

**PAIN RELIEF EXTRA STRENGTH- acetaminophen tablet  
SUPERVALU 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.*

-----

**Equaline 44-519 - Delisted**

***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. The maximum daily dose of this product is 6 gelcaps (3,000 mg) in 24 hours. 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

**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.

**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.**

**Overdose warning:** Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. Quick 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 (see overdose warning)**
- 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: do not use this adult extra strength product in children under 12 years of age; this will provide more than the recommended dose (overdose) of acetaminophen and may cause liver damage

**Other information**

- avoid high humidity
- 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**

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?**

**1-877-932-7948**

**Principal Display Panel**

**equaline®**

compare to the active ingredient in Extra Strength Tylenol® Rapid Release Gels†

NDC 41163-519-29

**extra strength  
pain relief  
rapid release  
acetaminophen**

pain reliever/fever reducer  
fast release

actual size  
aspirin-free

150gelcaps 500 mg each

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

**DOES NOT CONTAIN GLUTEN**

†This product is not manufactured or distributed by McNeil Consumer Healthcare, owner of the registered trademark Extra Strength Tylenol® Rapid Release Gels.

50844 REV0513E51929

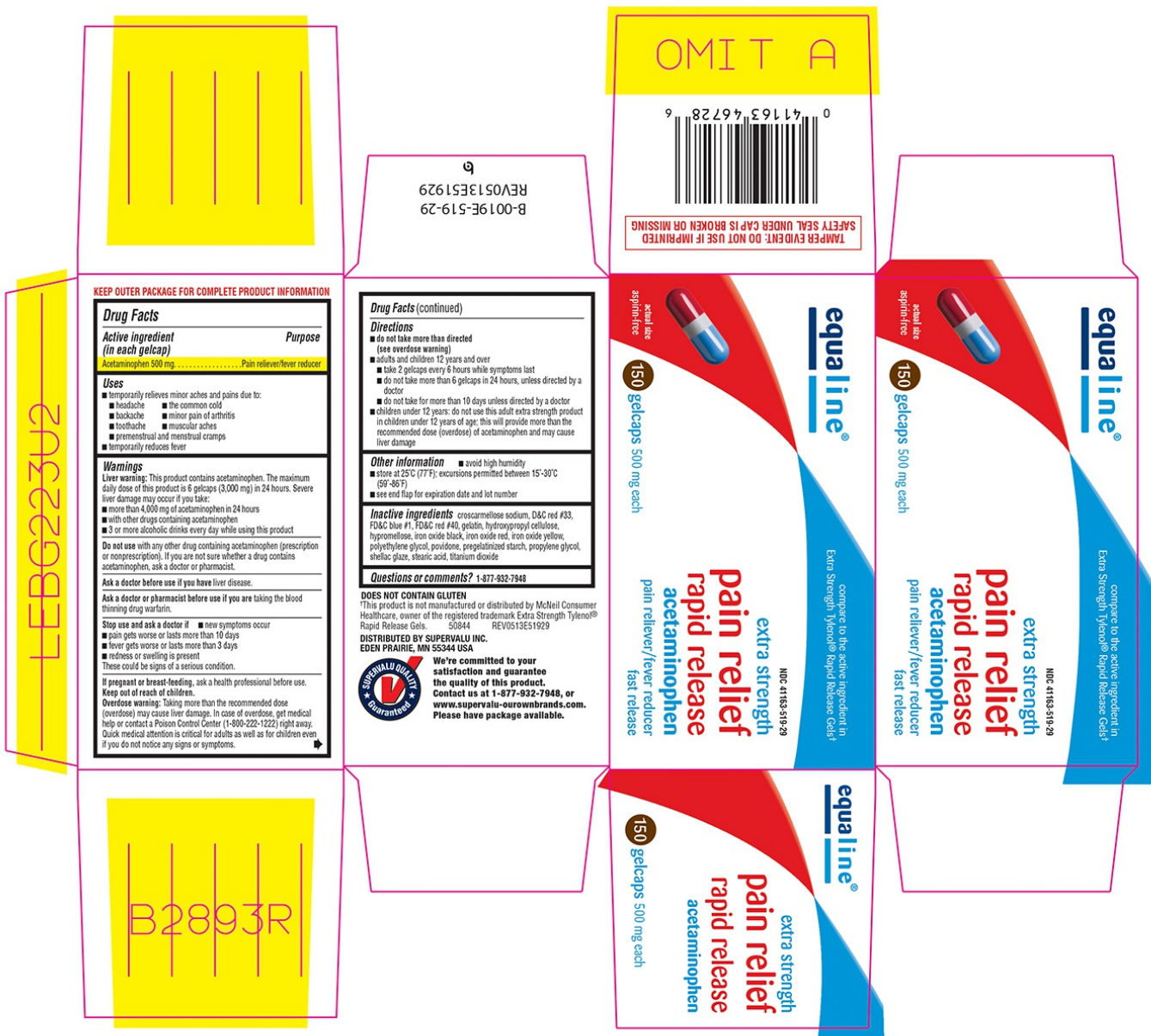
**DISTRIBUTED BY SUPERVALU INC.**

**EDEN PRAIRIE, MN 55344 USA**

**We're committed to your satisfaction and guarantee the quality of this product.**

**Contact us at 1-877-932-7948, or [www.supervalu-ourownbrands.com](http://www.supervalu-ourownbrands.com).**

**Please have package available.**



KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

**Drug Facts**

Active ingredient (in each gelcap)	Purpose
Acetaminophen 500 mg	Pain reliever/fever reducer

**Uses**

- temporarily relieves minor aches and pains due to:
  - headache
  - 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 6 gelcaps (3,000 mg) in 24 hours. 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

**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.

**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.**

**Overdose warning:** Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

**Drug Facts (continued)**

**Directions**

- do not take more than directed (see overdose warning)
- 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: do not use this adult extra strength product in children under 12 years of age; this will provide more than the recommended dose (overdose) of acetaminophen and may cause liver damage.

**Other information**

- avoid high humidity
- 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:** 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? 1-877-932-7948**

**DOES NOT CONTAIN GLUTEN**  
 †This product is not manufactured or distributed by McNeil Consumer Healthcare, owner of the registered trademark Extra Strength Tylenol® Rapid Release Gels. 50844 REV0513E51929

**DISTRIBUTED BY SUPERVALU INC.**  
 EDEN PRAIRIE, MN 55344 USA

**We're committed to your satisfaction and guarantee the quality of this product.**  
**Contact us at 1-877-932-7948, or [www.supervalu-ourownbrands.com](http://www.supervalu-ourownbrands.com).**  
**Please have package available.**



**PAIN RELIEF EXTRA STRENGTH**

acetaminophen tablet

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:41163-519
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN (UNII: 2G86QN327L)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	

**Product Characteristics**

<b>Color</b>	RED (red,gray and blue)	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	20mm
<b>Flavor</b>		<b>Imprint Code</b>	L;5
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41163-519-29	1 in 1 CARTON		
1		150 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:41163-519-08	1 in 1 CARTON		
2		24 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:41163-519-12	1 in 1 CARTON		
3		100 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:41163-519-15	1 in 1 CARTON		
4		50 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	05/10/2004	02/15/2019

**Labeler** - SUPERVALU INC. (006961411)

**Establishment**

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(41163-519)

**Establishment**

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(41163-519)

Revised: 2/2016

SUPERVALU INC.