

**ASPIRIN REGULAR STRENGTH- aspirin tablet, delayed release**  
**NCS HealthCare of KY, LLC dba Vanguard Labs**

*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 EC 325mg Tab-8324**

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

Aspirin 325 mg (NSAID)\*

\*nonsteroidal anti-inflammatory drug

***Purpose***

Pain reliever

***Uses***

- temporarily relieves minor aches and pains due to:
  - headache
  - menstrual pain
  - a cold
  - toothache
  - muscle pain
  - minor pain of arthritis
- or as recommended by your doctor

***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:

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

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

- take other drugs containing prescription or nonprescription NSAIDs [aspirin, ibuprofen, naproxen, or others]
- are age 60 or older

- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- 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**

- stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have asthma
- 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

- diabetes
- arthritis
- gout

**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:
  - vomit blood
  - feel faint
  - have bloody or black stools
  - have stomach pain that does not get better
- ringing in the ears or a loss of hearing occurs
- new symptoms occur
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present

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 right away.

***Directions***

- do not take more than directed
- drink a full glass of water with each dose
- adults and children 12 years and over: take 1 to 2 tablets every 4 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***

- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)

### ***Inactive ingredients***

black iron oxide, cellulose, colloidal anhydrous silica, corn starch, D&C yellow #10 aluminum lake, FD&C yellow #6 aluminum lake, hypromellose, polydextrose, polyethylene glycol, polyvinyl acetate phthalate, propylene glycol, shellac wax, simethicone, sodium alginate, sodium bicarbonate, stearic acid, talc, titanium dioxide, triacetin, triethyl citrate

### ***Questions or comments?***

**Call 1-800-645-2158**

Rev. 05-21 R-17

50844 REV0421A22712

Talk to your doctor or other healthcare provider before using this product for your heart.

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[www.rugbylaboratories.com](http://www.rugbylaboratories.com)

### ***Principal display panel***

<div>ASPIRIN    REGULAR STRENGTH</div> <div>aspirin tablet, delayed release</div>			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0615-8324(NDC:0536-1232)
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
FERROSOFERRIC OXIDE (UNII: XM0M87F357)			
STARCH, CORN (UNII: O8232NY3SJ)			
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)			

<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>POLYDEXTROSE</b> (UNII: VH2XOU12IE)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>Polyvinyl Acetate Phthalate</b> (UNII: 58QVG85GW3)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>SHELLAC</b> (UNII: 46N107B71O)	
<b>SODIUM ALGINATE</b> (UNII: C269C4G2ZQ)	
<b>SODIUM BICARBONATE</b> (UNII: 8MDF5V39QO)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>TRIACETIN</b> (UNII: XHX3C3X673)	
<b>TRIETHYL CITRATE</b> (UNII: 8Z96QXD6UM)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>POWDERED CELLULOSE</b> (UNII: SMD1X3XO9M)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	

### Product Characteristics

<b>Color</b>	orange	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	10mm
<b>Flavor</b>		<b>Imprint Code</b>	44;227
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0615-8324-39	30 in 1 BLISTER PACK; Type 0: Not a Combination Product	12/16/2019	09/30/2024

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	06/01/2019	09/30/2024

**Labeler** - NCS HealthCare of KY, LLC dba Vanguard Labs (050052943)

### Establishment

Name	Address	ID/FEI	Business Operations
NCS HealthCare of KY, LLC dba Vanguard Labs		050052943	repack(0615-8324)