

**CHILDRENS ACETAMINOPHEN- acetaminophen 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 44-447-Delisted**

***Active ingredient (in each tablet)***

Acetaminophen 80 mg

***Purpose***

Pain reliever/fever reducer

***Uses***

- temporarily relieves minor aches and pains due to:
  - headache
  - the common cold
  - flu
  - toothache
  - sore throat
- temporarily reduces fever

***Warnings***

**Liver warning:** This product contains acetaminophen. Severe liver damage may occur if your child takes:

- more than 5 doses in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen

**Allergy alert:** Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away.

**Sore throat warning:** If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

**Do not use**

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- if your child is allergic to acetaminophen or any of the inactive ingredients in this product

**Ask a doctor before use if your child has**

liver disease.

**Ask a doctor or pharmacist before use if your child is**

taking the blood thinning drug warfarin.

### **When using this product**

**do not exceed recommended dosage.**

### **Stop use and ask a doctor if**

- pain gets worse or lasts more than 5 days
- fever gets worse or lasts more than 3 days
- new symptoms occur
- redness or swelling is present

These could be signs of a serious condition.

### **Keep out of reach of children.**

In case of accidental overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

### **Directions**

- **this product does not contain directions or complete warnings for adult use**
- **do not give more than directed**
- find the right dose on chart below. If possible, use weight to dose; otherwise, use age.
- chew before swallowing; this product will soften in mouth for ease of chewing
- repeat dose every 4 hours while symptoms last
- do not give more than 5 times in 24 hours
- do not give for more than 5 days unless directed by a doctor

<b>Weight (lb)</b>	<b>Age (yr)</b>	<b>Dose (tablets)*</b>
Under 24	Under 2	Ask a doctor
24-35	2-3	2
36-47	4-5	3
48-59	6-8	4
60-71	9-10	5
72-95	11	6

\*or as 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
- avoid high humidity

### **Inactive ingredients**

citric acid, crospovidone, D&C red #27 aluminum lake, D&C red #30 aluminum lake, dextrans hydrated, ethylcellulose, flavors, magnesium stearate, mannitol, polyethylene, stearic acid, sucralose

### **Questions or comments?**

**Call 1-800-426-9391**

**Principal Display Panel**

**HEALTHCARE™**

**NDC 64092-031-20**

**†Compare to the active ingredient in  
Children's Tylenol® Meltaways®**

**Children's  
ACETAMINOPHEN**

**Pain Reliever • Fever Reducer  
Aspirin Free • Ibuprofen Free**

**Rapid Tabs**

**Bubble Gum  
Flavor**

**AGES 2-6**

**20 Chewable Tablets 80 mg EACH**

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

†This product is not manufactured or distributed by  
McNeil Consumer Healthcare, owner of the registered  
trademark Children's Tylenol® Meltaways®.  
50844 REV0416E44709

Distributed by:  
Great Lakes Wholesale & Marketing L.L.C.  
3729 Patterson Ave., S.E.  
Grand Rapids, MI 49512  
[www.glwholesale.com](http://www.glwholesale.com)

**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 Area  
Lot no. & Exp. Date

HEALTHCARE GUARANTEE  
If you are not completely satisfied with this product, regardless of reason, return your unopened product to Great Lakes Wholesale for a full refund.

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

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**HEALTHCARE**

**Children's ACETAMINOPHEN**  
Pain Reliever • Fever Reducer  
Aspirin Free • Ibuprofen Free

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Drug Facts (continued)

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50844 REV0416E44709  
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www.glw.com

B-0616-447-09  
REV0416E44709

**Drug Facts (continued)**

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**Drug Facts (continued)**

- If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
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Ask a doctor before use if your child has liver disease.

Ask a doctor or pharmacist before use if your child is taking the blood thinning drug warfarin.

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DG9146A

Healthcare 44-447

CHILDRENS ACETAMINOPHEN			
acetaminophen tablet, chewable			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:64092-031
Route of Administration	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	80 mg

**Inactive Ingredients**

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ETHYLCELLULOSE, UNSPECIFIED (UNII: 7Z8S9VYZ4B)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
CROSPVIDONE, UNSPECIFIED (UNII: 2S7830E561)	

**Product Characteristics**

Color	PINK	Score	no score
Shape	ROUND	Size	13mm
Flavor	BUBBLE GUM	Imprint Code	44;447
Contains			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64092-031-20	1 in 1 CARTON	02/03/2005	11/28/2020
1		20 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	02/03/2005	11/28/2020

**Labeler** - GREAT LAKES WHOLESAL, MARKET ING, & SALES, INC. (361925498)

**Establishment**

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(64092-031)

**Establishment**

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(64092-031)

### Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	PACK(64092-031)

### Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	PACK(64092-031)

### Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	PACK(64092-031)

Revised: 1/2018

GREAT LAKES WHOLESALE, MARKETING, & SALES, INC.