

PHARBETOL- acetaminophen 500mg tablet, coated
Ulai Health 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 caplet)

Acetaminophen 500 mg

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 4,000 mg of acetaminophen 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 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

- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- 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)**

adults and children 12 years and over	<ul style="list-style-type: none">• take 2 caplets every 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

- store at 20-25 °C (68-77 °F)

Inactive ingredients

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

Questions or comments?

(866) 562-2756 (Mon - Fri 8 AM to 4 PM EST)

PHARBEST

NDC 73057-350-11

Manufactured in the USA

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

Contains no Aspirin

PHARBETOL

Acetaminophen 500 mg each

Pain Reliever/Fever Reducer

1000 CAPLETS

PHARBEST
NDC 73057-350-11

Extra Strength
Contains no Aspirin

PHARBETOL
Acetaminophen 500 mg each
Pain Reliever/Fever Reducer

1000 CAPLETS

PH016

Manufactured in the USA

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

Org. 06/19

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Discontinued by
U.I. HEALTH LLC
Alexandria, VA 22312

THIS PACKAGE FOR HOUSEHOLD WITHOUT YOUNG CHILDREN

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

Drug Facts

Active ingredient (in each caplet)
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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 4,000 mg of acetaminophen 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 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 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 ■ pain gets worse or lasts more than 10 days ■ fever gets worse or lasts more than 3 days ■ redness or swelling is present ■ 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
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adults and children 12 years and over ■ take 2 caplets every 6 hours while symptoms last ■ do not take more than 6 caplets in 24 hours unless directed by a doctor
children under 12 years ■ do not use for more than 10 days unless directed by a doctor ■ ask a doctor

Other information
■ store at 20-25°C (68-77°F)

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

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

PHARBETOL

acetaminophen 500mg tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73057-350
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

Color	white	Score	no score
Shape	CAPSULE (Capsule shaped tablet)	Size	18mm
Flavor		Imprint Code	PH016
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73057-350-11	1000 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/08/2019	
2	NDC:73057-350-08	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/08/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	07/08/2019	

Labeler - Ulai Health LLC (081181535)