

## **ASPIRIN LOW DOSE CHEWABLE ORANGE- aspirin tablet, chewable MAJOR PHARMACEUTICALS**

*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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### **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

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

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**Other information**

- store at room temperature (15<sup>0</sup>-30<sup>0</sup>C)
- **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

MAJOR

NDC 0904-6794-80

Low Dose

Aspirin

81 mg

Pain Reliever (NSAID)

Chewable Orange Flavor

FOR PHARMACY DISPENSING

ONLY. NOT FOR RETAIL SALE.

90 TABLETS

# TEMPORARY GLUE

## Drug Facts (continued)

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 gets 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 to exceed 48 tablets in 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: 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?**  
(800) 616-2471

M-111  
Rev. 06/21  
Re-order No. 701002

**STOP PEELING**

# PERMANENT GLUE

MAJOR® NDC 0904-6794-89

## Low Dose Aspirin

81 mg

Pain Reliever (NSAID)  
Chewable Orange Flavor

FOR PHARMACY DISPENSING ONLY. NOT FOR RETAIL SALE.

90 Tablets

## Drug Facts

**Active ingredient (in each tablet)** Purpose  
Aspirin 81 mg (NSAID) ..... Pain reliever  
\*nonsteroidal anti-inflammatory drug

## 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

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MAJOR PHARMACEUTICALS  
Livonia, MI 48152

Peel here for more drug facts



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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:0904-6794
<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
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z 65AP)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
SILICON DIOXIDE (UNII: ETJ7Z 6XBU4)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
DEXTROSE MONOHYDRATE (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:0904-6794-89	90 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/27/2018	
2	NDC:0904-6794-80	1000 in 1 PACKAGE; Type 0: Not a Combination Product	09/27/2018	
3	NDC:0904-6794-30	300 in 1 CARTON	02/13/2023	
3		1 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** - MAJOR PHARMACEUTICALS (191427277)

**Registrant** - Pharbest Pharmaceuticals, Inc. (557054835)

Revised: 3/2023

MAJOR PHARMACEUTICALS