

**ASPIRIN LOW DOSE CHEWABLE ORANGE- aspirin tablet, chewable
ATLANTIC BIOLOGICALS CORP.**

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.

Drug Facts

Active ingredient (in each tablet)

Aspirin 81mg (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

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

Other information

- store at room temperature (15⁰-30⁰C)
- **⚠Tamper Evident:** ⚠do not use if safety seal under cap is broken or missing

Inactive ingredients

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

Questions or comments?

1-800-616-2471

DISTRIBUTED BY:

ATLANTIC BIOLOGICALS CORP.

MIAMI, FL 33179

NDC 17856-6794-01

ASPIRIN

LOW DOSE

CHEWABLE

ORANGE

PAIN RELIEVER

(NSAID)

81 mg

100 TAB

17856-6794-01
ASPIRIN
81 MG TAB



See package insert for indications and dosage schedule

store at room temperature(15°-30°) pain
reliever (NSAID)



17856-6794-01

**Dosage: 81 MG CHEWABLE
TAB**

ASPIRIN

Qty: 100 TABLETS



GTIN: 00178566794012

S/N: 01195702

Exp: 04/15/21

Lot: 011957

OTC

Packaged by: Unit Dose Solutions
Morrisville, NC 27560

Distributed by: AtlanticBiologicals Corp.
Miami FL 33179

Rev.09/19

Call to Reorder: 800.509.7592

ASPIRIN LOW DOSE CHEWABLE ORANGE

aspirin tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:17856-6794(NDC:0904-6794)
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
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
DEXTROSE MONOHYDRATE (UNII: LX22YL083G)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:17856-6794-1	100 in 1 BOX, UNIT-DOSE	10/15/2020	
1		1 in 1 POUCH; 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 - ATLANTIC BIOLOGICALS CORP. (047437707)

Establishment

Name	Address	ID/FEI	Business Operations
ATLANTIC BIOLOGICALS CORP.		047437707	relabel(17856-6794) , repack(17856-6794)

Revised: 10/2020

ATLANTIC BIOLOGICALS CORP.