
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII: 36209ITL9D) ACETAMINOPHEN										
In	active Ingr	edients								
			Ingredi	ent Name				9	Strength	
	VIDONE (UNII:		· · · · · · · · · · · · · · · · · · ·							
	ARCH, CORN (U		-							
				UNII: AG9B65	976B)					
ST	EARIC ACID (UI	NII: 4ELV7Z6	55AP)							
Pı	roduct Char	acteristi	ics							
Color wh			white	te Score			no score			
Shape RO			ROUND	JND Size			10mm			
Flavor				Imprint Code				PH020		
Co	ontains									
Pa	ackaging									
#	ltem Code		Package Description Ma			Mark	eting Start Date	art Marketing End Date		
1	NDC:16103- 353-07	1 in 1 CART	ΓΟΝ			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					007			
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 01/09/2007 Product								
	larketing	Inform	nation							
M		Арр	lication Numbe	graph		eting Start		eting End		
M	Marketing Category		Citati				Date		Date	
	Category C monograph n		Citati			01/09/20			Date	

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: 6/2023

Pharbest Pharmaceuticals, Inc.