

NIGHTTIME SLEEP-AID NON-HABIT FORMING- diphenhydramine hci liquid
AptaPharma Inc.

Nighttime Sleep-Aid

Drug Facts

Active ingredient

(in each 30 mL dose cup or 2 tablespoons)

Diphenhydramine HCl 50 mg

Purpose

Nighttime sleep-aid

Uses

- reduces time to fall asleep if you have difficulty falling asleep
- for relief of occasional sleeplessness

Warnings

Do not use ■ for children under 12 years of age.

■ with any other product containing diphenhydramine, even one used on skin

■ with any other drugs that cause drowsiness such as antihistamines and nighttime cough, cold/flu products

Ask a doctor before use if you have

- heart disease
- trouble urinating due to enlarged prostate gland
- glaucoma
- a breathing problem such as asthma, emphysema or chronic bronchitis

Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers or any other sleep aid

When using this product

- do not use more than directed
- avoid alcoholic beverages and other drugs that cause drowsiness
- drowsiness will occur
- be careful when driving a motor vehicle or operating machinery
- alcohol, sedatives, and tranquilizers may increase drowsiness

Stop use and ask a doctor if

■ sleeplessness persists continuously for more than 2 weeks.
Insomnia may be a symptom of serious underlying medical illness.

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- take only as recommended
- Use dosage cup or tablespoon

Age	Dose
Adults & children 12 years & over	One Dose = 2 tablespoons (30 mL) at bed time if needed or as directed by a doctor

Other information

- each 30 mL dose (2 tablespoons) contains: sodium 23 mg
- dosage cup provided
- store at room temperature

Inactive ingredients

citric acid, FD&C Blue #1, FD&C Red #40, flavor, high fructose corn syrup, poloxamer 407, propylene glycol, purified water, sodium benzoate, sodium citrate, sodium saccharin

Questions? Call weekdays from 9:30 AM to 4:30 PM EST at
1-877-798-5944

Nighttime Sleep-Aid Label

NDC 76281-522-28

AP SAFE

***COMPARE TO the
active ingredient in ZzzQUIL™
NIGHTTIME SLEEP-AID**

**Nighttime
Sleep-Aid**

Diphenhydramine HCl

**Non-Habit Forming
Not for treating Cold or Flu**

**Warming Berry
Flavored Liquid**

12 FL OZ (354 mL)

DO NOT USE IF IMPRINTED SHRINK BAND IS MISSING OR BROKEN

Failure to follow these warnings could result in serious consequences

Drug Facts

Active ingredient

Purpose

(in each 30 mL dose cup or 2 tablespoons)

Diphenhydramine HCl 50 mg.....Nighttime sleep-aid

Uses

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Drug Facts(continued)

Directions

- take only as recommended
- Use dosage cup or tablespoon

Age	Dose
Adults & children 12	One Dose = 2 tablespoons (30 mL) at bed

years & over

time if needed or as directed by a doctor

Other information

- each 30 mL dose (2 tablespoons) contains: sodium 23 mg
- dosage cup provided
- store at room temperature

Inactive ingredients

citric acid, FD&C Blue #1, FD&C Red #40, flavor, high fructose corn syrup, poloxamer 407, propylene glycol, purified water, sodium benzoate, sodium citrate, sodium saccharin

Questions? Call weekdays from 9:30 AM to 4:30 PM EST at **1-877-798-5944**

*This product is not manufactured or distributed by Procter & Gamble, owner of the registered trademark ZzzQuil™

**Manufactured by: Aptapharma Inc.,
1533 Union Ave.,
Pennsauken, NJ 08110**

AP-LR-10

Drug Facts (continued)	
Directions ■ take only as recommended ■ use dosage cup or tablespoon	
Age	Dose
Adults & children 12 years & over	One Dose = 2 tablespoons (30 mL) at bed time if needed or as directed by a doctor
Other information ■ each 30 mL dose (2 tablespoons) contains: sodium 23 mg ■ dosage cup provided ■ store at room temperature	
Inactive ingredients citric acid, FD&C Blue #1, FD&C Red #40, flavor, high fructose corn syrup, poloxamer 407, propylene glycol, purified water, sodium benzoate, sodium citrate, sodium saccharin	
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Pennsauken, NJ 08110
AP-LR-10



