ASPIRIN LOW DOSE CHEWABLE ORANGE- aspirin tablet, chewable NCS HealthCare of KY, LLC dba Vangard 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.

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 recommneded 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

years and over	24 hours unless directed by a doctor
children under 12 years	consult a doctor

Other information

- store at room temperature (15°-30°C)
- Tamper Evident

Inactive ingredients

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

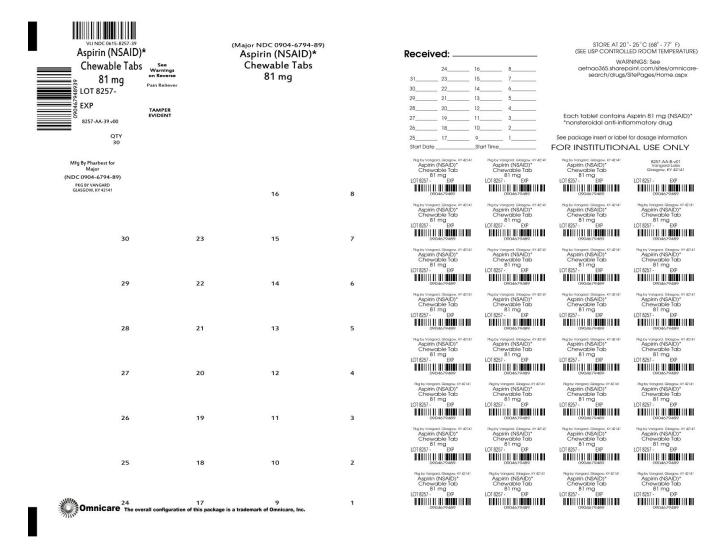
Questions or comments?

(800) 616-2471

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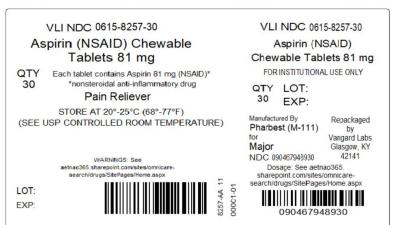
Rev. 06/21

PRINCPAL DISPLAY PANEL



PRINCIPAL DISPLAY PANEL UD





ASPIRIN LOW DOSE CHEWABLE ORANGE

aspirin tablet, chewable

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

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	AS PIRIN	81 mg		

Inactive Ingredients		
Ingredient Name Strength		
STARCH, CORN (UNII: 08232NY3SJ)		
STEARIC ACID (UNII: 4ELV7Z65AP)		

FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
SILICON DIOXIDE (UNII: ETJ7Z 6XBU4)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
DEXTROSE MONOHYDRATE (UNII: LX22YL083G)	

Product Characteristics				
Color	orange	Score	no score	
Shape	ROUND	Size	8mm	
Flavor		Imprint Code	PH034	
Contains				

P	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 Vangard Labs (050052943)

Establishment				
Name	Address	ID/FEI	Business Operations	
NCS HealthCare of KY, LLC dba Vangard Labs		050052943	repack(0615-8257)	

Revised: 6/2022 NCS HealthCare of KY, LLC dba Vangard Labs