

PHARBETOL REGULAR STRENGTH- acetaminophen tablet

Coupler Enterprises

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.

Acetaminophen 325 mg - Pharbest

Drug Facts

Active ingredient (per 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
 - menstrual cramps
- Temporarily reduces fever

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if

- Adult takes more than 12 tablets in 24 hours, which is the maximum daily amount
- Child takes more than 5 doses in 24 hours
- Taken with other drugs containing acetaminophen
- Adult has 3 or more alcoholic drinks every day while using this product

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 and children
- 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 sign of a serious condition.

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of the reach of children.

Overdose warning:

Taking more than the recommended dose (overdose) may cause liver damage. In the case of accidental overdose, get medical help or contact a Poison Control Center right away.

Directions

- do not take more than directed (see overdose warning).

Adults and children 12 years and over	Take 2 tablets every 4 to 6 while symptoms last. Do not take more than 12 tablets in 24 hours.
Children 6 to under 12 years	Take 1 tablet every 4 to 6 while symptoms last. Do not take more than 5 tablets in 24 hours.
Children under 6 years	Do not use adult regular strength products in children under 6 years of age; this will provide more than the recommended dose (overdose) and may cause liver damage.

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)
- use by expiration date on package

Inactive ingredients:

Povidone, pregelatinized starch, sodium starch glycolate, stearic acid.

Questions?

Adverse drug event call: (866) 562-2756

PHARBETOL REGULAR STRENGTH

acetaminophen tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67046-023(NDC:16103-353)
Route of Administration	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 (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
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:67046-023-30	30 in 1 BLISTER PACK; Type 0: Not a Combination Product	01/09/2007	
2	NDC:67046-023-60	60 in 1 BLISTER PACK; Type 0: Not a Combination Product	01/09/2007	
3	NDC:67046-023-62	60 in 1 BLISTER PACK; 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 not final	part343	01/09/2007	

Labeler - Coupler Enterprises (945429777)

Establishment

Name	Address	ID/FEI	Business Operations
Coupler Enterprises		945429777	repack(67046-023)

Revised: 2/2021

Coupler Enterprises