

**ASPIRIN LOW DOSE CHEWABLE ORANGE- aspirin tablet, chewable**  
**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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**Asprin NSAID Chewable 81mg Tabs- Pharbest-8257**

**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 or as recommended by your doctor
- ask your doctor about other uses for Chewable Aspirin 81 mg

**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

- 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 are allergic to aspirin or 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**

- 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 have asthma
- you are taking a diuretic

**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**

- 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
  - pain gets worse or lasts more than 10 days
  - fever get worse or lasts more than 3 days
  - redness or swelling is present
  - ringing in the ears or loss of hearing occurs
  - any 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 accidental overdose, get medical help or contact a Poison Control Center right away.

**Directions**

- drink a full glass of water with each dose

adults and children 12	take 4 to 8 tablets every 4 hours not to exceed 48 tablets in
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years and over	24 hours unless directed by a doctor
children under 12 years	consult a doctor

**Other information**

- store at room temperature (15<sup>o</sup>-30<sup>o</sup>C)
- **Tamper Evident**

**Inactive ingredients**

corn starch, dextrose monohydrate, FD&C yellow #6, orange flavor, silicon dioxide, sodium saccharine, stearic acid

**Questions or comments?**

(800) 616-2471

M-111

Rev. 06/21

**PRINCIPAL DISPLAY PANEL**



VU NDC 0615-8257-39

Aspirin (NSAID)\*  
Chewable Tabs  
81 mg

LOT 8257-

EXP

8257-AA-39 v00

QTY  
30

Mfg By Parbest for  
Major  
(NDC 0904-6794-89)  
PKG BY VANGARD  
GLASGOW, KY 42141

See  
Warnings  
on Reverse  
Pain Reliever

TAMPER  
EVIDENT

(Major NDC 0904-6794-89)  
Aspirin (NSAID)\*  
Chewable Tabs  
81 mg

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

31	24	16	8
30	22	14	6
29	21	13	5
28	20	12	4
27	19	11	3
26	18	10	2
25	17	9	1
Start Date		Start Time	

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

WARNINGS: See  
aetnao365.sharepoint.com/sites/omnicare-  
search/drugs/SitePages/Home.aspx

Each tablet contains Aspirin 81 mg (NSAID)\*  
\*nonsteroidal anti-inflammatory drug

See package insert or label for dosage information  
**FOR INSTITUTIONAL USE ONLY**

16	8
30	23
29	22
28	21
27	20
26	19
25	18
24	17
15	7
14	6
13	5
12	4
11	3
10	2
9	1

Pkg by Vanguard, Glasgow, KY 42141 Aspirin (NSAID)* Chewable Tab 81 mg LOT 8257 - EXP 09046794899	Pkg by Vanguard, Glasgow, KY 42141 Aspirin (NSAID)* Chewable Tab 81 mg LOT 8257 - EXP 09046794899	Pkg by Vanguard, Glasgow, KY 42141 Aspirin (NSAID)* Chewable Tab 81 mg LOT 8257 - EXP 09046794899	8257-AA-B-01 Vanguard Labs Glasgow, KY 42141 LOT 8257 - EXP 09046794899
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24 The overall configuration of this package is a trademark of Omnicare, Inc. 17 9 1

# PRINCIPAL DISPLAY PANEL UD

Pkg By Vanguard, Glasgow, KY 42141 Aspirin (NSAID)* Chewable Tab 81 mg LOT 8257- EXP 0904679489	Pkg By Vanguard, Glasgow, KY 42141 Aspirin (NSAID)* Chewable Tab 81 mg LOT 8257- EXP 0904679489	Pkg By Vanguard, Glasgow, KY 42141 Aspirin (NSAID)* Chewable Tab 81 mg LOT 8257- EXP 0904679489	Pkg By Vanguard, Glasgow, KY 42141 Aspirin (NSAID)* Chewable Tab 81 mg LOT 8257- EXP 0904679489	Pkg By Vanguard, Glasgow, KY 42141 Aspirin (NSAID)* Chewable Tab 81 mg LOT 8257- EXP 0904679489	Pkg By Vanguard, Glasgow, KY 42141 Aspirin (NSAID)* Chewable Tab 81 mg LOT 8257- EXP 0904679489
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8257-AA-UDI-1-000

<p>VLI NDC 0615-8257-30</p> <p><b>Aspirin (NSAID) Chewable Tablets 81 mg</b></p> <p>QTY 30 Each tablet contains Aspirin 81 mg (NSAID)* *nonsteroidal anti-inflammatory drug</p> <p><b>Pain Reliever</b></p> <p>STORE AT 20°-25°C (68°-77°F) (SEE USP CONTROLLED ROOM TEMPERATURE)</p> <p>WARNINGS: See aetnao365.sharepoint.com/sites/omnicare- search/drugs/SitePages/Home.aspx</p> <p>LOT: EXP:</p>	<p>VLI NDC 0615-8257-30</p> <p><b>Aspirin (NSAID) Chewable Tablets 81 mg</b></p> <p>FOR INSTITUTIONAL USE ONLY</p> <p>QTY 30 LOT: EXP:</p> <p>Manufactured By <b>Pharbest (M-111)</b> for <b>Major</b> NDC 090467948930 42141</p> <p>Repackaged by Vanguard Labs Glasgow, KY 42141</p> <p>Dosage: See aetnao365. sharepoint.com/sites/omnicare- search/drugs/SitePages/Home.aspx</p> <p>090467948930</p>
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## ASPIRIN LOW DOSE CHEWABLE ORANGE

aspirin tablet, chewable

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0615-8257(NDC:0904-6794)
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ASPIRIN</b> (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	81 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	

<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>DEXTROSE MONOHYDRATE</b> (UNII: LX22YL083G)	

### Product Characteristics

<b>Color</b>	orange	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	8mm
<b>Flavor</b>		<b>Imprint Code</b>	PH034
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0615-8257-39	30 in 1 BLISTER PACK; Type 0: Not a Combination Product	11/12/2018	
2	NDC:0615-8257-05	15 in 1 BLISTER PACK; Type 0: Not a Combination Product	02/21/2020	
3	NDC:0615-8257-30	6 in 1 BOX, UNIT-DOSE	05/31/2022	
3		5 in 1 BLISTER PACK; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part343	09/27/2018	

**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(0615-8257)

Revised: 6/2022

NCS HealthCare of KY, LLC dba Vanguard Labs