FASPRIN - aspirin tablet, orally disintegrating Nobel Laboratories, 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.

Drug Facts

Active Ingredient (In Each Tablet)

Aspirin 81 mg

Purpose

Pain Reliever/Fever Reducer

Uses

For temporary relief of minor aches and pains

Warnings:

Reye's syndrome: Children and teenagers should not use this medicine for chicken pox or flu symptoms before a doctor is consulted about Reye's syndrome, a rare but serious illness reported to be associated with aspirin.

Alcohol Warning: If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take aspirin or other pain relievers/fever reducers. Aspirin may cause stomach bleeding.

- If you are allergic to aspirin
- With any other pain reliever/fever reducer
- If you have ever had an allergic reaction to any other pain reliever/fever reducer
- For pain for more than 10 days or for fever for more than 3 days unless directed by a doctor
- With any other product containing aspirin

Ask doctor before using if you have:

- Asthma
- Bleeding problems
- Stomach problems (such as heartburn, upset stomach or stomach pain) gastric ulcers

Ask a doctor or pharmacist before use if you are taking a prescription drug for:

- Anticoagulation (thinning of blood)
- Diabetes
- Gout
- Arthritis

Stop use and ask a doctor if:

- Ringing in the ears or loss of hearing occurs
- Pain or fever persists or gets worse
- New symptoms occur
- Redness or swelling is present

If pregnant or breast-feeding baby,

ask a health professional before use. IT IS ESPECIALLY IMPORTANT NOT TO USE ASPIRIN DURING THE LAST 3 MONTHS OF PREGNANCY UNLESS SPECIFICALLY 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. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

Directions: Remove tablet from backing by bending at perforation and peeling back cover. Place tablet on tongue and allow saliva to dissolve the tablet for rapid absorption. **Adults:** Take 1 tablet daily, do not exceed 36 tablets in 24 hours, or as directed by a doctor. **Children:** Consult a doctor.

Inactive Ingredients:

Citric Acid, Crospovidone, D and C Yellow #10, Flavor, Glucosamine Sulfate-K, Mannitol, Sodium Stearyl Fumarate, Sorbitol, Sunnette K, Zinc Gluconate

Manufactured for: Nobel Laboratories, LLC 3413 Spanish Oak Drive Austin, TX 787314

www.NobelLabs.com

Store Product Below 90 degrees F. Protect from heat, light and moisture. U.S Patents 6,596,708 / 6,930,099 and Patents Pending

Package Label Section



FASPRIN

aspirin tablet, orally disintegrating									
Product Information									
Product Type	HUMAN OTC DRUG	Item Code (Source)		NDC:10	NDC:10597-559				
Route of Administration	ORAL								
Active Ingredient/Active Moi	ety								
Ingredient Name			Basis of Strength		Strength				
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E) ASPIRIN					81 mg				
Inactive Ingredients									
	Ingredient Name				Strength				
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)									
CROSPOVIDONE (UNII: 68401960MK)									
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)									
GLUCOSAMINE (UNII: N08U5BOQ1K)									
MANNITOL (UNII: 30WL53L36A)									

	I OWN II	RATE (UNII: 7CV7WJK4UI)					
SORBITOL (UNII: 5	06T60A	.25R)					
ZINC GLUCONATE	(UNII: U	J6WSN5SQ1Z)					
Product Charac	terist	ics					
Color	у	rellow (yellow)	Score	Score		no score	
Shape	F	ROUND (Round)	Size	Size		9 mm	
Flavor			Imprint	Imprint Code		F	
Contains							
Packaging							
			Marketing Start Date				
# Item Cod	e	Package Description	Marketin	ig Start Date	Ma	rketing End Date	
		Package Description30 in 1 BOX	Marketin	ıg Start Date	Ma	rketing End Date	
1 NDC:10597-559-0	5		Marketin	ig Start Date	Ma	rketing End Date	
1 NDC:10597-559-0	5	30 in 1 BOX	Marketin	ng Start Date	Ma	rketing End Date	
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Labeler - Nobel Laboratories, LLC (022735189)

Establishment						
Name	Address	ID/FEI	Business Operations			
Avema Pharma Solutions		804087794	manufacture			

Revised: 11/2010

Nobel Laboratories, LLC