ACETAMINOPHEN AND DIPHENHYDRAMINE HYDROCHLORIDE- acetaminophen and diphenhydramine hydrochloride tablet, film coated
J.P. BUSINESS ENTERPRISE

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.

ACETAMINOPHEN AND DIPHENHYDRAMINE HCL TABLETS

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 2 caplets in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while you are using this product

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 cirrhosis
- asthma
- breathing problems such as emphysema or chronic bronchitis
- trouble in 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 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 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 or 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

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

Inactive ingredients

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

Questions or comments?

1-888-333-9792

Distributed By: J.P Business Enterprise Lake Grove, NY 11755

PRINCIPAL DISPLAY PANEL - 24 Caplet Bottle Carton

VALUMEDS

SEE NEW WARNINGS INFORMATION

Compare to the active ingredients
in **TYLENOL ® PM ***

EXTRA STRENGTH

PAIN RELIEF PM

PAIN RELIEVER • NIGHTTIME SLEEP AID

Acetaminophen 500 mg
Diphenhydramine HCl 25 mg

24 CAPLETS

OMPLETE
ORMATION

Purpose

.....Pain reliever
httime Sleep aid

nal headaches
ying

minophen.
oduct if you take
s the maximum

hen
ile you are

ing
iption).
s
t

hydramine,

y of the

▶

Drug Facts (continued)

- breathing problems such as emphysema or chronic bronchitis
- trouble in 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 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. ▶

Drug Facts (continued)

Directions

- **do not take more than recommended** (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 or 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

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

Inactive ingredients

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

Questions or comments? 1-888-333-9792

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

Distributed By: J.P Business Enterprise
Lake Grove, NY 11755

ORIG 2/13

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 TYLENOL® PM*

KEEP OUTER CARTON FOR C
WARNINGS AND PRODUCT INF

Drug Facts

Active ingredients
(in each caplet)

Acetaminophen 500mg.....
Diphenhydramine HCl 25mg.....Mg

Uses for the temporary relief of occasio
and minor aches and pains with accompan
sleeplessness

Warnings

Liver warning: This product contains aceta
Severe liver damage may occur with this pr
- more than 2 caplets in 24 hours, which i
daily amount
- with other drugs containing acetaminopt
- 3 or more alcholic drinks every day whi
using this product

Do not use ■ with other products containi
acetaminophen (prescription or nonprescri
If you are not sure whether a drug contains
acetaminophen, ask a doctor or pharmacis
- in children under 12 years of age
- with any other products containing dipher
even one used on skin
- if you are allergic to acetaminophen or an
inactive ingredients in this product

Ask a doctor before use if you have
■ liver cirrhosis ■ asthma

VALUMEDS

EXTRA STRENGTH

PAIN RELIEF PM

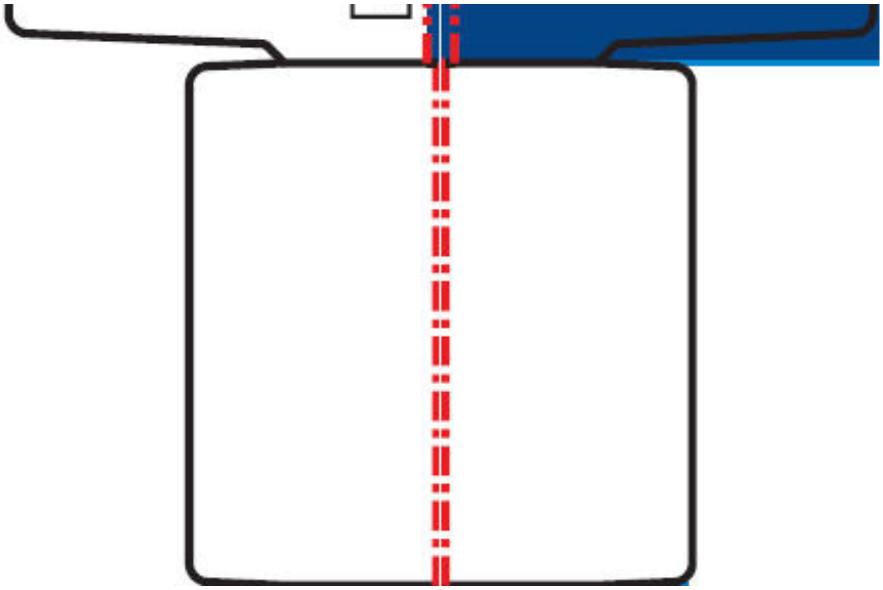
PAIN RELIEVER • NIGHTTIMESLEEP AID

Acetaminophen 500 mg
Diphenhydramine HCl 25 mg

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

0 40232 00471 1

LOT:
EXP:



ACETAMINOPHEN AND DIPHENHYDRAMINE HYDROCHLORIDE

acetaminophen and diphenhydramine hydrochloride tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:59105-001
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**
HYPROMELLOSES (UNII: 3NXW29V3WO)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POVIDONE K30 (UNII: U725QWY32X)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

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:59105-001-24	1 in 1 CARTON	08/20/2013	
1		24 in 1 BOTTLE; 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	08/20/2013	

Labeler - J.P. BUSINESS ENTERPRISE (078775890)

Establishment

Name	Address	ID/FEI	Business Operations
ELYSIUM PHARMACEUTICALS LTD		915664486	manufacture(59105-001)

Revised: 12/2019 J.P. BUSINESS ENTERPRISE