

**ASPIRIN 81 MG- aspirin tablet, chewable**  
**Reliable 1 Laboratories LLC**

*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 USP 81 mg Chewable Tablets**

**Drugs Facts**

**Active ingredients (in each tablet)**

Aspirin USP 81 mg (NSAID)\*

\*nonsteroidal anti-inflammatory drug

**Purpose**

Pain reliever

**Uses**

- temporarily relieves minor aches and pains
- for other uses, see your doctor, but do not use for more than 10 days without consulting your doctor because serious side effects may occur

**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 NSID, 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 non-prescription NSAIDs (ibuprofen, naproxen, or others)
- take more or for a longer time than directed
- have 3 or more alcoholic drinks every day while using this product

**Drug Facts** continued on back of label

**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

**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 are taking a diuretic
- you have asthma

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

- taking a prescription drug for diabetes, gout or arthritis
- under a doctor's care for any serious condition
- taking any other drug

**Stop use and ask a doctor 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 more than 10 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present in the painful area
- any new symptoms appear
- ringing in the ears or loss of hearing occurs

These could be signs of a serious condition

**Keep out of reach of children.** In case of 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 years & older:** take 4 to 8 tablets every 4 hours while symptoms last, but not more than 48 tablets in 24 hours
- **children under 12 years:** ask a doctor

**Other information**

- Store at room temperature 15°-30°C (59°-86°F)

**Inactive ingredients**

compressible sugar, corn starch, FD&C yellow #6 alum. lake, magnesium stearate,

orange flavor, silicon dioxide

***Questions or comments?***

call **516-341-0666**, 8:30 am - 4:30 pm ET, Monday - Friday

**TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS  
BROKEN OR MISSING**

\*Reliable 1 Laboratories LLC is not affiliated with the owner of the trademark BAYER®.

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**NDC 69618-014-36**

**ORANGE FLAVORED**

**Aspirin USP 81 mg (NSAID)**

**Adult Low Strength**

**PAIN RELIEVER**

**36 CHEWABLE TABLETS**

**\*Compare to Active Ingredient in Aspirin Regimen BAYER® Chewable**

NDC 69618-014-36



**ORANGE FLAVORED**  
**Aspirin USP**  
**81 mg (NSAID)**

**Adult Low Strength**  
**PAIN RELIEVER**

**36 CHEWABLE TABLETS**

Compare to Active Ingredient in Aspirin Regular Bayer® Chewable

**Drug Facts**

**Active Ingredient (in each tablet) Purpose**

Aspirin USP 81 mg (NSAID)\* ..... Pain reliever  
 \*nonsteroidal anti-inflammatory drug

**Uses** ■ temporarily relieves minor aches and pains for other uses, see your doctor, but do not use for more than 10 days without consulting your doctor because serious side effects may occur.

**Warnings**

**Risk of 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 non-prescription NSAIDs (ibuprofen, naproxen, or others)  
 ■ take more or for a longer time than directed  
 ■ have 3 or more alcoholic drinks every day while using this product

**Drug Facts** continued on back of label

**TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING**

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Rev. 0715



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Lot No.:  
 Exp. Date:

**Drug Facts (continued)**

**Do not use** ■ if you have ever had an allergic reaction to any other pain reliever/fever reducer or for at least 7 days after tonsillectomy or oral surgery

**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 are taking a diuretic  
 ■ you have asthma

**Ask a doctor or pharmacist before use if you are**  
 ■ taking a prescription drug for diabetes, gout or arthritis  
 ■ under a doctor's care for any serious condition  
 ■ taking any other drug

**Stop use and ask a doctor if**  
 ■ you experience any of the following signs of stomach bleeding: ■ feel faint ■ vomit blood  
 ■ have bloody or black stools  
 ■ pain gets worse or lasts more than 10 days  
 ■ fever gets worse or lasts more than 3 days  
 ■ redness or swelling is present in the painful area  
 ■ any new symptoms appear  
 ■ ringing in the ears or loss of hearing occurs  
 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** DRINK A FULL GLASS OF WATER WITH EACH DOSE ■ adults and children 12 years & older: take 4 to 8 tablets every 4 hours while symptoms last, but not more than 48 tablets in 24 hours  
 ■ children under 12 years: ask a doctor

**Other information**  
 ■ store at room temperature 15°-30°C (59°-86°F)

**Inactive ingredients** compressible sugar, corn starch, FD&C yellow #6 aluminum lake, magnesium stearate, orange flavor, silicon dioxide

**Questions or comments?** call 816-941-0000, 8:30 am - 4:30 pm ET, Monday - Friday

**ASPIRIN 81 MG**

aspirin tablet, chewable

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69618-014
<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
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<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>SUCROSE</b> (UNII: C151H8M554)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	

### Product Characteristics

<b>Color</b>	orange	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	8mm
<b>Flavor</b>	ORANGE	<b>Imprint Code</b>	AP;009
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69618-014-36	36 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/01/2015	



ASPIRIN  
81mg Chew Tablet

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part343	11/01/2015	

**Labeler** - Reliable 1 Laboratories LLC (079718111)

**Registrant** - Reliable 1 Laboratories LLC (079718111)

Revised: 3/2023

Reliable 1 Laboratories LLC