

**ASPIRIN CHEWABLE- aspirin chewable tablet**  
**NCS HealthCare of KY, Inc 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 Chewable 81mg**

**Active ingredient(s)**

Aspirin 81mg (NSAID)\*

\*nonsteroidal anti-inflammatory drug

**Purpose**

Pain Reliever

**Use(s)**

for the temporary relief of minor aches and pains.

**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 are rare but serious illness.

Allergy alert: Aspirin may cause a severe allergic reaction which may include: facial swelling, hives, asthma (wheezing), shock

Stomach Bleeding Warning: This product contains an 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 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**

If you have ever had an allergic reaction to any other pain reliever/fever reducer for at least 7 days after tonsillectomy or oral surgery unless directed by a doctor.

**Ask a doctor before use if**

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

**Ask a doctor or pharmacist before use if**

If you are taking a prescription drug for diabetes, gout or arthritis.

**Stop use and ask a doctor if**

an allergic reaction occurs. Seek medical help right away. 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 for more than 10 days, redness or swelling is present, new symptoms appear, ringing in the ears or a loss of hearing occurs. These could be signs of a serious condition.

### **Pregnancy/Breastfeeding**

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**

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222).

### **Directions**

Drink a full glass of water with each dose

Adults and children 12 years and over: take 4 to 8 tablets every 4 hours not to exceed 48 tablets in 24 hours unless directed by a doctor.

Children under 12 years: ask a doctor.

### **Storage**

Store a 20 - 25 degrees C (68 - 77 degrees F)

### **Inactive ingredients**

dextrose excipient, FD&C yellow no. 6 lake, flavors, saccharin sodium, starch

### **Questions**

Questions or Comments? 1-800-616-2471

### **Principal Display Panel**

Aspirin 81mg Chewable Tablets



VLI NDC: 0615-3508-39  
**ASPIRIN (NSAID)  
 CHEWABLE TABS  
 81 mg**

SEE NEW  
 WARNINGS  
 INFORMATION  
 ON REVERSE

PAIN RELIEVER

TAMPER  
 EVIDENT

LOT  
 3508

EXP

10981-39

QTY  
 30

MFG BY PERRIGO  
 for MAJOR  
 PKG BY VANGARD  
 GLASGOW, KY 42141

(MAJOR NDC 0904-4040-73)  
**Aspirin (NSAID\*)**  
**Chewable Tabs 81 mg**  
 \*nonsteroidal  
 anti-inflammatory drug

Received: \_\_\_\_\_

24	16	8
31	23	15
30	22	14
29	21	13
28	20	12
27	19	11
26	18	10
25	17	9

START DATE \_\_\_\_\_ START TIME \_\_\_\_\_

STORE AT 20°-25°C (68°-77°F)  
 (SEE USP CONTROLLED ROOM TEMPERATURE)

**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:** This product contains an 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 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. **Keep out of the reach of children.**

See Package Label Binder for full labeling information and additional warnings.  
**FOR INSTITUTIONAL USE ONLY**

16	8
30	23
29	22
28	21
27	20
26	19
25	18
24	17
17	9

<p>Pkg By Vangard, Glasgow, KY 42141          ASPIRIN (NSAID)          CHEWABLE TAB 81 mg          WARNINGS: See package label binder.          LOT 3508</p>	<p>Pkg By Vangard, Glasgow, KY 42141          ASPIRIN (NSAID)          CHEWABLE TAB 81 mg          WARNINGS: See package label binder.          LOT 3508</p>	<p>Pkg By Vangard, Glasgow, KY 42141          ASPIRIN (NSAID)          CHEWABLE TAB 81 mg          WARNINGS: See package label binder.          LOT 3508</p>	<p>10980 Rev 00          Vangard Logo          Glasgow, KY 42141</p>
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**Omnicare** The overall configuration of this package is a trademark of Omnicare, Inc.

# ASPIRIN CHEWABLE

aspirin chewable tablet

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0615-3508(NDC:0904-4040)
<b>Route of Administration</b>	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
DEXTROSE (UNII: IY9XDZ35W2)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
STARCH, CORN (UNII: O8232NY3SJ)	

**Product Characteristics**

<b>Color</b>	ORANGE	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	8 mm
<b>Flavor</b>	ORANGE	<b>Imprint Code</b>	L;467
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:06 15-3508-31	31 in 1 BLISTER PACK		
2	NDC:06 15-3508-39	30 in 1 BLISTER PACK		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part343	12/12/2007	

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

**Establishment**

Name	Address	ID/FEI	Business Operations
NCS HealthCare of KY, Inc dba Vanguard Labs		050052943	RELABEL(06 15-3508) , REPACK(06 15-3508)

Revised: 2/2013

NCS HealthCare of KY, Inc dba Vanguard Labs