

ASPIRIN - aspirin 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.

Regular Strength Enteric Anti-inflammatory/Analgesic Aspirin

ACTIVE INGREDIENT (IN EACH TABLET)

Aspirin 325 mg (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 to 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

Acetylated monoglycerides, corn starch, croscarmellose sodium, D&C Yellow 10, FD&C Yellow #6, hypromellose, hypromellose phthalate, microcrystalline cellulose, mineral oil, polyethylene glycol 400, polysorbate 80, titanium dioxide

How Supplied

Aspirin is supplied by **State of Florida DOH Central Pharmacy** as follows:

NDC	Strength	Quantity/Form	Color	Source Prod. Code
53808-1028-1	325 MG	30 Tablets in a Blister Pack	ORANGE	0603-0168

This Product was Repackaged By:

State of Florida DOH Central Pharmacy

104-2 Hamilton Park Drive

Tallahassee, FL 32304

USA

PACKAGE LABEL

Label Image for **53808-1028**

325mg



ASPIRIN

aspirin tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53808-1028(NDC:0603-0168)
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
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
HYDROXYPROPYL CELLULOSE (TYPE H) (UNII: RFW2ET671P)	
STARCH, CORN (UNII: O8232NY3SJ)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
HYPROMELLOSE PHTHALATE (31% PHTHALATE, 40 CST) (UNII: G4U024CQK6)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
MINERAL OIL (UNII: T5L8T28FGP)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	

Product Characteristics

Color	ORANGE	Score	no score
Shape	ROUND	Size	8mm
Flavor		Imprint Code	A
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53808-1028-1	30 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part343	11/01/2014	

Labeler - State of Florida DOH Central Pharmacy (829348114)

Establishment

Name	Address	ID/FEI	Business Operations
State of Florida DOH Central Pharmacy		829348114	repack(53808-1028)

Revised: 1/2015

State of Florida DOH Central Pharmacy