# ASPIRIN- as pirin tablet Advance Pharmaceutical 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.

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## **ASPIRIN 325mg**

## **Active Ingredient**

(in each tablet)

Aspirin 325 mg (NSAID) \*

\*nonsteroidal anti-inflammatory drug

## Purpose

Pain Reliever

#### Uses

temporarily relieves

- headache
- menstrual pain
- minor pain or arthritis
- muscle pain
- toothache
- pain and fever and cold

## 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
- take other drugs containing prescription or nonprescription NSAIDs (ibuprofen, naproxen, or 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, lever 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 experiences 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 older :** 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**

corn starch, PVP

## **Questions or Comments**

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

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

For temporary relief of minor aches and pains

## PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



325 mg (5gr)
PAIN RELIEVER/FEVER REDUC

\*Compare to active ingredient in Bayer® Aspirin Regimen 325 mg Aspirin Regimen 325 mg ASPIRIN TABLE

**Drug Facts** 

Active ingredient (in each tablet)

Purpose

Aspirin 325 mg (NSAID)\*......Pain reliever/Fever reducer \*nonsteroidal anti-inflammatory drug

- Uses temporarily relieves headache
- menstrual pain
- minor pain of arthritis
- muscle pain toothache
- 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 sign of Reye's syndrome, a rare but serious illness.

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- take more or for a longer time than directed
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Drug Facts continued on back of label

## TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

\*Advance Pharmaceutical Inc. is not affiliated with the owner of the trademark BAYER® Aspirin Regimen 325 mg.

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



LA0413



## Drug Facts (continued)

Do not use if you have ever had an allergic reaction to any other pain reliever/fever reducer

#### Ask a doctor before use if

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## Stop use and ask a doctor if

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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.

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PAIN RELIEVER/FEVER REDUCE 325 mg (5gr) Aspirin Regimen 325 mg \*Compare to active

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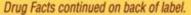
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Manufactured by: Advance Pharmaceutical Inc., Holtsville, NY 11742, USA





## Drug Facts (continued)

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NDC: 17714-010-01 - 100 Tablets

NDC: 17714-010-03 - 300 Tablets

## **ASPIRIN**

aspirin tablet

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:17714-010	
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)			
PO VIDO NE (UNII: FZ989 GH94E)			

Product Characteristics				
Color	white	Score	no score	
Shape	ROUND	Size	10 mm	
Flavor		Imprint Code	AP;010	
Contains				

P	Packaging					
#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>		
1	NDC:17714-010-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	12/0 1/20 15			
2	NDC:17714-010-03	300 in 1 BOTTLE; Type 0: Not a Combination Product	12/0 1/20 15			
3	NDC:17714-010-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	01/09/2002			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part343	01/09/2002		

## Labeler - Advance Pharmaceutical Inc. (078301063)

## Registrant - Advance Pharmaceutical Inc. (078301063)

Establishment					
Name	Address	ID/FEI	Business Operations		
Advance Pharmaceutical Inc.		078301063	manufacture(17714-010)		

Revised: 10/2017 Advance Pharmaceutical Inc.