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

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.

Nighttime Sleep-Aid

Drug Facts

Active ingredient

(in each 30 mL dose cup or 2 tablespoons)
Diphenhydramine HCI 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 prostrate 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 HCI

Non-Habit Forming
Not for treating Cold or Flu

Warming Berry Flavored Liquid

12 FL OZ (354 mL)

DO NOTUSE IF IMPRINTEDSHRINK BAND IS MISSING OR BROKEN
Failure to follow these warnings could result in serious consequences

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Drug Facts(continued)

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*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

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	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	01/01/2018	

Labeler - AptaPharma Inc. (790523323)

Registrant - AptaPharma Inc. (790523323)

Establishment

Name	Address	ID/FEI	Business Operations
AptaPharma Inc.		790523323	manufacture(76281-522) , pack(76281-522) , label(76281-522)

Revised: 3/2018 AptaPharma Inc.