

ADULT LOW DOSE ENTERIC COATED ASPIRIN - aspirin tablet, coated **TYA Pharmaceuticals**

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.

Active ingredient (in each tablet)

Aspirin 81 mg(NSAID)* *nonsteroidal anti-inflammatory drug

Purpose

Pain reliever

Uses

- for the temporary relief of minor aches and pains
- ask your doctor about other uses for aspirin

Warnings

This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you: 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.

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. **Reye's Syndrome:**

Aspirin may cause a severe allergic reaction which may include: **Allergy Alert:**

- hives
- facial swelling
- asthma (wheezing)
- shock

Stomach bleeding warning:

- 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

if your are allergic to aspirin or any other pain reliever/fever reducer. **Do not use**

Ask a doctor before use if

- the stomach bleeding warning applies to you
- you are taking a diuretic
- you have a history of stomach problems, such as heartburn

- you have: -high blood pressure -heart disease -liver cirrhosis -kidney disease -asthma

Ask a doctor or pharmacist before use if you are

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

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
- an allergic reaction occurs. Seek medical help right away
- pain gets worse or lasts more than 10 days
- redness or swelling is present
- fever gets worse or lasts more than 3 days
- any new symptoms occur
- ringing in the ears or loss of hearing occurs

If pregnant or breast-feeding,

In case of overdose , get medical help or contact a Poison Control Center right away. **Keep out of reach of children.**

Directions

- drink a full glass of water with each dose
- swallow whole, do not chew or crush
- do not exceed recommended dose
- adults and children 12 years and older: take 4-8 tablets every 4 hours, as needed, not more than 48 tablets in 24 hours, or as directed by a doctor
- children under 12 years: ask a doctor

Other information

- store at room temperature 15°C - 30°C (59°F - 86°F)
- for institutional use only

Inactive ingredients

cellulose, D and C yellow #10, FD and C yellow #6, hypromellose, iron oxide, PEG, polydextrose, polyvinyl acetate phthalate, propylene glycol, silica, sodium alginate, sodium bicarbonate, starch, stearic acid, talc, titanium dioxide, triacetin, triethyl citrate, wax. May also contain: acetylated monoglycerides, croscarmellose sodium, hypromellose, phthalate, lactose, methacrylic acid, mineral oil, polysorbate 80, sodium lauryl sulfate.

ADULT LOW DOSE ENTERIC COATED ASPIRIN (ASPIRIN) TABLET, COATED

ASPIRIN 81MG TABLET (100CTBTL)

57896-981-01

LOT: XXXXX

EXP: XX-XX-XX

MFR: GERICARE

REPACKAGED BY: T.Y.A. PHARMACEUTICALS
2930 CRESCENT DR.
TALLAHASSEE, FL 32301
(850) 385-0228



DOSE: SEE PACKAGE INSERT

ADULT LOW DOSE ENTERIC COATED ASPIRIN

aspirin tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:64725-0981(NDC:50844-600)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	81 mg

Inactive Ingredients

Ingredient Name	Strength
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
STARCH, CORN (UNII: O8232NY3SJ)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
METHACRYLIC ACID (UNII: 1CS02G8656)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	

SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	

Product Characteristics

Color	yellow	Score	no score
Shape	ROUND	Size	6mm
Flavor		Imprint Code	L
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64725-0981-1	100 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part343	07/01/2000	

Labeler - TYA Pharmaceuticals (938389038)

Registrant - TYA Pharmaceuticals (938389038)

Establishment

Name	Address	ID/FEI	Business Operations
TYA Pharmaceuticals		938389038	RELABEL(64725-0981) , REPACK(64725-0981)