PAIN RELIEF EXTRA STRENGTH- acetaminophen tablet Valu Merchandisers Company

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.

Best Choice 44-519

Active ingredient (in each gelcap)

Acetaminophen 500 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. Severe liver damage may occur if you take

- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 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

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

Ask a doctor before use if you have

liver disease.

Ask a doctor or pharmacist before use if you are

taking the blood thinning drug warfarin.

Stop use and ask a doctor if

- new symptoms occur
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present

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 gelcaps every 6 hours while symptoms last
 - do not take more than 6 gelcaps in 24 hours, unless directed by a doctor
 - do not take for more than 10 days unless directed by a doctor
- children under 12 years: ask a doctor

Other information

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

Inactive ingredients

croscarmellose sodium, D&C red #33, FD&C blue #1, FD&C red #40, gelatin, hydroxypropyl cellulose, hypromellose, iron oxide black, iron oxide red, iron oxide yellow, polyethylene glycol, povidone, pregelatinized starch, propylene glycol, shellac glaze, stearic acid, titanium dioxide

Questions or comments?

1-800-426-9391

Principal Display Panel

COMPARE TO THE ACTIVE INGREDIENT IN EXTRA STRENGTH TYLENOL® RAPID RELEASE GELS*

Best

Choice®

EXTRA STRENGTH

Pain Relief

ACETAMINOPHEN

Pain Reliever/Fever Reducer Contains No Aspirin **RAPID RELEASE**

100 GELCAPS 500 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 Johnson & Johnson Corporation, owner of the registered trademark Extra Strength Tylenol® Rapid Release Gels. 50844 REV0417F51912

Best Choice® 100% Guaranteed www.bestchoicebrand.com

PROUDLY DISTRIBUTED BY: VALU MERCHANDISERS, CO. 5000 KANSAS AVE KANSAS CITY, KS 66106



Best Choice 44-519

PAIN RELIEF EXTRA STRENGTH acetaminophen tablet **Product Information** HUMAN OTC DRUG NDC:63941-519 Product Type Item Code (Source) Route of Administration ORAL

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
ACETAMINO PHEN (UNII: 36209 ITL9 D) (ACETAMINO PHEN - UNII: 36209 ITL9 D)	ACETAMINOPHEN	500 mg		

Inactive Ingredients	
Ingredient Name	Strength
CROSCARMELLOSE SODIUM (UNII: M28 OL1HH48)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
HYDRO XYPRO PYL CELLULO SE, UNSPECIFIED (UNII: 9 XZ8 H6 N6 OH)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29 V3WO)	
FERROSOFERRIC OXIDE (UNII: XM0 M8 7F357)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
PO VIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
STARCH, CORN (UNII: O8232NY3SJ)	
SHELLAC (UNII: 46N107B71O)	

Product Characteristics				
Color	RED, BLUE	Score	no score	
Shape	OVAL	Size	19 mm	
Flavor		Imprint Code	L;5	
Contains				

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:63941-519- 12	1 in 1 CARTON	05/10/2004		
1		100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product			
2	NDC:63941-519- 15	1 in 1 CARTON	05/10/2004		
2		50 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	05/10/2004		

Labeler - Valu Merchandisers Company (868703513)

Establishment				
Name	Address	ID/FEI	Business Operations	
LNK International, Inc.		038154464	PACK(63941-519)	

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	MANUFACTURE(63941-519), PACK(63941-519)

Establishment				
Name	Address	ID/FEI	Business Operations	
LNK International, Inc.		967626305	PACK(63941-519)	

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	PACK(63941-519)

Revised: 7/2019 Valu Merchandisers Company