ACETAMINOPHEN PM EXTRA STRENGTH- acetaminophen, diphenhydramine hcl 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 44-556

Active ingredients (in each gelcap)

Acetaminophen 500 mg
Diphenhydramine HCl 25 mg

Purpose

Pain reliever
Nighttime sleep-aid

Uses

temporary relief of occasional headaches and minor aches and pains with accompanying sleeplessness

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

- with any other product containing diphenhydramine, even one used on skin
- in children under 12 years of age
- 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 you have

- a breathing problem such as emphysema or chronic bronchitis
- liver disease
- glaucoma
- difficulty in urination due to enlargement of the prostate gland

Ask a doctor or pharmacist before use if you are

- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers

When using this product

- avoid alcoholic beverages
- drowsiness will occur
- do not drive a motor vehicle or operate machinery

Stop use and ask a doctor if

- sleeplessness persists continuously for more than 2 weeks. Insomnia may be a symptom of a serious underlying medical illness.
- new symptoms occur
- redness or swelling is present
- pain gets worse or lasts more than 10 days
- 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 gelcaps at bedtime
  - do not take more than 2 gelcaps of this product in 24 hours
- children under 12 years: do not use

Other information

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

Inactive ingredients

ammonium hydroxide, colloidal silicon dioxide, croscarmellose sodium, FD&C blue #1, FD&C red #3, gelatin, hydroxypropyl cellulose, hypromellose, iron oxide black, iron oxide red, iron oxide yellow, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, propylene glycol, shellac glaze, simethicone, stearic acid, titanium dioxide

Questions or comments?

1-877-932-7948

Principal Display Panel

EQUALINE®

compare to
Extra Strength Tylenol® PM
active ingredients*

NDC 41163-956-09

extra strength
acetaminophen PM gelcaps
acetaminophen 500 mg
diphenhydramine HCl 25 mg
pain reliever/nighttime sleep aid

• *non-habit forming*
• *rapid release*

20 gelcaps

actual size

DOES NOT CONTAIN GLUTEN

*This product is not manufactured or distributed by Johnson & Johnson Corporation, owner of the registered trademark Extra Strength Tylenol® PM.

100 % *Quality*
GUARANTEED

DISTRIBUTED BY SUPERVALU INC.
EDEN PRAIRIE, MN 55344 USA

877-932-7948
supervaluprivatebrands.com

50844 REV0417F55609

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

Equaline 44-556

ACETAMINOPHEN PM EXTRA STRENGTH

acetaminophen, diphenhydramine hcl tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:41163-956
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 3 (UNII: PN2ZH5LOQY)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
GELATIN (UNII: 2G86QN327L)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
STARCH, CORN (UNII: O8232NY3SJ)	
AMMONIA (UNII: 5138Q19F1X)	

Product Characteristics

Color	BLUE (Light) , BLUE (Dark)	**Score**	no score
Shape	OVAL	**Size**	20mm
Flavor		**Imprint Code**	L;6
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41163-956-09	1 in 1 CARTON	12/17/2007	
1		20 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:41163-956-10	1 in 1 CARTON	12/17/2007	
2		40 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
3	NDC:41163-956-31	1 in 1 CARTON	12/17/2007	03/17/2018

3		80 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	12/17/2007	

Labeler - SUPERVALU INC. (006961411)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(41163-956)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	PACK(41163-956)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	PACK(41163-956)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	MANUFACTURE(41163-956) , PACK(41163-956)

Revised: 3/2020 SUPERVALU INC.