PHARBETOL- acetaminophen 500mg tablet, coated
A-S Medication Solutions

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 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	○ 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 take 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 20º-25ºC (68º-77ºF)

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

HOW SUPPLIED

Product: 50090-1191

NDC: 50090-1191-0 40 TABLET, COATED in a BOTTLE

Acetaminophen 500mg

PHARBETOL
acetaminophen 500mg tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50090-1191(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

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50090-1191-0	40 in 1 BOTTLE; 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 - A-S Medication Solutions (830016429)

Establishment

Name	Address	ID/FEI	Business Operations
A-S Medication Solutions		830016429	RELABEL(50090-1191) , REPACK(50090-1191)

Revised: 6/2019

A-S Medication Solutions