

## **GERITREX ASPIRIN- aspirin tablet, coated**

**Geritrex 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.*

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### **Aspirin 325mg**

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Pain Reliever/Fever Reducer  
(NSAID)

### **Drug Facts**

#### **Active ingredient (in each tablet)**

Aspirin 325 mg (NSAID)\*

\*nonsteroidal anti-inflammatory drug

### **Purpose**

Pain reliever/fever reducer

### **Uses**

temporarily relieves:

- pain and fever of colds
- toothache
- headache
- muscle pain
- minor pain of arthritis
- menstrual pain

### **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 an NSAID, which may cause severe stomach bleeding. The chance is higher if you

- 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]
- are age 60 or older
- take more or for a longer time than directed
- have 3 or more alcoholic drinks every day while using this product

#### **Do not use**

- if you are allergic to aspirin or any other pain reliever/fever reducer
- if you have ever had an allergic reaction to this product or any of its ingredients

#### **Ask a doctor before use if**

- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, or kidney disease
- stomach bleeding warning applies to you
- you are taking a diuretic
- you have asthma

#### **Ask a doctor or pharmacist before use if you are** taking a prescription drug for

- gout
- diabetes
- arthritis

#### **Stop use and ask a doctor if**

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

These could be signs 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.

#### **Directions**

- drink a full glass of water with each dose
- adults and children 12 years and over: take 1 or 2 tablets every 4 hours or 3 tablets every 6 hours not to exceed 12 tablets in 24 hours unless directed by a doctor
- children under 12 years: do not use unless directed by a doctor

#### **Other information**

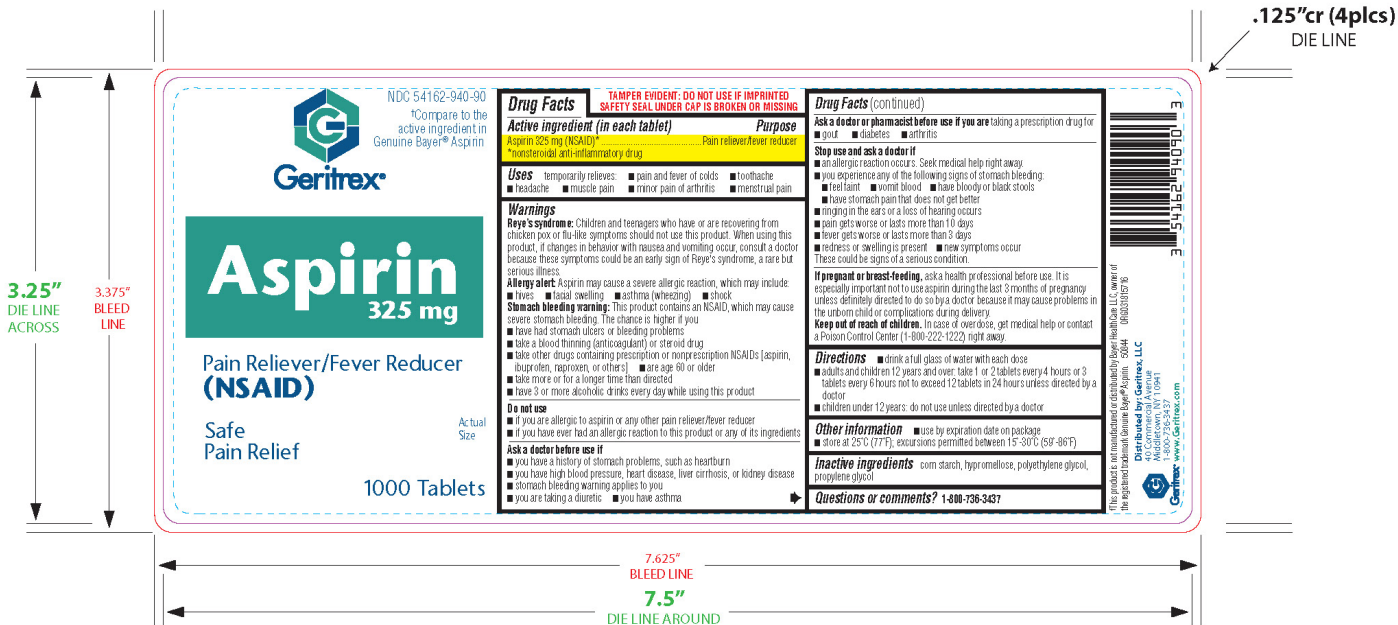
- use by expiration date on package
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)

Inactive ingredients

corn starch, hypromellose, polyethylene glycol, propylene glycol

Questions or comments?

1-800-736-3437



GERITREX ASPIRIN

aspirin tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54162-940
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)			
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)			
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			

### Product Characteristics

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	10 mm
<b>Flavor</b>		<b>Imprint Code</b>	44;157
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54162-940-90	1000 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/11/2018	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	10/11/2018	

**Labeler** - Geritrex LLC (112796248)

Revised: 10/2018

Geritrex LLC