# LOW DOSE ASPIRIN- as pirin tablet, chewable GREAT LAKES WHOLESALE, MARKETING, & SALES, INC.

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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#### Healthcare 44-218 SJ

#### Active ingredient (in each chewable tablet)

Aspirin 81 mg (NSAID)\*
\*nonsteroidal anti-inflammatory drug

#### **Purpose**

Pain reliever

#### Uses

for the temporary relief of minor aches and pains or as recommended by your doctor

### **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
- shock
- asthma (wheezing)

**Stomach bleeding warning:** This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you

- 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
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- are age 60 or older
- 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
- if you have ever had an allergic reaction to this product or any of its ingredients

#### 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:
  - vomit blood
  - have bloody or black stools
  - feel faint
  - have stomach pain that does not get better
- ringing in the ears or a loss of hearing occurs
- pain gets worse or lasts more than 10 days
- redness or swelling is present
- 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 overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

#### Directions

- drink a full glass of water with each dose
- chew or crush tablets completely before swallowing; do not swallow tablets whole
- adults and children 12 years and over: take 4 to 8 chewable tablets every 4 hours not to exceed 48 chewable tablets in 24 hours unless directed by a doctor
- children under 12 years: do not use unless directed by a doctor

#### Other information

- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- see end flap for expiration date and lot number

#### **Inactive ingredients**

corn starch, dextrates hydrated, FD&C yellow #6 aluminum lake, flavor, maltodextrin, sucralose

#### **Questions or comments?**

Call 1-800-426-9391

**Principal Display Panel** 

HEALTH**CARE**TM

NDC 64092-150-36

81 mg LOW STRENGTH Low Dose Aspirin Chewable Tablets Pain Reliever (NSAID)

For Aspirin Regimen Users\*\*

For Minor Aches and Pains Orange Flavored

Chew or crush tablets completely before swallowing.

<sup>†</sup>Compare to the active ingredient in St. Joseph® 81 mg Chewable Aspirin

36 CHEWABLE TABLETS

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

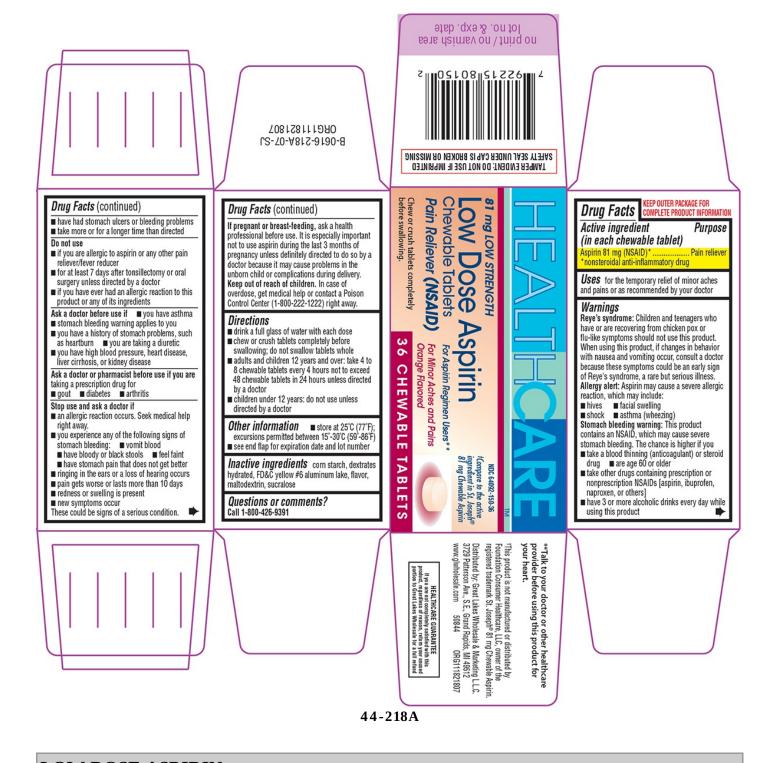
\*\*Talk to your doctor or other healthcare provider before using this product for your heart.

<sup>†</sup>This product is not manufactured or distributed by Foundation Consumer Healthcare, LLC, owner of the registered trademark St. Joseph® 81 mg Chewable Aspirin.

Distributed by: Great Lakes Wholesale & Marketing L.L.C. 3729 Patterson Ave., S.E., Grand Rapids, MI 49512 www.glwholesale.com 50844 ORG111821807

#### **HEALTHCARE GUARANTEE**

If you are not completely satisfied with this product, regardless of reason, return your unused portion to Great Lakes Wholesale for a full refund



### LOW DOSE ASPIRIN

aspirin tablet, chewable					
Product Information					
Product Type	HUMAN OTC DRUG	Item Code (S	ource)	NDC:640	92-150
Route of Administration	ORAL				
Active Ingredient/Active Moiety					
Ingredient Name Basis of Strength Strength					Strength

Inactive Ingredients				
Ingredient Name	Strength			
STARCH, CORN (UNII: O8232NY3SJ)				
DEXTROSE MONO HYDRATE (UNII: LX22YL083G)				
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)				
MALTO DEXTRIN (UNII: 7CVR7L4A2D)				
SUCRALOSE (UNII: 96K6UQ3ZD4)				

Product Characteristics				
Color	ORANGE	Score	no score	
Shape	ROUND	Size	8mm	
Flavor	ORANGE	Imprint Code	44;218	
Contains				

F	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64092-150- 36	1 in 1 CARTON	09/12/1990	
1		36 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC MONOGRAPH NOT FINAL	part343	09/12/1990			

# Labeler - GREAT LAKES WHOLESALE, MARKETING, & SALES, INC. (361925498)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(64092-150)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(64092-150)

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
LNK International, Inc.		967626305	PACK(64092-150)

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
LNK International, Inc.		868734088	PACK(64092-150)

Revised: 3/2020

GREAT LAKES WHOLESALE, MARKETING, & SALES, INC.