

ENTERIC COATED ASPIRIN - regular strength tablet

State of Florida DOH Central Pharmacy

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 Regular Strength

ACTIVE INGREDIENTS (IN EACH TABLET)

Aspirin 325mg (NSAID*)

*nonsteroidal anti-inflammatory drug

PURPOSE

Pain reliever

USES

for the temporary relief of minor aches and pains or as recommended by your doctor. **Because of its delayed action, this product will not provide fast relief of headaches or other symptoms needing immediate relief.**

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 other pain relievers/fever reducers

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 have asthma
- you are taking a diuretic

Ask a doctor or pharmacist before use if you are

taking a prescription drug for:

- anticoagulation (thinning the blood)
- diabetes
- gout
- 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
- new symptoms occur
- redness or swelling is present
- ringing in the ears or loss of hearing occurs
- pain gets worse or lasts for more than 10 days

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 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.

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 not to exceed 12 tablets in 24 hours unless directed by a doctor
- children under 12 years: consult a doctor

OTHER INFORMATION

- store at room temperature
- do not use if imprinted safety seal under cap is broken or missing

You may report serious side effects to: 1-888-952-0050

INACTIVE INGREDIENTS

corn starch, croscarmellose sodium, Dimethicone, D&C Yellow # 10 aluminum lake, FD&C Yellow #6 aluminum lake, hypromellose, methacrylic acid copolymer, microcrystalline cellulose, mineral oil, polysorbate 80, sodium hydroxide, sodium lauryl sulfate, talc, titanium dioxide, triethyl citrate.

SUPPLIER STATEMENT

This Product was Manufactured By:

Qualitest Pharmaceuticals, Inc

Huntsville, AL

USA

And Repackaged By:

State of Florida DOH Central Pharmacy

104-2 Hamilton Park Drive

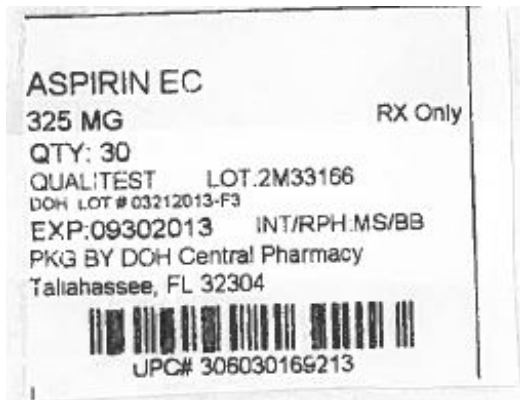
Tallahassee, FL 32304

USA

PACKAGE LABEL

Label Image for **53808-1034**

325mg



ENTERIC COATED ASPIRIN

regular strength tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53808-1034(NDC:0603-0169)
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)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TALC (UNII: 7SEV7J4R1U)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A (UNII: NX76LV5T8J)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
MINERAL OIL (UNII: T5L8T28FGP)	

Product Characteristics

Color	ORANGE	Score	no score
Shape	ROUND	Size	11mm
Flavor		Imprint Code	T
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53808-1034-1	30 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part343	01/01/2014	

Labeler - State of Florida DOH Central Pharmacy (829348114)

Establishment

Name	Address	ID/FEI	Business Operations
State of Florida DOH Central Pharmacy		829348114	repack(53808-1034)

Revised: 9/2014

State of Florida DOH Central Pharmacy