

NORTH ASPIRIN - aspirin tablet
North Safety Products

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

Active ingredient

Aspirin 325 mg (NSAID)

"nonsteroidal anti-inflammatory drug"

Purpose

Pain reliever/fever reducer

Uses

for the temporary relief of minor aches and pains associated with:

- a cold
- headache
- toothache
- muscular aches
- backache - premenstrual and menstrual periods
- minor pain from arthritis
- and to reduce fever

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 a nonsteroidal anti-inflammatory drug (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 prescriptions 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:

stomach bleeding warning applies to you

- you have a history of stomach problems such as heartburn
- high blood pressure
- heart disease
- liver cirrhosis
- kidney disease or are taking a diuretic
- ulcers
- bleeding problems
- reached age 60 or older
- taking any other drug containing an NSAID (prescription or nonprescription)
- taking a blood thinning (anticoagulant) or steroid drug

Stop use and ask a doctor if:

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

If pregnant or breast feeding

ask a health professional before use. **It is especially important not to use aspirin during the last three 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 the reach of children

In case of overdose, get medical help or contact 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 with water every 4 hours while symptoms persist.
- not more than 12 tablets in 24 hours
- children under 12 years: consult a doctor

Other information

- store at room temperature 15° - 30° C (59° - 86° F)
- tamper evident packets
- do not use if open or torn

Inactive ingredients

corn starch, povidone, silicon dioxide, stearic acid

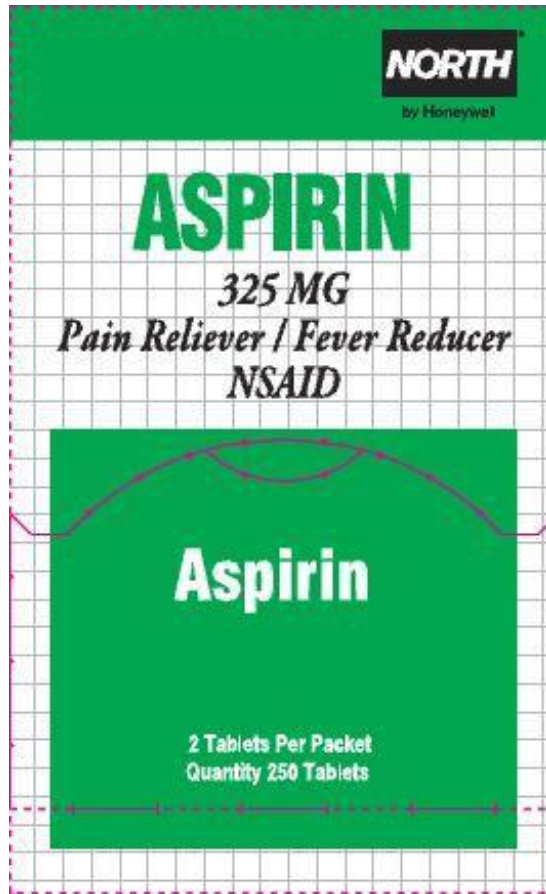
* croscarmellose sodium, *hypromellose,* microcrystalline cellulose,*mineral oil, * polyethylene glycol

propylene glycol, titanium dioxide, *contains one or more of these ingredients

Questions or comments?

1-800-430-4110

Principal Display Panel



NORTH ASPIRIN			
aspirin tablet			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0498-0113
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
Aspirin (UNII: R16CO5Y76E) (Aspirin - UNII:R16CO5Y76E)		Aspirin	325
Inactive Ingredients			
Ingredient Name			Strength
CORN STARCH 3-E-DODECENYL SUCCINIC ANHYDRIDE MODIFIED (UNII: QG4MW19XYX)			

CROSPVIDONE (UNII: 68401960MK)	
CHOLESTERYL STEARATE (UNII: I1Q82N9DYQ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSE 2208 (100 MPA.S) (UNII: B1QE5P712K)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CHOLETH-20 (UNII: TTL8TE641X)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Product Characteristics

Color	white (White)	Score	2 pieces
Shape	ROUND	Size	10mm
Flavor		Imprint Code	FR21
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-0113-05	50 in 1 BOX, UNIT-DOSE		
1		2 in 1 PACKET		
2	NDC:0498-0113-10	100 in 1 BOX, UNIT-DOSE		
2		2 in 1 PACKET		
3	NDC:0498-0113-25	250 in 1 BOX, UNIT-DOSE		
3		2 in 1 PACKET		
4	NDC:0498-0113-50	500 in 1 BOX, UNIT-DOSE		
4		2 in 1 PACKET		
5	NDC:0498-0113-01	2 in 1 PACKET		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part343	11/07/2011	

Labeler - North Safety Products (019777263)

Establishment

Name	Address	ID/FEI	Business Operations
North Safety Products		019777263	manufacture(0498-0113) , pack(0498-0113)

Establishment

Name	Address	ID/FEI	Business Operations
Ultra Tab Laboratories		151051757	manufacture(0498-0113)

