

ASPIRIN- aspirin tablet
HART Health

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 (NSAID)* 325mg (*non-steroidal anti-inflammatory drug)

Uses:

Temporarily relieves minor aches and pains due to:

- headache
- backache
- muscular aches
- minor arthritis pain
- common cold
- toothache
- menstrual cramps

Temporarily reduces fever

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

Allergy alert: Aspirin may cause a several 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 more or for a longer time than directed
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or non-prescription NSAIDs (aspirin, ibuprofen, naproxen, others)

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 are taking a diuretic
- you have asthma, high blood pressure, heart disease, liver cirrhosis, or kidney disease

Ask a doctor or pharmacist before use if you:

- take any other drug containing an NSAID
- take a blood thinning (anticoagulant) or steroid drug
- take any drug for diabetes, gout, or arthritis

Stop use and ask a doctor if:

- an allergic reaction occurs, seek medical help right away
- fever gets worse or lasts more than 3 days
- pain gets worse or lasts more than 10 days
- redness or swelling is present in the painful area
- new symptoms occur
- you have any of the following signs of stomach bleeding: feel faint, vomit blood, have bloody or black stools, or stomach pain that does not get better

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. 1-800-222-1222

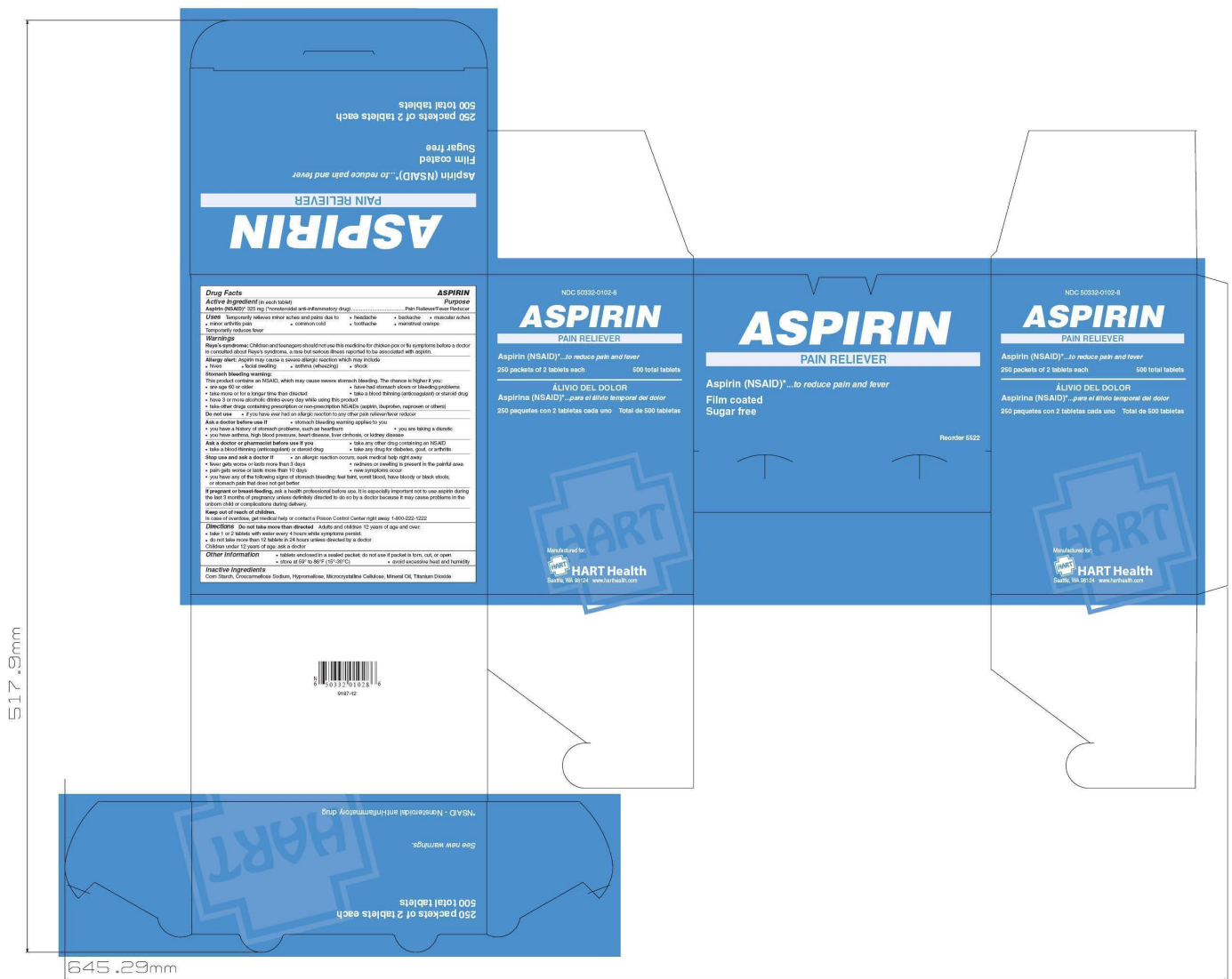
Directions: Do not take more than directed.

Adults and children 12 years of age and over:

- take 1 or 2 tablets with water every 4 hours while symptoms persist
- do not take more than 12 tablets in 24 hours unless directed by a doctor

Children under 12 years of age: ask a doctor

Inactive Ingredients: Corn Starch, Croscarmellose Sodium, Hypromellose, Microcrystalline Cellulose, Mineral Oil, Titanium Dioxide



ASPIRIN

aspirin tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50332-0102-8
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)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	

MINERAL OIL (UNII: T5L8T28FGP)

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

Product Characteristics

Color	white	Score	no score
Shape	ROUND	Size	11mm
Flavor		Imprint Code	TCL011
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50332-0102-4	50 in 1 BOX, UNIT-DOSE		
1		2 in 1 PACKET		
2	NDC:50332-0102-7	125 in 1 BOX, UNIT-DOSE		
2		2 in 1 PACKET		
3	NDC:50332-0102-8	250 in 1 BOX, UNIT-DOSE		
3		2 in 1 PACKET		
4	NDC:50332-0102-1	500 in 1 BOX, UNIT-DOSE		
4		2 in 1 PACKET		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part343	06/04/1986	

Labeler - HART Health (069560969)

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HART Health