ASPIRIN CHEWABLE- as pirin chewable tablet NCS HealthCare of KY, Inc 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.

Aspirin Chewable 81mg

Active ingredient(s)

Aspirin 81mg (NSAID)*

*nonsteriodal 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 symproms 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 prignancy 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

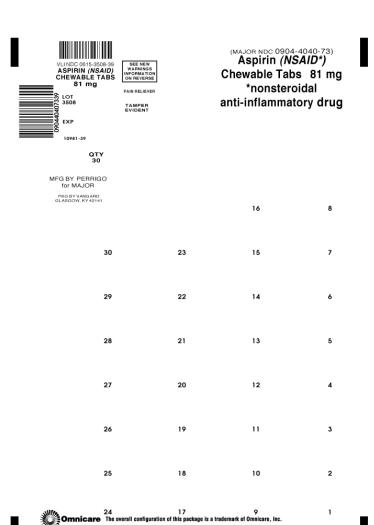
dextrose excipient, FD&C yellow no. 6 lake, flavors, saccharin sodium, starch

Questions

Questions or Comments? 1-800-616-2471

Principal Display Panel

Aspirin 81mg Chewable Tablets



Recei	ived:						ROOM TEMPERATURE
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	24	16	8	•	this product, if	changes in b	ot use this product. When using ehavior with nausea and
31 ———	23	15	7	•	vomiting occur	consult a do	octor because these symptoms eye's syndrome, a rare but
30 ——	22	14	6		serious illness	. Allergy aler	rt: Aspirin may cause a severe v include: • hives • facial
29 ——	—21 —	— 13 —	5		swelling • asth	ma (wheezin	g) • shock. Stomach bleeding
28	20	12	4	bleeding.	The chance is higher if you	u: • are age 6	may cause severe stomach 0 or older • have had stomach ng (anticoagulant) or steroid
27 ——	19	—11—	3				
26	18	10	2	(aspirin, it	ouprofen, naproxen, or oth	ers) • have 3	or more alcoholic drinks every onger time than directed.
25	17	9	1				
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	0904404073	•	0904404073		0904404073	III	0904404073

ASPIRIN CHEWABLE

aspirin chewable tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0615-3508(NDC:0904-4040)
Route of Administration	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: IY9 XDZ35W2)				
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)				
SACCHARIN SO DIUM (UNII: SB8 ZUX40 TY)				
STARCH, CORN (UNII: O8232NY3SJ)				

Product Characteristics					
Color	ORANGE	Score	no score		
Shape	ROUND	Size	8 mm		
Flavor	ORANGE	Imprint Code	L;467		
Contains					

I	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:0615-3508-31	31 in 1 BLISTER PACK				
2	NDC:0615-3508-39	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 Vangard Labs (050052943)

Establishment						
Name	Address	ID/FEI	Business Operations			
NCS HealthCare of KY, Inc dba Vangard Labs		050052943	RELABEL(0615-3508), REPACK(0615-3508)			

Revised: 2/2013 NCS HealthCare of KY, Inc dba Vangard Labs