EXTRA STRENGTH PAIN RELIEF PM- acetaminophen and diphenhydramine hydrochloride tablet
Spirit Pharmaceutical LLC

EXTRA STRENGTH PAIN RELIEF PM

Drug Facts

Active ingredients (in each caplet)	***Purpose***
Acetaminophen 500mg	Pain reliever
Diphenhydramine HCl 25mg	Nighttime Sleep aid

Uses

for the 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 with this product 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 you are 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 other products containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist
- in children under 12 years of age
- with any other products containing diphenhydramine, even one used on skin
- if you are allergic to acetaminophen or any of the inactive ingredients in this product

Ask a doctor before use if you have

- liver disease

- breathing problems such as emphysema or chronic bronchitis
- trouble urinating due to an enlargement of the 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
- pain gets worse or lasts for more than 10 days
- fever gets worse or lasts more than 3 days
- new symptoms occur
- 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 directed dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

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 of age and over:	▪ take 2 caplets at bedtime or as directed by a doctor ▪ do not take more than 2 caplets in a 24 hour period
children under 12 years of age:	▪ do not use this adult product in children under 12 years of age. This will provide more than the recommended dose (overdose)

	and may cause liver damage

Other information

- **each caplet contains:** magnesium 0.05 mg
- store between 20°-25°C (68°-77°F)
- see end panel for lot number and expiration

Inactive ingredients

FD&C blue # 1, FD&C blue # 2, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol-400, povidone, pregelatinized starch, stearic acid, titanium dioxide

Questions or comments?

1-888-333-9792

DISTRIBUTED BY:

SPIRIT PHARMACEUTICALS, LLC.

