# PAIN RELIEVER PM EXTRA STRENGTH- acetaminophen, diphenhydramine hcl capsule, gelatin coated

#### **Best Choice (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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#### **Drug Facts**

#### Active ingredients (in each geltab)

#### Acetaminophen 500 mg

Diphenhydramine HCl 25 mg

#### **Purposes**

#### Pain reliever

Nighttime sleep-aid

#### Uses

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

#### **Warnings**

**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.

**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

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

#### Ask a doctor before use if you have

- liver disease
- a breathing problem such as emphysema or chronic bronchitis
- trouble urinating due to an enlarged prostate gland
- glaucoma

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

• taking the blood thinning drug warfarin

• taking sedatives or tranquilizers

#### When using this product

- drowsiness will occur
- avoid alcoholic drinks
- 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.

**Overdose warning**: In case of overdose, get medical help or contact a Poison Control Center 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 geltabs at bedtime. Do not take more than 2 geltabs of this product in 24 hours.
- children under 12 years: do not use

#### Other information

- store at 20-25°C (68-77°F)
- avoid high humidity and excessive heat

#### **Inactive ingredients**

corn starch, croscarmellose sodium\*, D&C red #27 aluminum lake, edible black ink, FD&C blue #1 aluminum lake, gelatin, glycerin, hypromellose, maltodextrin, microcrystalline cellulose, polyethylene glycol, povidone, purified water, silicon dioxide, sodium starch glycolate\*, stearic acid, titanium dioxide

\*contains one or more of these ingredients

#### **Questions or comments?**

Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

#### **Principal Display Panel**

COMPARE TO THE ACTIVE INGREDIENTS IN EXTRA STRENGTH TYLENOL® PM†

#### **EXTRA STRENGTH**

#### **PAIN RELIEF PM**

#### **ACETAMINOPHEN 500 mg**

DIPHENHYDRAMINE HCl 25 mg

PAIN RELIEVER / NIGHTTIME SLEEP-AID

#### **GELTABS**

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

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

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION PROUDLY DISTRIBUTED BY:

VALU MERCHANDISERS, CO.

KANSAS CITY, KS 66106

www.bestchoicebrand.com

#### **Product Label**

Exp. Date:

ot No.:

PLD-F30S FC002794

0 70038 BEST CHOICE 583 W

trouble uninating due to an enlarged prostate gland

Purposes

Active ingredients

**Drug Facts** 

(in each geltab)

Ask a doctor or pharmacist before use if you are

 taking the blood thinning drug warfarin taking sedatives or tranquilizers

....Nighttime sleep-aid

Diphenhydramine HCl 25 mg.

do not drive a motor vehicle or operate machinery

underlying medical illness.

f a skin reaction occurs, stop use and seek medical help

■ skin reddening
■ blisters
■ rash

reactions. Symptoms may include:

Liver warning: This product contains acetaminophen.

ight away.

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

contains one or more of these ingredients

titanium dioxide

Questions or comments?

new symptoms occur

pain gets worse or lasts more than 10 days

If pregnant or breast-feeding, ask a health professional

before use.

Keep out of reach of children.

do not take more than directed (see overdose

in 24 hours.

# Orug Facts (continued)

children under 12 years: do not use

Orug Facts (continued)

When using this product

drowsiness will occur

minor aches and pains with accompanying sleeplessness

Warnings Allergy alert: Acetaminophen may cause severe skin

temporary relief of occasional headaches and

avoid alcoholic drinks

edible black ink, FD&C blue #1 aluminum lake, gelatin cellulose, polyethylene glycol, povidone, purified water

croscarmellose sodium\*, D&C red #27 aluminum lake glycerin, hypromellose, maltodextrin, microcrystalline silicon dioxide, sodium starch glycolate", stearic acid,

Inactive ingredients com starch,

avoid high humidity and excessive heal

store at 20-25°C (68-77°F) Other information

Stop use and ask a doctor if

sleeplessness persists continuously for more than

2 weeks. Insomnia may be a symptom of a serious

redness or swelling is present

fever gets worse or lasts more than 3 days

These could be signs of a serious condition

3 or more alcoholic drinks every day while using this

 with other drugs containing acetaminophen Severe liver damage may occur if you take:

Consumer Healthcare, distributor of Extra Strength Tylenol® PM This product is not manufactured or distributed by McNeil Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

Best Choice, 100% Guaranteed

www.bestchoicebrand.con

away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms Overdose warning: In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) righ

whether a drug contains acetaminophen, ask a doctor or

(prescription or nonprescription). If you are not sure

with any other drug containing acetaminophen

Do not use

product

with any other product containing diphenhydramine.

pharmacist

even one used on skin

# Directions

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY

KANSAS CITY, KS 66106

SEAL UNDER CAP IS BROKEN OR MISS

VALU MERCHANDISERS, CO. PROUDLY DISTRIBUTED BY

5000 KANSAS AVE

WARNINGS AND PRODUCT INFORMATION KEEP OUTER CARTON FOR COMPLETE

bedtime. Do not take more than 2 geltabs of this product adults and children 12 years and over: take 2 geltabs at

 a breathing problem such as emphysema or chronic Ask a doctor before use if you have ■ in children under 12 years of age liver disease Best Choice®

bronchitis

STRENGTH Relief PM

ACETAMINOPHEN 500 mg DIPHENHYDRAMINE HCI 25 mg PAIN RELIEVER / NIGHTTIME SLEEP-AID

**Geltabs** 



#### Best Choice Extra Strength Pain Relief PM Geltabs

#### PAIN RELIEVER PM EXTRA STRENGTH

acetaminophen, diphenhydramine hcl capsule, gelatin coated

Product Information
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Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63941-231
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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
<b>DIPHENHYDRAMINE HYDRO CHLO RIDE</b> (UNII: TC2D6JAD40) (DIPHENHYDRAMINE UNII:8GTS82S83M)	- DIPHENHYDRAMINE HYDROCHLORIDE	25 mg

Inactive Ingredients		
Ingredient Name	Strength	
STARCH, CORN (UNII: O8232NY3SJ)		
CROSCARMELLOSE SODIUM (UNII: M28 O L1HH48)		
<b>D&amp;C RED NO. 27</b> (UNII: 2LRS185U6K)		
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)		
GELATIN (UNII: 2G86QN327L)		
GLYCERIN (UNII: PDC6A3C0OX)		
HYPROMELLOSES (UNII: 3NXW29V3WO)		
MALTO DEXTRIN (UNII: 7CVR7L4A2D)		
CELLULO SE, MICRO CRYSTALLINE (UNII: OP1R32D61U)		
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)		
PO VIDO NE (UNII: FZ989 GH94E)		
WATER (UNII: 059QF0KO0R)		
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)		
STEARIC ACID (UNII: 4ELV7Z65AP)		
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)		
ALUMINUM O XIDE (UNII: LMI26 O 69 33)		
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)		

Product Characteristics			
Color	BLUE, WHITE	Score	no score
Shape	ROUND	Size	13mm
Flavor		Imprint Code	BPI50
Contains			

kaging	

# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:63941-231- 50	1 in 1 BOX	03/08/2013	
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 FINAL	part341	03/08/2013	

### Labeler - Best Choice (Valu Merchandisers Company) (868703513)

Revised: 10/2018 Best Choice (Valu Merchandisers Company)