

PLUS PHARMA NSAID 325 MG- aspirin tablet
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.

Drug Facts

Active ingredient (in each tablet)

Aspirin 325 mg (NSAID)*

* nonsteroidal anti-inflammatory drug

Purposes

Pain reliever/fever reducer

Uses

for temporary relief of

- headache
- muscular aches
- backache
- minor pain of arthritis
- the common cold
- toothache
- menstrual cramps
- minor aches and pains
- temporarily reduces fever

Warnings

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

This product contains a nonsteroidal anti-inflammatory drug (NSAID), which may cause severe stomach bleeding. The chance is higher if you **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

Do not use

with any other product containing Aspirin or if you have ever had an allergic reaction 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 are taking a diuretic

Ask a doctor or pharmacist before use if you are

taking a prescription drug for

- anticoagulation (blood thinning)
- gout
- diabetes
- 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
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- new symptoms occur
- ringing in the ears or hearing loss occurs
- redness or swelling is present

, ask a health professional before use. It is especially important not to use Aspirin during 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. **If pregnant or breast-feeding**

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
- **Do not take more than directed**
- take 1 to 2 tablets every 4 hours, or 3 tablets every 6 hours as needed. Do not take more than 12 tablets in 24 hours **Adults and children 12 years and older:**
- ask a doctor **Children under 12:**

Other information

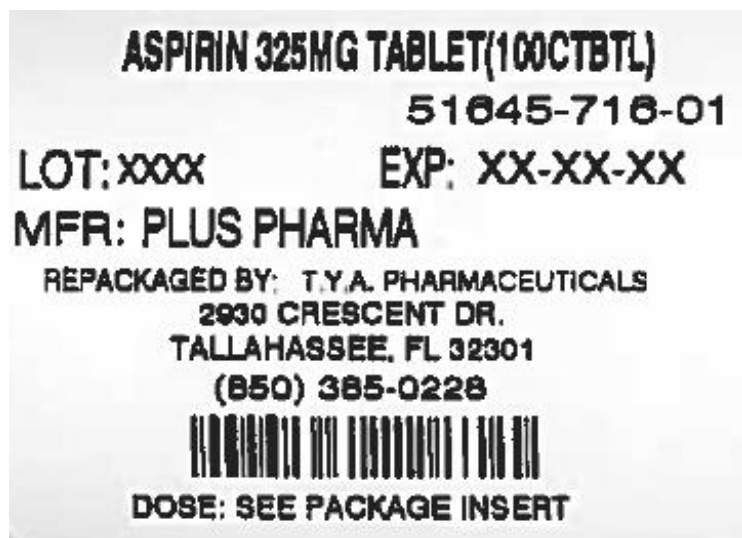
- **Do not use if imprinted safety seal under cap is broken or missing.**
- Store at room temperature

Inactive ingredients

Corn Starch, Povidone.

Questions?

If you have any questions or comments, or to report an adverse event, please contact (800) 795-9775.

PLUS PHARMA NSAID 325 MG (ASPIRIN) TABLET**PLUS PHARMA NSAID 325 MG**

aspirin tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:64725-0716(NDC:51645-716)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)		ASPIRIN	81 mg
Inactive Ingredients			
Ingredient Name		Strength	
STARCH, CORN (UNII: O8232NY3SJ)			
POVIDONES (UNII: FZ989GH94E)			
Product Characteristics			
Color	white	Score	no score
Shape	ROUND (bi-convex tablet)	Size	10mm
Flavor		Imprint Code	Aspirin;GPI
Contains			
Packaging			
#	Item Code	Package Description	Marketing Start Date
1	NDC:64725-0716-1	100 in 1 BOTTLE	
Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part343	09/29/2014	

Labeler - TYA Pharmaceuticals (938389038)

Registrant - TYA Pharmaceuticals (938389038)

Establishment			
Name	Address	ID/FEI	Business Operations
TYA Pharmaceuticals		938389038	RELABEL(64725-0716) , REPACK(64725-0716)