

EXTRA STRENGTH ASPIRIN- extra strength aspirin tablet
Health Pharma USA 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.

Extra Strength Aspirin

Drug facts

Purpose

Pain reliever/ Fever reducer

Active ingredient (in each tablet)

Aspirin 325mg

Uses

Temporarily relieves minor aches and pains due to:

- headache
- muscular aches
- backache
- minor pain of arthritis
- the common cold
- toothache
- premenstrual and menstrual cramps

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 behaviour 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 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 any other pain reliever/fever reducer

Ask a doctor before use if

- you have asthma

- 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

Ask a doctor or pharmacist before use if you are

- taking a prescription drug for diabetes, gout, or arthritis
- taking any other drug or are under a doctor's care for any serious condition

Stop use and ask a doctor if:

1. you experience any of the following signs of stomach bleeding:
 - feel faint
 - have bloody or black stools
 - vomit blood
 - have stomach pain that does not get better
2. an allergic reaction occurs.
 - seek medical help right away.
3. ringing in the ears or loss of hearing occurs
4. pain gets worse or lasts for more than 3 days
5. redness or swelling present
6. new symptoms occur

These could be sign 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 (1-800-222-1222) right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

- **Do not take more than directed**
- Drink a full glass of water with each dose
- **Adults and children 12 years of age and over:**
 1. take 1 to 2 tablets every 4 hours while symptoms last
 2. do not take more than 12 tablets in 24 hours unless directed by a doctor
 3. do not use for more than 10 days unless directed by a doctor
- **Children under 12 years:** do not use unless directed by a doctor

Other Information

- Store at controlled room temperature 25°C (77°F) excursions permitted between 15-30°C (59-86°F)

Inactive ingredients

- Corn starch
- Carnuba Wax
- Hypromellose
- Polyethylene Glycol
- Povidone
- Talc
- Titanium dioxide

Questions or comments?

Call toll free 1-844-832-1138 Monday through Friday 9AM -5PM EST www.healthpharma.us

Extra Strength Aspirin

Aspirin 325 mg

Compare to Bayer® EXTRA STRENGTH active ingredients



Health Pharma USA LLC

1600 Hart Street, Rahway, NJ 07065

Phone: 732-540-8421

FINISHED BULK LABEL _____ of _____ BOXES

PRODUCT NAME: Aspirin film coated White Tablets,325 mg

PRODUCT Code # PC050

Batch #

Labeler code -71679-050-00

NET WEIGHT (KG)

Tablets /BOX

AVG TABLET WT. (mg)

18.00 kg

49,605 Tablets

363 mg

BULK PACKAGING: 2 MIL clear Polyethylene Bag in Brown Flute Double Wall Corrugated Boxes.

BULK PRODUCT: Package immediately upon receipt.

WARNING: Keep out of Children. This bulk shipment is intended for further processing only. Repackage contents as soon as possible. This is a shipping container only and will not protect contents from damage by heat, cold and moisture indefinitely. Manufacturer will not accept responsibility for spoilage or violations of the food, Drug and cosmetic act due to prolonged storage in this container. Contents must be repackaged prior to resale and must be labeled in full compliance with the requirement of the Food, Drug and Cosmetic Act.

STORAGE: Store at a controlled room temperature 15-30°C (59-86° F)

EXTRA STRENGTH ASPIRIN

extra strength aspirin tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71679-050
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
TALC (UNII: 7SEV7J4R1U)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
POVIDONE (UNII: FZ989GH94E)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
STARCH, CORN (UNII: O8232NY3SJ)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	

Product Characteristics

Color	white	Score	no score
Shape	ROUND	Size	9mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71679-050-00	1 in 1 CARTON	08/01/2020	
1		49605 in 1 BAG; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part343	08/01/2020	

Labeler - Health Pharma USA LLC (080804485)**Establishment**

Name	Address	ID/FEI	Business Operations
Health Pharma USA LLC		080804485	manufacture(71679-050)