

**PHARBETOL- acetaminophen 500mg tablet, coated**  
**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.*

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**Drug Facts**

**Active ingredient (in each caplet)**

Acetaminophen 500mg

**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. Severe liver damage may occur if you take

- more than 8 caplets in 24 hours
- with other drugs containing acetaminophen
- 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
- 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"><li>◦ take 2 caplets, every 6 hours while symptoms last</li><li>◦ do not take more than 6 caplets in 24 hours, unless directed by a doctor</li><li>◦ do not take for more than 10 days unless directed by a doctor</li></ul>
children under 12 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**

hypromellose, povidone, pregelatinized corn starch, sodium starch glycolate, stearic acid, talc, triacetin

**Questions?**

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

**PHARBEST**

**NDC 16103-350-11**

**Manufactured in the USA**

**Extra Strength \*COMPARE TO the active ingredient in EXTRA STRENGTH TYLENOL®**

# CAPLETS

Do not use with any other product containing acetaminophen

# PHARBETOL

Acetaminophen 500 mg

Pain Reliever • Fever Reducer

1000 CAPLETS

**PHARBEST** NDC 16103-350-11 **Manufactured in the USA**

**Extra Strength** \*Compare to the active ingredient in Extra Strength Tylenol® Caplet

Do not use with any other product containing acetaminophen

**PHARBETOL**  
Acetaminophen 500mg  
Pain Reliever • Fever Reducer

**1000 CAPLETS**

**This Package for Households Without Young Children**

**Drug Facts**  
**Active ingredient (in each caplet)** Acetaminophen 500mg.....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, and temporarily reduces fever.

**Warnings**  
**Liver warning:** This product contains acetaminophen. Severe liver damage may occur if you take more than 8 caplets in 24 hours, which is the maximum daily amount, with other acetaminophen containing acetaminophen, 9 or more alcoholic drinks every day, while using this product.  
**Allergy alert:** acetaminophen may cause severe skin reactions. Symptoms may include: skin redness, 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, fever gets worse or lasts more than 3 days, or symptoms occur in a condition where swelling is present. These may include: sore throat, sinusitis, and tonsillitis.

**If seasick or travel-sick, 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 take 2 caplets, every 4 to 6 hours while symptoms last. Do not take more than 6 caplets in 24 hours, unless directed by a doctor.  
do not use for more than 10 days unless directed by a doctor.  
children under 12 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** hypromellose, povidone, pregelatinized corn starch, sodium starch glycolate, stearic acid, talc, triacetin

**Questions? Adverse drug event call:** 1-866-562-2756 Mon - Fri, 8AM to 4 PM.  
\*This product is not manufactured or distributed by McNeil Consumer Healthcare Division of McNeil-PPC, Inc., owner of the registered trademark "Tylenol".

**Manufactured By:** Pharbesterol Pharmaceutical, Inc. 14 Engineers Lane, Farmingdale NY 11735

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## PHARBETOL

acetaminophen 500mg tablet, coated

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:16103-350
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg

### Inactive Ingredients

Ingredient Name	Strength
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TRIACETIN (UNII: XHX3C3X673)	

### Product Characteristics

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	CAPSULE (Capsule Shaped Tablet (Caplet))	<b>Size</b>	18mm
<b>Flavor</b>		<b>Imprint Code</b>	PH016
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:16103-350-04	1 in 1 CARTON	03/01/2018	
1		30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:16103-350-08	1 in 1 CARTON	03/01/2018	
2		100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
3	NDC:16103-350-10	500 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/01/2018	
4	NDC:16103-350-11	1000 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/01/2018	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	03/01/2018	

**Labeler** - Pharbest Pharmaceuticals, Inc. (557054835)

**Registrant** - Pharbest Pharmaceuticals, Inc. (557054835)

### Establishment

Name	Address	ID/FEI	Business Operations
Pharbest Pharmaceuticals, Inc.		557054835	manufacture(16103-350) , label(16103-350) , pack(16103-350)

Revised: 3/2018

Pharbest Pharmaceuticals, Inc.