

**PHARBETOL REGULAR STRENGTH- acetaminophen tablet**  
**Pharbest Pharmaceuticals, Inc.**

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**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	<ul style="list-style-type: none"><li>• take 2 tablets, every 4 to 6 hours while symptoms last</li><li>• do not take more than 10 tablets in 24 hours, unless directed by a doctor</li><li>• do not use for more than 10 days unless directed by a doctor</li></ul>
children 6 to under 12 years	<ul style="list-style-type: none"><li>• take 1 tablet every 4 to 6 hours while symptoms last</li><li>• do not take more than 5 tablets in 24 hours</li><li>• do not use for more than 5 days unless directed by a doctor</li></ul>
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 TABLETS**

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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)**  
Acetaminophen 325 mg (Pain reliever/fever reducer)

**Purpose**  
Pain reliever/fever reducer

**Uses**  
Temporarily relieves minor aches and pains due to:  
 • the common cold  
 • headache  
 • backache  
 • minor pain or 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 4 tablets (1,300 mg) in 24 hours for adults and 3 tablets (975 mg) in 24 hours for children. See label for more information.  
 Do not take 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  
 • you are taking other drugs that may cause severe skin reactions. Symptoms may include:  
 • skin redness  
 • blisters  
 • rash  
 • itching  
 • skin peeling  
 • 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 a 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 a pain gets worse or lasts more than 10 days in adults or a pain gets worse or lasts more than 5 days in children under 12 years. Fever gets worse or lasts more than 3 days in children under 12 years.  
 • fever gets worse or lasts more than 3 days in children under 12 years  
 • new symptoms occur  
 • 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 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 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 to under 12  
 • 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 3 days unless directed by a doctor

children under 6 years  
 • ask a doctor

**Other information**  
 • store at 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)

LRev 08/21  
 0 16103-35311-0

\*This product is not manufactured or distributed by McKesson Consumer Healthcare Division of McKesson Specialty Health, owner of the registered trademark "Pharbest".  
 Manufactured by:  
 Pharbetol Pharmaceuticals, Inc.  
 Farmingdale, NY 11735

## PHARBETOL REGULAR STRENGTH

acetaminophen tablet

### Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:16103-353

<b>Route of Administration</b>	ORAL
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### 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: O8232NY3S)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

### Product Characteristics

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	10mm
<b>Flavor</b>		<b>Imprint Code</b>	PH020
<b>Contains</b>			

### 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.