NDC 76281-522-28

*COMPARE TO the active ingredient in ZzzQUIL™
NIGHTTIME SLEEP-AID

Nighttime Sleep-Aid

Diphenhydramine HCl

Non-Habit Forming
Not for treating Cold or Flu

Warming Berry Flavored Liquid



12 FL OZ (354 mL)

Drug Facts	
Active ingredient (in each 30 mL dose cup or 2 tablespoons) Diphenhydramine HCl 50 mg	
Purpose Nighttime sleep-aid	
Uses ■ reduces time to fall asleep if you have difficulty falling asleep ■ for relief of occasional sleeplessness	
Warnings Do not use ■ for children under 12 years of age. ■ with any other product containing diphenhydramine, even one used on skin ■ with any other drugs that cause drowsiness such as antihistamines and nighttime cough, cold/flu products Ask a doctor before use if you have ■ heart disease ■ trouble urinating due to an enlarged prostate gland ■ glaucoma ■ a breathing problem such as asthma, emphysema or chronic bronchitis Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers or any other sleep aid When using this product ■ do not use more than directed ■ avoid alcoholic beverages and other drugs that cause drowsiness ■ drowsiness will occur ■ be careful when driving a motor vehicle or operating machinery ■ alcohol, sedatives, and tranquilizers may increase drowsiness Stop use and ask a doctor if ■ sleeplessness persists continuously for more than 2 weeks. Insomnia may be a symptom of serious underlying medical illness. If pregnant or breast-feeding , ask a health professional before use. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.	

Drug Facts (continued)	
Directions	
<ul style="list-style-type: none"> take only as recommended use dosage cup or tablespoon 	
Age	Dose
Adults & children 12 years & over	One Dose = 2 tablespoons (30 mL) at bed time if needed or as directed by a doctor
Other information	
<ul style="list-style-type: none"> each 30 mL dose (2 tablespoons) contains: sodium 23 mg dosage cup provided store at room temperature 	
Inactive ingredients	
citric acid, FD&C Blue #1, FD&C Red #40, flavor, high fructose corn syrup, poloxamer 407, propylene glycol, purified water, sodium benzoate, sodium citrate, sodium saccharin	
Questions? Call weekdays from 9:30 AM to 4:30 PM EST at 1-877-789-5944	

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Manufactured by: AptaPharma Inc.,
1533 Union Ave.,
Pennsauken, NJ 08110

AP-LR-10



NDC 76281-522-28

***COMPARE TO the active ingredient in ZzzQUIL™ NIGHTTIME SLEEP-AID**

Nighttime Sleep-Aid

Diphenhydramine HCl

Non-Habit Forming
Not for treating Cold or Flu

Warming Berry Flavored Liquid

12 FL OZ (354 mL)

DO NOT USE IF IMPRINTED SHRINK BAND IS MISSING OR BROKEN

Failure to follow these warnings could result in serious consequences

Drug Facts	
Active ingredient	Purpose
(in each 30 mL dose cup or 2 tablespoons) Diphenhydramine HCl 50 mg	Nighttime sleep-aid
Uses	
<ul style="list-style-type: none"> reduces time to fall asleep if you have difficulty falling asleep for relief of occasional sleeplessness 	
Warnings	
<p>Do not use</p> <ul style="list-style-type: none"> for children under 12 years of age. with any other product containing diphenhydramine, even one used on skin with any other drugs that cause drowsiness such as antihistamines and nighttime cough, cold/flu products <p>Ask a doctor before use if you have</p> <ul style="list-style-type: none"> heart disease trouble urinating due to an enlarged prostate gland glaucoma a breathing problem such as asthma, emphysema or chronic bronchitis <p>Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers or any other sleep aid</p> <p>When using this product</p> <ul style="list-style-type: none"> do not use more than directed avoid alcoholic beverages and other drugs that cause drowsiness drowsiness will occur be careful when driving a motor vehicle or operating machinery alcohol, sedatives, and tranquilizers may increase drowsiness <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> sleeplessness persists continuously for more than 2 weeks. <p>Insomnia may be a symptom of serious underlying medical illness.</p> <p>If pregnant or breast-feeding, ask a health professional before use.</p> <p>Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.</p>	

6 OZ

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Active ingredient *Purpose*
(in each 30 mL dose cup or 2 tablespoons)
Diphenhydramine HCl 50 mg Nighttime sleep-aid

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Ask a doctor before use if you have

■ heart disease ■ trouble urinating due to an enlarged prostate gland ■ glaucoma ■ a breathing problem such as asthma, emphysema or chronic bronchitis



NDC 75281-522-25

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active ingredient in ZzzQuil™
NIGHTTIME SLEEP-AID

Nighttime Sleep-Aid

Diphenhydramine HCl

Non-Habit Forming
Not for treating Cold or Flu

Warming Berry
Flavored Liquid



6 FL OZ (177 mL)

Drug Facts (continued)

Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers or any other sleep aid

When using this product

- do not use more than directed
- avoid alcoholic beverages and other drugs that cause drowsiness
- drowsiness will occur
- be careful when driving a motor vehicle or operating machinery
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Stop use and ask a doctor if

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Manufactured by: AptaPharma Inc., Made in USA
1533 Union Ave. AP-18-17
Pennsauken, NJ 08110



PEEL HERE

EXP.