RONKONKOMA, NY 11779

Principal display panel

VALUMEDS™

SEE NEW WARNINGS INFORMATION

Compare to the active ingredients in

EXTRA STRENGTH TYLENOL®PM*

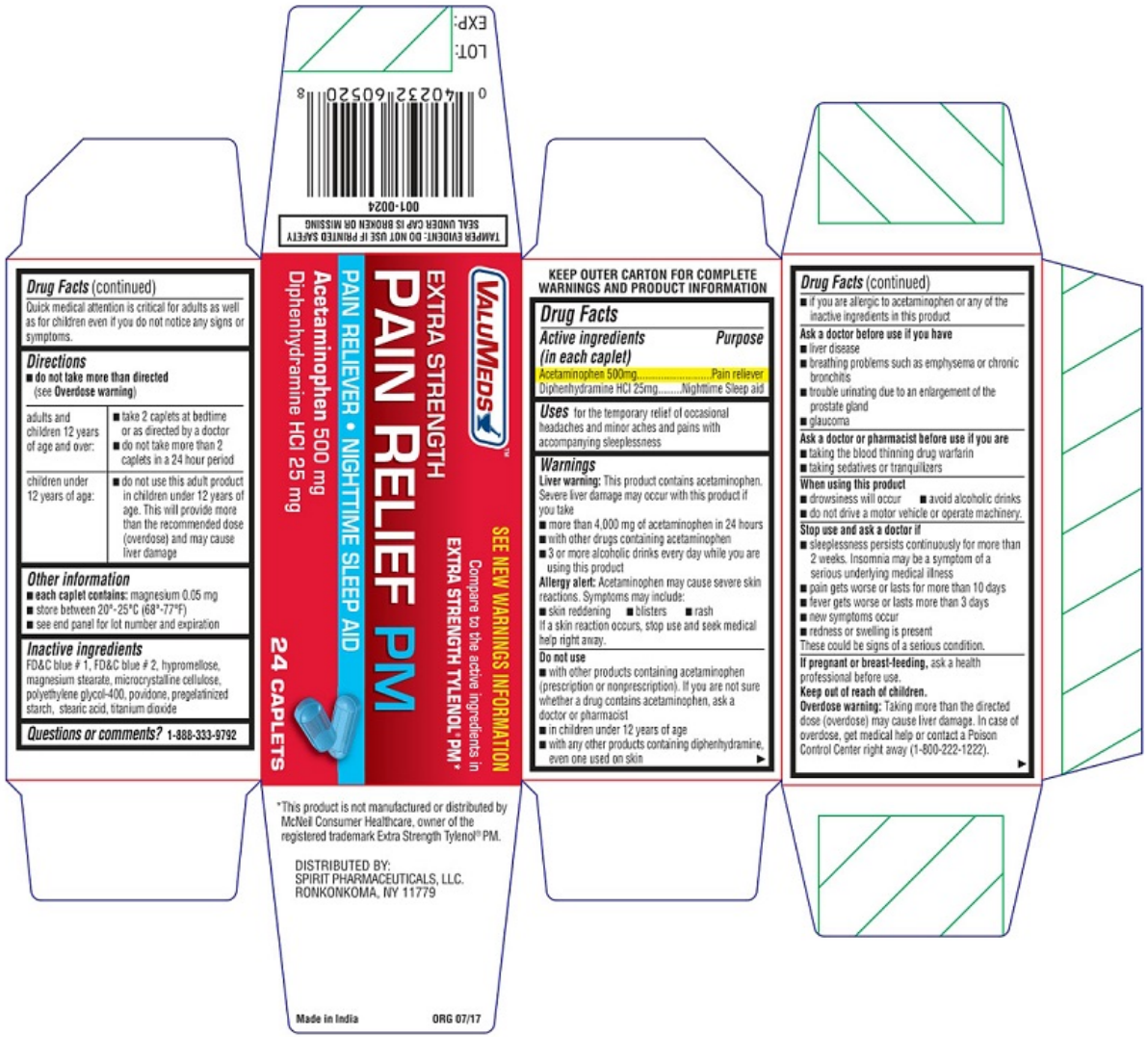
EXTRA STRENGTH

PAIN RELIEF PM

PAIN RELIEVER NIGHTTIME SLEEP AID

Acetaminophen 500 mg

Diphenhydramine HCl 25 mg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TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING
Drug Facts (continued)
Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.
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Questions or comments? 1-888-333-9792
ValuMeds
EXTRA STRENGTH
PAIN RELIEF PM
PAIN RELIEVER • NIGHTTIME SLEEP AID
Acetaminophen 500 mg
Diphenhydramine HCl 25 mg
24 CAPLETS
SEE NEW WARNINGS INFORMATION
Compare to the active ingredients in EXTRA STRENGTH TYLENOL® PM*
*This product is not manufactured or distributed by McNeil Consumer Healthcare, owner of the registered trademark Extra Strength Tylenol® PM.
DISTRIBUTED BY:
SPIRIT PHARMACEUTICALS, LLC.
RONKONKOMA, NY 11779
Made in India
ORG 07/17
KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION
Drug Facts
Active ingredients (in each caplet) Purpose
Acetaminophen 500mg.....Pain reliever
Diphenhydramine HCl 25mg.....Nighttime Sleep aid
Uses for the temporary relief of occasional headaches and minor aches and pains with accompanying sleeplessness
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Liver warning: This product contains acetaminophen. Severe liver damage may occur with this product 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 you are 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 other products containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist
■ in children under 12 years of age
■ with any other products containing diphenhydramine, even one used on skin ▶
Drug Facts (continued)
■ if you are allergic to acetaminophen or any of the inactive ingredients in this product
Ask a doctor before use if you have
■ liver disease
■ breathing problems such as emphysema or chronic bronchitis
■ trouble urinating due to an enlargement of the 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
■ pain gets worse or lasts for more than 10 days
■ fever gets worse or lasts more than 3 days
■ new symptoms occur
■ 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 directed dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). ▶

Drug Facts (continued)

■ fever gets worse or lasts more than 3 days
■ redness or swelling is present ■ new symptoms occur
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 right away. (1-800-222-1222) 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 recommended** (see **Overdose warning**)

adults and children 12 years and over	■ take 2 caplets at bedtime ■ do not take more than 2 caplets of this product in 24 hours
children under 12 years	do not use this adult product in children under 12 years of age; this will provide more than the recommended dose (overdose) and may cause liver damage

Other information

■ **each caplet contains:** magnesium 0.05 mg
■ store between 20-25°C (68-77°F)

Inactive ingredients

FD&C Blue # 1, FD&C Blue # 2, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, pregelatinized starch, povidone K-30, purified water, stearic acid, titanium dioxide

Questions or comments? 1-888-333-9792

ValuMeds™

Compare to the active ingredients in Tylenol® PM†

EXTRA STRENGTH

PAIN RELIEF PM

Acetaminophen 500 mg
Diphenhydramine HCl 25 mg

pain reliever
nighttime sleep aid

375 CAPLETS

Actual Size

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

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■ 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 other products containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist
■ with any product containing diphenhydramine, even one used on skin
■ in children under 12 years of age
■ if you have ever had an allergic reaction to this product or any of its ingredients

Ask a doctor before use if you have
■ liver disease
■ breathing problems 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
■ pain gets worse or lasts for more than 10 days

Drug Facts (continued under label)

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

Distributed By:
Spirit Pharmaceuticals, LLC
Ronkonkoma, NY 11779
ORIG 06/18

Made in India

ITEM#68923-9

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PEEL HERE

LOT:

