

LOW DOSE ASPIRIN- aspirin tablet, chewable
GREAT LAKES WHOLESAL, 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.

Healthcare 44-218-Delisted

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 a blood thinning (anticoagulant) or steroid drug
- are age 60 or older
- 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 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

- you have asthma
- stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you are taking a diuretic
- you have high blood pressure, heart disease, liver cirrhosis, or kidney disease

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
- fever gets worse or lasts more than 3 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 at 20 weeks or later in 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

- **do not take more than directed**
- 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, dextrans hydrated, FD&C yellow #6 aluminum lake, flavor, maltodextrin, sucralose

Questions or comments?

Call 1-800-426-9391

Principal Display Panel

Healthcare™

NDC 64092-150-36

81 mg LOW STRENGTH

Low Dose Aspirin

Chewable Tablets

Pain Reliever (**NSAID**)

Chew or crush tablets completely before swallowing.

For Aspirin Regimen Users**

For Minor Aches and Pains

Orange Flavored

Actual Size

†Compare to the active ingredient in St. Joseph® 81 mg Chewable Aspirin

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.

†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 REV0122A21807

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

no print / no varnish area
lot no. & exp. date

7 922215 80150 2



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

KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

Drug Facts
Active ingredient (in each chewable tablet)
Aspirin 81 mg (NSAID)* Pain reliever
*nonsteroidal anti-inflammatory drug

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

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 a blood thinning (anticoagulant) or steroid drug ■ are age 60 or older
 ■ 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

HEALTHCARE™

81 mg LOW STRENGTH

Low Dose Aspirin
Chewable Tablets
Pain Reliever (NSAID)

For Aspirin Regimen Users**
For Minor Aches and Pains
Orange Flavored

NDC 64092-150-36
*Compare to the active ingredient in St. Joseph® 81 mg Chewable Aspirin

Chew or crush tablets completely before swallowing.

36 CHEWABLE TABLETS

Actual Size



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

*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 REV0122A21807

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

B-0616-218A-07-SJ
REV0122A21807

Drug Facts (continued)
If pregnant or breast-feeding, ask a health professional before use, especially if you are not to use aspirin at 20 weeks or later in pregnancy unless definitely directed to do so by a doctor because it may cause serious 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
 ■ do not take more than directed
 ■ 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

Drug Facts (continued)
 ■ have had stomach ulcers or bleeding problems
 ■ 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
 ■ you have asthma
 ■ stomach bleeding warning applies to you
 ■ you have a history of stomach problems, such as heartburn ■ you are taking a diuretic
 ■ you have high blood pressure, heart disease, liver cirrhosis, or kidney disease

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
 ■ fever gets worse or lasts more than 3 days
 ■ redness or swelling is present
 ■ new symptoms occur
 These could be signs of a serious condition.

Blank area for additional information or instructions.

Healthcare 44-218A

LOW DOSE ASPIRIN

aspirin tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:64092-150
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)	
DEXTROSE MONOHYDRATE (UNII: LX22YL083G)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64092-150-36	1 in 1 CARTON	09/12/1990	09/20/2024
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	09/20/2024

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.		832867837	manufacture(64092-150)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	manufacture(64092-150)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	pack(64092-150)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(64092-150)

Revised: 6/2023

GREAT LAKES WHOLESALE, MARKETING, & SALES, INC.