

## **PHARBETOL REGULAR STRENGTH- acetaminophen tablet**

### **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.*

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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 11 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 starch, sodium starch glycolate, stearic acid

## Questions?

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

## HOW SUPPLIED

Product: 50090-2156

NDC: 50090-2156-1 6 TABLET in a BOTTLE

## Acetaminophen



## PHARBETOL REGULAR STRENGTH

acetaminophen tablet

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:50090-2156(NDC:16103-353)
<b>Route of Administration</b>	ORAL		

### 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, UNSPECIFIED (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3S)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

### Product Characteristics

Color	white	Score	no score
Shape	ROUND	Size	10mm
Flavor		Imprint Code	PH020
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50090-2156-1	6 in 1 BOTTLE; Type 0: Not a Combination Product	10/21/2015	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	01/09/2007	

**Labeler** - A-S Medication Solutions (830016429)

### Establishment

Name	Address	ID/FEI	Business Operations
A-S Medication Solutions		830016429	RELABEL(50090-2156) , REPACK(50090-2156)

Revised: 2/2021

A-S Medication Solutions