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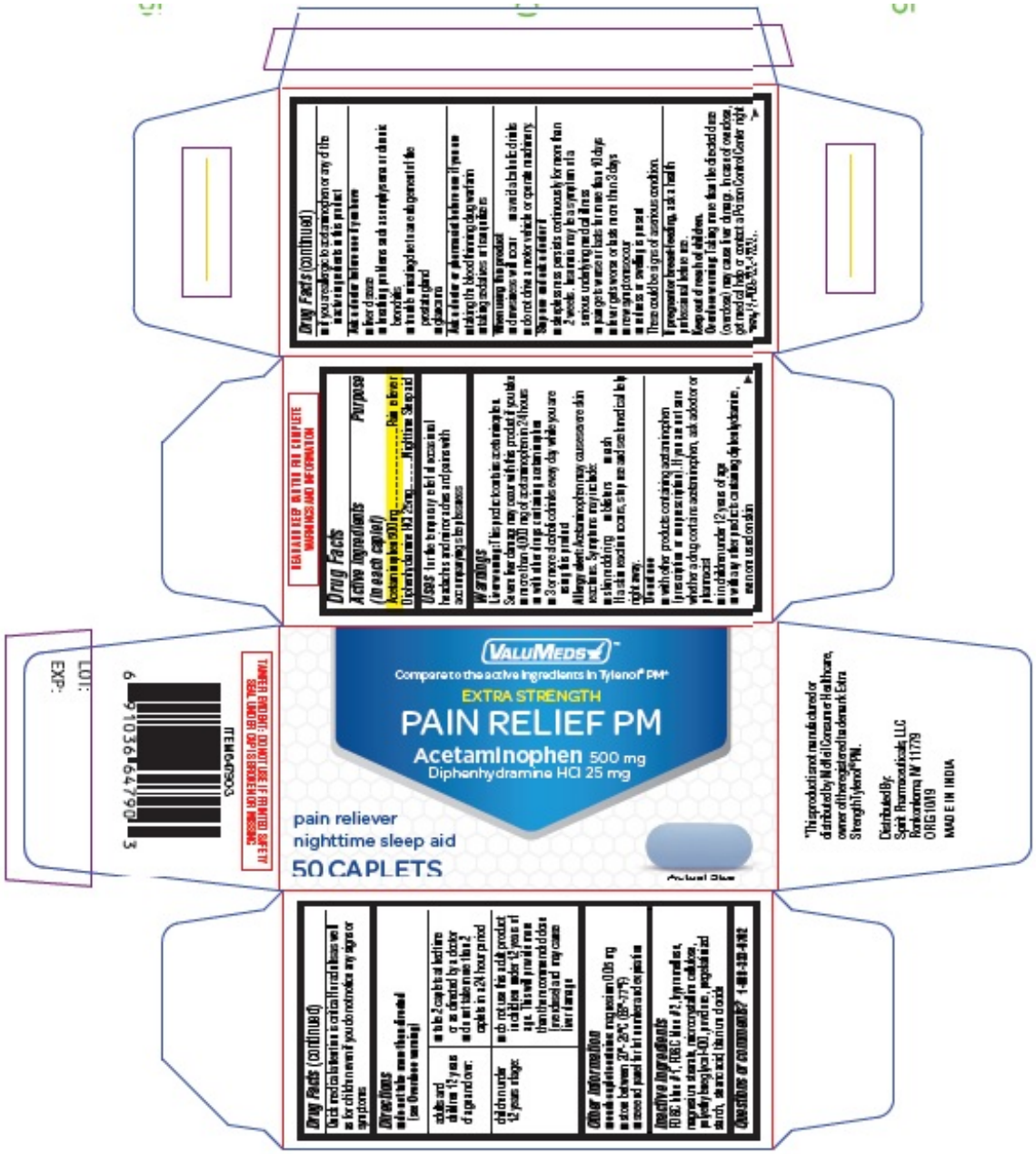

EXTRA STRENGTH PAIN RELIEF PM

acetaminophen and diphenhydramine hydrochloride tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68210-0099
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
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
HYPROMELLOSE 2208 (15000 MPA.S) (UNII: Z78RG6M2N2)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
STARCH, CORN (UNII: O8232NY3SJ)	
POVIDONE K30 (UNII: U725QWY32X)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	blue	**Score**	no score
Shape	OVAL	**Size**	18mm
Flavor		**Imprint Code**	S525
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68210-0099-2	1 in 1 CARTON	04/11/2018	
1		24 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:68210-0099-3	1 in 1 CARTON	04/11/2018	
2		50 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:68210-0099-5	375 in 1 PACKAGE; Type 0: Not a Combination Product	03/12/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	04/10/2018	

Labeler - Spirit Pharmaceutical LLC (179621011)

Revised: 12/2023 Spirit Pharmaceutical LLC