PAIN RELIEVER REGULAR STRENGTH- acetaminophen tablet
Harmon Store 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.

Core Values 44-104

Active ingredient (in each tablet)

Acetaminophen 325 mg

Purpose

Pain reliever/fever reducer

Uses

- temporarily relieves minor aches and pains due to:
- headache
- the common cold
- backache
- minor pain of arthritis
- toothache
- muscular aches
- premenstrual and menstrual cramps
- temporarily reduces fever

Warnings

Liver warning: This product contains acetaminophen. The maximum daily dose of this product is 10 tablets (3,250 mg) in 24 hours for adults or 5 tablets (1,625 mg) in 24 hours for children. Severe liver damage may occur if

- adult takes more than 4,000 mg of acetaminophen in 24 hours
- child takes more than 5 doses in 24 hours, which is the maximum daily amount
- taken with other drugs containing acetaminophen
- adult has 3 or more alcoholic drinks every day while using this product

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.

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 you are allergic to acetaminophen or any of the inactive ingredients in this product

Ask a doctor before use if the user has

liver disease.

Ask a doctor or pharmacist before use if the user is

taking the blood thinning drug warfarin.

Stop use and ask a doctor if

- pain gets worse or lasts more than 10 days in adults
- redness or swelling is present
- pain gets worse or lasts more than 5 days in children under 12 years
- new symptoms occur
- fever gets worse or lasts more than 3 days

These could be signs of a serious condition.

If pregnant or breast-feeding,

ask a health professional before use.

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

- **do not take more than directed**

adults and children 12 years and over	■ take 2 tablets every 4 to 6 hours while symptoms last ■ do not take more than 10 tablets in 24 hours ■ do not take for more than 10 days unless directed by a doctor
	■ take 1 tablet every 4 to 6 hours

children 6-11 years	while symptoms last ■ do not take more than 5 tablets in 24 hours ■ do not take for more than 5 days unless directed by a doctor
children under 6 years	ask a doctor

Other information

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

Inactive ingredients

corn starch, povidone, sodium starch glycolate, stearic acid

Questions or comments?

1-800-426-9391

Principal Display Panel

COREVALUES™

Compare to active ingredient in
Tylenol® Regular Strength†

Regular Strength
Pain Reliever
Acetaminophen 325 mg
Pain Reliever/Fever Reducer

Actual Size

100 tablets

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 Tylenol® Regular Strength.

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Core Values 44-104

PAIN RELIEVER REGULAR STRENGTH

acetaminophen tablet

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63940-104
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg

Inactive Ingredients	
Ingredient Name	**Strength**
STARCH, CORN (UNII: O8232NY3SJ)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

Product Characteristics			
Color	WHITE	**Score**	2 pieces
Shape	ROUND	**Size**	10mm
Flavor		**Imprint Code**	44;104
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63940-104-12	1 in 1 CARTON	07/13/1990	
1		100 in 1 BOTTLE; 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	07/13/1990	

Labeler - Harmon Store Inc. (804085293)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	MANUFACTURE(63940-104)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(63940-104)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	PACK(63940-104)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	PACK(63940-104)

Revised: 3/2020

Harmon Store Inc.