

ASPIRIN 325 MG EC- aspirin tablet
Denton Pharma, Inc. dba Northwind Pharmaceuticals

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.

ASPIRIN 325 MG EC TABLET

Drug Facts

Aspirin USP, 325 mg (NSAID)*

*nonsteroidal anti-inflammatory drug

Pain Reliever/Fever Reducer

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.

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 (ibuprofen, naproxen, or others)
- take more or for a longer time than directed
- have 3 or more alcoholic drinks every day while using this product

Drug Facts continued on back of label

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
- under a doctor's care for any serious condition
- taking any other drug

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 loss of hearing occurs

These could be signs of a serious condition

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, not more than 12 tablets in 24 hours
- **children under 12 years:** ask a doctor

Other information

- store at room temperature 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, povidone, sodium lauryl sulfate, starch, stearic acid, talc, titanium dioxide

Questions or comments?

Questions or comments ? call 516-341-0666, 8:30 am - 4:30 pm ET, Monday - Friday

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



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Distributed by: **Reliable 1 Laboratories LLC, Valley Stream, NY 11580**

www.reliable1labs.com

Principal Display Panel

NDC: 70934-561-90

 <p>NDC: 70934-561-90 Aspirin Tablets Enteric Coated USP 325 mg (NSAID) 90 Tablets</p> <p>Dosage: See package insert Store at 15° - 30°C (59° - 86°F) (See USP Controlled Room Temperature) Keep out of the reach of children. Store in original container. Reye's syndrome: Children/teenagers who have / are recovering from chicken pox or flu-like symptoms should not use this product. If changes in behavior with nausea / vomiting occur, consult doctor (symptoms may be early sign of Reye's syndrome, serious illness). Allergy alert: Aspirin may cause severe allergic reaction such as: hives, asthma (wheezing), facial swelling, shock. Product may cause severe stomach bleeding. Active ingredient (in each tablet) Aspirin USP 325mg Pain Reliever/Fever Reducer Repackaged From: 69618-015-10 Reliable 1 Laboratories LLC, Lot 0000000000 Repackaged By: Northwind Pharmaceuticals North Blenheim, NY 12131 GTIN: 00370934561909 SIN: 0000000000000000 EXP: 00/00/0000 LOT: 0000000000</p>	<p>LCN#: 00 Rev. A 05/20</p> 	<p>Aspirin Tablets USP 325 mg 90 Tablets NDC: 70934-561-90 MFG: 69618-015-10 Lot #: 0000000000 Exp.Date: 0000000000</p>	
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ASPIRIN 325 MG EC			
aspirin tablet			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70934-561(NDC:69618-015)
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
POVIDONE (UNII: FZ989GH94E)			
METHACRYLIC ACID (UNII: 1CS02G8656)			
STEARIC ACID (UNII: 4ELV7Z65AP)			
STARCH, CORN (UNII: O8232NY3SJ)			
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)			
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)			
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)			
HYPROMELLOSES (UNII: 3NXW29V3WO)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)			
TALC (UNII: 7SEV7J4R1U)			

SODIUM LAURYL SULFATE (UNII: 368GB5141J)

POLYETHYLENE GLYCOL 1000 (UNII: U076Q6Q621)

Product Characteristics

Color	orange	Score	no score
Shape	ROUND	Size	10mm
Flavor		Imprint Code	AP;110
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70934-561-90	90 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/05/2020	



ASPIRIN
325mg EC Tablet

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part343	05/05/2020	

Labeler - Denton Pharma, Inc. dba Northwind Pharmaceuticals (080355546)

Registrant - Denton Pharma, Inc. dba Northwind Pharmaceuticals (080355546)

Establishment

Name	Address	ID/FEI	Business Operations
Denton Pharma, Inc. dba Northwind Pharmaceuticals		080355546	repack(70934-561)

Revised: 5/2020

Denton Pharma, Inc. dba Northwind Pharmaceuticals