LOT.

Drug Facts (continued)

If pregnant or breast-feeding, ask a health professional before use. **Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- take only as recommended
- use dosage cup or tablespoon

Age	Dose
Adults & children 12 years & over	One Dose = 2 tablespoons (30 mL) at bed time if needed or as directed by a doctor

Other information

- each 30 mL dose (2 tablespoons) contains: sodium 23 mg
- dosage cup provided
- store at room temperature

Inactive ingredients

citric acid, FD&C Blue #1, FD&C Red #40, flavor, high fructose corn syrup, poloxamer 407, propylene glycol, purified water, sodium benzoate, sodium citrate, sodium saccharin

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NDC 76281-522-25

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NIGHTTIME SLEEP-AID

Nighttime Sleep-Aid

Diphenhydramine HCl

Non-Habit Forming

Not for treating Cold or Flu

Warming Berry
Flavored Liquid

6 FL OZ (177 mL)



Drug Facts (continued)

Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers or any other sleep aid

When using this product

■ do not use more than directed
■ avoid alcoholic beverages and other drugs that cause drowsiness
■ drowsiness will occur
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PEEL HERE

EXP.

LOT.

Drug Facts (continued)

If pregnant or breast-feeding, ask a health professional before use. **Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

■ take only as recommended
■ use dosage cup or tablespoon

Age	Dose
Adults & children 12 years & over	One Dose = 2 tablespoons (30 mL) at bed time if needed or as directed by a doctor

Other information

■ each 30 mL dose (2 tablespoons) contains:
sodium 23 mg
■ dosage cup provided
■ store at room temperature

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4 OZ

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(in each 30 mL dose cup or 2 tablespoons)
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■ heart disease ■ trouble urinating due to an enlarged prostate gland ■ glaucoma ■ a breathing problem such as asthma, emphysema or chronic bronchitis

Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers or any other sleep aid

When using this product ■ do not use more than directed
■ avoid alcoholic beverages and other drugs that cause drowsiness ▶



NDC 76281-522-24

*COMPARE TO the
active ingredient in ZzzQUIL™
NIGHTTIME SLEEP-AID

Nighttime Sleep-Aid

Diphenhydramine HCl

Non-Habit Forming
Not for treating Cold or Flu

Warming Berry
Flavored Liquid

4 FL OZ (118 mL)



Drug Facts (continued)

■ drowsiness will occur
■ be careful when driving a motor vehicle or operating machinery
■ alcohol, sedatives, and tranquilizers may increase drowsiness

Stop use and ask a doctor if

■ sleeplessness persists continuously for more than 2 weeks. Insomnia may be a symptom of serious underlying medical illness.

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Made in USA

AP-LR-21

Manufactured by: AptaPharma Inc.,
1533 Union Ave.
Pennsauken, NJ 08110



EXP.

LOT.

PEEL HERE

Drug Facts (continued)

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

■ take only as recommended
■ use dosage cup or tablespoon

Age	Dose
Adults & children 12 years & over	One Dose = 2 tablespoons (30 mL) at bed time if needed or as directed by a doctor

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Drug Facts

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Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers or any other sleep aid

When using this product ■ do not use more than directed
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NDC 76281-522-24

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NIGHTTIME SLEEP-AID

Nighttime Sleep-Aid

Diphenhydramine HCl

Non-Habit Forming
Not for treating Cold or Flu

Warming Berry
Flavored Liquid

4 FL OZ (118 mL)



Drug Facts (continued)

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■ be careful when driving a motor vehicle or operating machinery
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Made in USA

AP-UR-21

Manufactured by: AptaPharma Inc.,
1533 Union Ave.
Pennsauken, NJ 08110



EXP.

LOT.

PEEL HERE

Drug Facts (continued)

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NIGHTTIME SLEEP-AID NON-HABIT FORMING

diphenhydramine hci liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76281-522
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	50 mg in 30 mL

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76281-522-28	354 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2018	
2	NDC:76281-522-25	177 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2018	
3	NDC:76281-522-24	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	01/01/2018	

Labeler - Aptapharma Inc. (790523323)

Registrant - Aptapharma Inc. (790523323)

Establishment

Name	Address	ID/FEI	Business Operations
Aptapharma Inc.		790523323	manufacture(76281-522)

Revised: 12/2023

Aptapharma Inc.