

ASPIRIN- aspirin tablet
Aphena Pharma Solutions - Tennessee, 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.

ENTERIC COATED ASPIRIN 325mg

Active Ingredient

(in each tablet)

Aspirin 325 mg (NSAID) *

*nonsteroidal anti-inflammatory drug

Purpose

Pain reliever/ Fever Reducer

Uses

temporarily relieves

- headache
- menstrual pain
- muscle pain
- toothache
- minor pain or arthritis
- pain and fever of colds

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 signs of Reye's syndrome, a rare but serious illness.

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

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

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

Do not use

- if you have ever had an allergic reaction to any other pain reliever / fever reducer

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 diabetes, gout or arthritis
- taking any other drug
- under a doctor's care for any serious condition

Stop use and ask a doctor if

- 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 in the painful area
 - any new symptoms appear
 - ringing in the ears or a loss of hearing occurs

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.

Directions

DRINK A FULL GLASS OF WATER WITH EACH DOSE

- **adults and children 12 years and over** : 1-2 tablets every 4 hours while symptoms last, but not more than 12 tablets in 24 hours.
- **Children under 12 years** : ask a doctor

Other Information

- avoid excessive heat or humidity
- store at 15-30 °C (59-86 °F)

Inactive Ingredients

croscarmellose sodium, D&C Yellow #10 (Al-Lake), FD&C yellow #6 (Al-Lake), HPMC, methacrylic acid copolymer, polyethylene glycol, propylene glycol, PVP, sodium lauryl sulfate, starch, stearic acid, talc, titanium dioxide

Questions or Comments

Call 631-981-4600, 8.30am – 4.30 pm ET Monday-Friday

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS

BROKEN OR MISSING

Manufactured by: Advance Pharmaceutical, Inc. Holtsville, NY 11742

Repackaging Information

Please reference the **How Supplied** section listed above for a description of individual tablets. This drug product has been received by Aphenia Pharma - TN in a manufacturer or distributor packaged configuration and repackaged in full compliance with all applicable cGMP regulations. The package configurations available from Aphenia are listed below:

Count	325mg
100	71610-034-65

Store between 20°-25°C (68°-77°F). See USP Controlled Room Temperature. Dispense in a tight light-resistant container as defined by USP. Keep this and all drugs out of the reach of children.

Repackaged by:



Cookeville, TN 38506

20180218JH

PRINCIPAL DISPLAY PANEL - 325mg

NDC 71610-034 - Aspirin EC (NSAID) 325mg - Rx Only



ASPIRIN

aspirin tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:716 10-0 34(NDC:54738-111)
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
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
METHACRYLIC ACID (UNII: 1CS02G8656)	
POLYETHYLENE GLYCOL 1000 (UNII: U076Q6Q621)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POVIDONE (UNII: FZ989GH94E)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	

Product Characteristics

Color	orange	Score	no score
Shape	ROUND	Size	10mm
Flavor		Imprint Code	AP;011
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71610-034-65	100 in 1 BOTTLE; Type 0: Not a Combination Product	01/26/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part343	05/01/2015	

Labeler - Aphenia Pharma Solutions - Tennessee, LLC (128385585)

Establishment

Name	Address	ID/FEI	Business Operations
Aphenia Pharma Solutions - Tennessee, LLC		128385585	REPACK(71610-034)

