# HEADACHE RELIEF PM- acetaminophen, aspirin, diphenhydramine citrate tablet, film coated 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.

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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 in 24 hours, which is the maximum daily amount
- 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

- drowsiness may occur
- be careful when driving a motor vehicle or operating machinery
- avoid alcoholic beverages

### 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
- pain gets worse or lasts for more than 10 days
- painful area is red or swollen
- new symptoms occur

- ringing in the ears or a loss of hearing occurs
- 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 HEADACHE†

Best Choice®

**Headache Relief PM** 

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

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 REV0117A67415

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	Basis of Strength	Strength		
ACETAMINO PHEN (UNII: 36209 ITL9 D) (ACETAMINO PHEN - UNII: 36209 ITL9 D)	ACETAMINOPHEN	250 mg		
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	250 mg		
<b>DIPHENHYDRAMINE CITRATE</b> (UNII: 4OD433S209) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE CITRATE	38 mg		

Inactive Ingredients	
Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
CROSPOVIDONE, UNSPECIFIED (UNII: 2S7830E561)	
FD&C BLUE NO. 1ALUMINUM LAKE (UNII: J9EQA3S2JM)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MALTO DEXTRIN (UNII: 7CVR7L4A2D)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
MICRO CRYSTALLINE CELLULO SE (UNII: OP1R32D61U)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
PO VIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM SULFATE (UNII: 0 YPR6 5R21J)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
ZINC STEARATE (UNII: H92E6QA4FV)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

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

Packaging
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# Item Code	Package Description	Market	ing Start Date	Marketing End Date
1 NDC:63941-674-15	1 in 1 CARTON	08/31/20	16	
1	50 in 1 BOTTLE; Type 0: Not a Combination	Product		
Marketing Infe	ormation			
Marketing Info	ormation			
Marketing Info		raph Citation Mar	keting Start Date	Marketing End Date
	gory Application Number or Monog	-	keting Start Date	e Marketing End Date

## Labeler - Valu Merchandisers Company (868703513)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(63941-674)

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

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	PACK(63941-674)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	PACK(63941-674)

Revised: 11/2019 Valu Merchandisers Company