# HEADACHE RELIEF PM- acetaminophen, aspirin, diphenhydramine citrate tablet, film coated Valu Merchandisers Company

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**Best Choice 44-674** 

#### Active ingredients (in each caplet)

Acetaminophen 250 mg Aspirin 250 mg (NSAID)\* Diphenhydramine citrate 38 mg \*nonsteroidal anti-inflammatory drug

#### **Purpose**

Pain reliever Pain reliever Nighttime sleep-aid

#### Uses

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

#### Warnings

**Reye's syndrome:** Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.

Allergy alert: Aspirin may cause a severe allergic reaction, which may include:

- hives
- facial swelling
- shock
- asthma (wheezing)

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

- blisters
- rash
- skin reddening

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

**Liver warning:** This product contains acetaminophen. Severe liver damage may occur if you take

• more than 4,000 mg of acetaminophen in 24 hours

- 3 or more alcoholic drinks every day while using this product
- with other drugs containing acetaminophen

**Stomach bleeding warning:** This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you

- are age 60 or older
- have 3 or more alcoholic drinks every day while using this product
- have had stomach ulcers or bleeding problems
- take other drugs containing prescription or nonprescription NSAIDs [aspirin, ibuprofen, naproxen or others]
- take more or for a longer time than directed
- take a blood thinning (anticoagulant) or steroid drug

#### Do not use

- if you have ever had an allergic reaction to acetaminophen, aspirin, or any other pain reliever/fever reducer
- 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.
- with any other product containing diphenhydramine, even one used on skin

#### Ask a doctor before use if

- stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have glaucoma
- you have asthma
- you have difficulty in urination due to enlargement of the prostate gland
- you are taking a diuretic
- · you have a breathing problem such as emphysema or chronic bronchitis
- you have liver disease
- you have high blood pressure, heart disease, liver cirrhosis, or kidney disease

# Ask a doctor or pharmacist before use if you are taking

- a prescription drug for:
  - diabetes
  - gout
  - arthritis
- any other drug, or are under a doctor's care for any serious condition
- sedatives or tranquilizers
- any product that contains aspirin, acetaminophen, or any other pain reliever/fever reducer

# When using this product

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

# Stop use and ask a doctor if

- an allergic reaction occurs. Seek medical help right away.
- you experience any of the following signs of stomach bleeding:
  - feel faint
  - vomit blood
  - have bloody or black stools
  - have stomach pain that does not get better
- ringing in the ears or a loss of hearing occurs
- pain gets worse or lasts for more than 10 days
- redness or swelling is present
- new symptoms occur
- sleeplessness persists continuously for more than 2 weeks. Insomnia may be a symptom of a serious underlying medical illness.

These could be signs of a serious condition.

#### If pregnant or breast-feeding,

ask a health professional before use. It is especially important not to use aspirin during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

#### 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 caplets at bedtime, with a full glass of water
- do not take more than 2 caplets in 24 hours, unless directed by a doctor
- children under 12 years: do not use

#### 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

## Inactive ingredients

corn starch, crospovidone, FD&C blue #1 aluminum lake, hypromellose, maltodextrin, medium chain triglycerides, microcrystalline cellulose, polydextrose, povidone, sodium lauryl sulfate, sodium starch glycolate, sodium sulfate, stearic acid, talc, titanium dioxide, yellow iron oxide, zinc stearate

#### Questions or comments?

1-800-426-9391

### **Principal Display Panel**

COMPARE TO THE ACTIVE INGREDIENTS IN EXCEDRIN® PM HEADACHET

Best Choice®

**Headache Relief PM** 

ACETAMINOPHEN
Aspirin (NSAID)
Diphenhydramine citrate
Pain Reliever/Nighttime Sleep Aid
Caffeine Free

**Actual Size** 

50 Caplets Non-Habit Forming

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

†This product is not manufactured or distributed by Novartis AG, owner of the registered trademark Excedrin® PM Headache. 50844 REV0418A67415

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

Best Choice®

100% Guaranteed

www.bestchoicebrand.com



#### **HEADACHE RELIEF PM**

acetaminophen, aspirin, diphenhydramine citrate tablet, film coated

<b>Product Information</b>			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63941-674
Route of Administration	ORAL		

#### **Active Ingredient/Active Moiety**

Ingredient Name	<b>Basis of Strength</b>	Strength
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	250 mg
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	250 mg
<b>DIPHENHYDRAMINE CITRATE</b> (UNII: 40D433S209) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE CITRATE	38 mg

Inactive Ingredients	
Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
CROSPOVIDONE, UNSPECIFIED (UNII: 2S7830E561)	
FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POVIDONE, UNSPECIFIED (UNII: FZ 989GH94E)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
SODIUM SULFATE (UNII: 0YPR65R21J)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE YELLOW (UNII: EX43802MRT)	
ZINC STEARATE (UNII: H92E6QA4FV)	

Product Characteristics				
Color	blue	Score	no score	
Shape	OVAL	Size	17mm	
Flavor		Imprint Code	674	
Contains				

F	Packaging			
#	tem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63941- 674-15	1 in 1 CARTON	08/31/2016	
1		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 Drug	M013	08/31/2016		

# **Labeler -** Valu Merchandisers Company (868703513)

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
LNK International, Inc.		038154464	pack(63941-674)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(63941-674)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(63941-674)

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
LNK International, Inc.		967626305	pack(63941-674)

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
LNK International, Inc.		117025878	manufacture(63941-674)

Revised: 11/2023 Valu Merchandisers Company