

PHARBEST REGULAR STRENGTH ASPIRIN- aspirin tablet
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.

Drug Facts

Active ingredient (in each tablet)

Aspirin 325mg (NSAID)[†]

[†]nonsteroidal anti-inflammatory drug

Purpose

Pain reliever/fever reducer

Uses

- temporarily relieves minor aches and pains due to:
- headache
- muscle pain
- toothache
- menstrual pain
- colds
- minor pains of arthritis
- temporarily reduces fever

Warnings

Reye's syndrome: Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.

Allergy alert: Aspirin may cause a severe allergic reaction which may include

- hives
- facial swelling
- asthma (wheezing)
- shock

Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug

- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed

Do not use

- if you are allergic to aspirin or any other pain reliever/fever reducer
- if you have ever had an allergic reaction to this product or any of its ingredients

Ask a doctor before use if

- stomach bleeding warning applies to you
- you have a history of stomach problems such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, or kidney disease
- you are taking a diuretic
- you have asthma

Ask a doctor or pharmacist before use if you are

taking a prescription drug for

- gout
- diabetes
- arthritis

Stop use and ask a doctor if

- an allergic reaction occurs. Seek medical help right away.
- you experience any of the following signs of stomach bleeding •feel faint •vomit blood •have bloody or black stools •have stomach pain that does not get better
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- ringing in the ears or loss of hearing occurs
- new symptoms occur

If pregnant or breast-feeding

ask a health professional before use. **It is especially important not to use aspirin during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.**

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

Directions

- drink a full glass of water with each dose

adults and children 12 take 1 or 2 tablets every 4 hours or 3 tablets every 6 hours,

years and over not to exceed 12 tablets in 24 hours
 children under 12 years ask a doctor

Other information

- store at 20-25°C (68-77°F)
- avoid excess heat and moisture

Inactive ingredient

corn starch

Questions or comments?

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

PHARBEST

NDC 16103-365-11

Manufactured in the USA

***Compare to the active ingredient in Genuine Bayer® Aspirin**

Aspirin

Regular Strength

Pain Reliever/Fever Reducer (NSAID)

1000 TABLETS

Aspirin, 325 mg each

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 Aspirin, 325 mg each

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 tablet) Aspirin 325 mg (NSAID).....Pain reliever/fever reducer
Uses temporarily relieves minor aches and pains due to: ■ headache ■ muscle pain ■ toothache ■ menstrual pain ■ colds ■ minor pain of arthritis ■ temporarily reduces fever
Warnings **Reye's syndrome:** Children and teenagers who have or are recovering from viral infections should not take this product. If changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.
Allergy alert: Aspirin may cause a severe allergic reaction which may include: ■ hives ■ facial swelling ■ asthma (wheezing) ■ shock
Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you ■ are age 60 or older ■ have had stomach ulcers or bleeding problems ■ take a blood thinning (anticoagulant) drug ■ take aspirin or other NSAIDs (aspirin, ibuprofen, or celecoxib) ■ take aspirin or other NSAIDs every day while using this product ■ take more or for a longer time than directed
Do not use ■ if you are allergic to aspirin or any other pain reliever/fever reducer ■ if you have ever had an allergic reaction to this product or any of its ingredients
Ask a doctor before use if ■ stomach bleeding warning applies to you ■ you have a history of stomach problems, such as heartburn ■ you have high blood pressure, heart disease, liver cirrhosis, or kidney disease ■ you are taking a diuretic ■ you have asthma
Ask a doctor or pharmacist before use if you are taking a prescription drug for ■ gout ■ diabetes ■ arthritis
Stop use and ask a doctor if ■ an allergic reaction occurs. Seek medical help right away. ■ you experience any of the following signs of stomach bleeding: ■ feel faint ■ vomit blood ■ have bloody or black stools ■ have stomach pain that does not get better ■ pain gets worse or lasts more than 10 days ■ fever gets worse or lasts more than 3 days ■ redness or swelling is present ■ ringing in the ears or a loss of hearing occurs ■ new symptoms occur
If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use aspirin during the last 3 months of pregnancy. Aspirin use during the last 3 months of pregnancy or while breastfeeding may cause bleeding in your baby or other problems. **Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

Directions ■ drink a full glass of water with each dose
 ■ adults and children 12 years and over take 1 or 2 tablets every 4 hours or 3 tablets every 6 hours, not to exceed 12 tablets in 24 hours
 ■ children under 12 years ask a doctor

Other information ■ store at 20-25°C (68-77°F) ■ avoid excess heat and moisture

Inactive ingredient corn starch

Questions or comments? (866) 562-2756 (Mon-Fri 8 AM to 4 PM EST)

*This product is not manufactured or distributed by Bayer. It is a generic equivalent to Bayer's Aspirin.
 Manufactured by:
 Pharbest Pharmaceuticals Inc.,
 Farmingdale, NY 11735

PHARBEST REGULAR STRENGTH ASPIRIN

aspirin tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:16103-365
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Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	325 mg

Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	white	Score	no score
Shape	ROUND (ROUND TABLET)	Size	10mm
Flavor		Imprint Code	PH033
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:16103-365-08	1 in 1 CARTON	01/12/2007	
1		100 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:16103-365-11	1000 in 1 BOTTLE; Type 0: Not a Combination Product	01/12/2007	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part343	01/12/2007	

Labeler - Pharbest Pharmaceuticals, Inc (557054835)

Registrant - Pharbest Pharmaceuticals, Inc (557054835)

Establishment

Name	Address	ID/FEI	Business Operations
Pharbest Pharmaceuticals, Inc		557054835	analysis(16103-365) , manufacture(16103-365) , label(16103-365) , pack(16103-365)