NYTOL- diphenhydramine hcl tablet
Medtech Products 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.

Nytol

Drug Facts

Active Ingredient

Diphenhydramine HCl, 25 mg

Purpose

Nighttime sleep-aid

Use

relieves occasional sleeplessness

Warnings

Do not use

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

Ask a doctor or pharmacist before use if you are

taking sedatives or tranquilizers

Ask a doctor before use if you have

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

When using this product

- avoid alcoholic beverages
- be careful when driving a moter vehicle or operating machinery

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 care professional before use.

Keep out of reach of children.

In case of overdose, gret medical help or contact a Poison Control center (1-800-222-1222) right away.

Directions

- **adults and children 12 years of age and over:** take 2 caplets (50 mg) at bedtime if needed, or as directed by a doctor
- **children under 12 years:** do not use

Other information

- each caplot contains: c**alcium 12 mg**
- store at 20°-25°C (68°-77°F)

Inactive ingredients

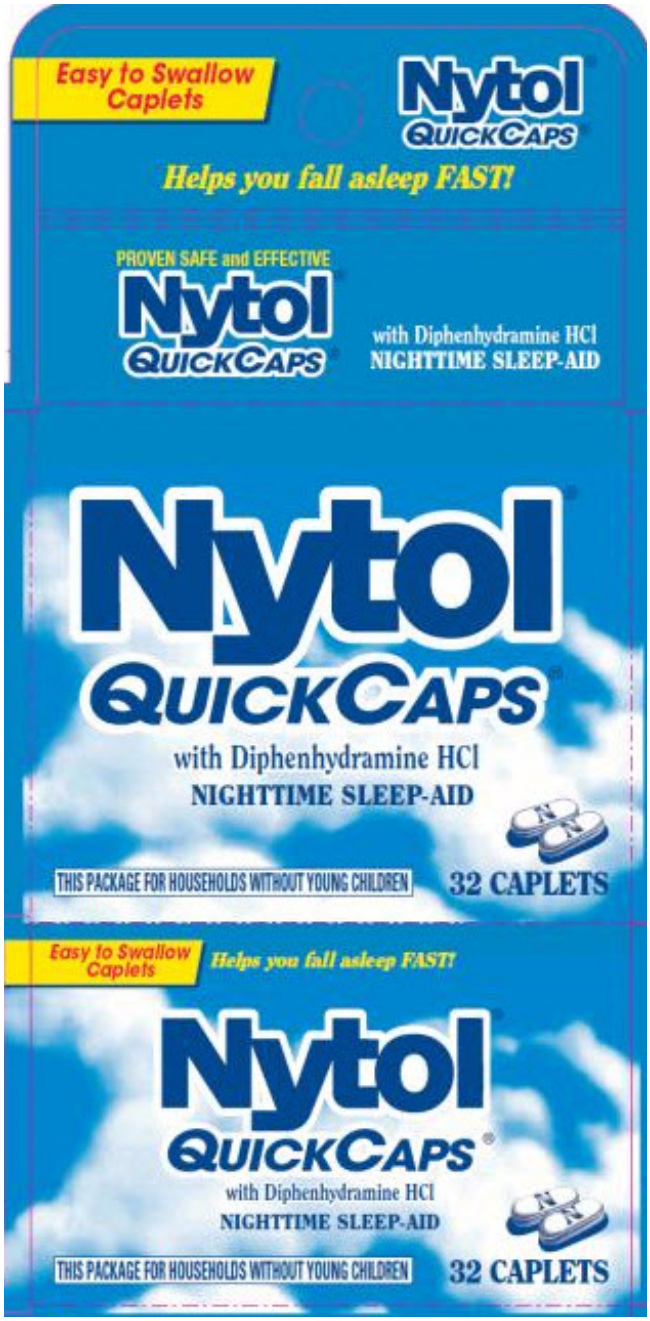
crosscarmellose sodium, dicalcium phosphate, hypromellose, lactose, magnesium stearate, microcrystalline cellulose, mineral oil, silica, stearic acid, talc, titanium dioxide, tracetin

PRINCIPAL DISPLAY PANEL

Nytol QuickCaps with Diphenhydramine HCl

Nighttime Sleep-Aid

32 caplets

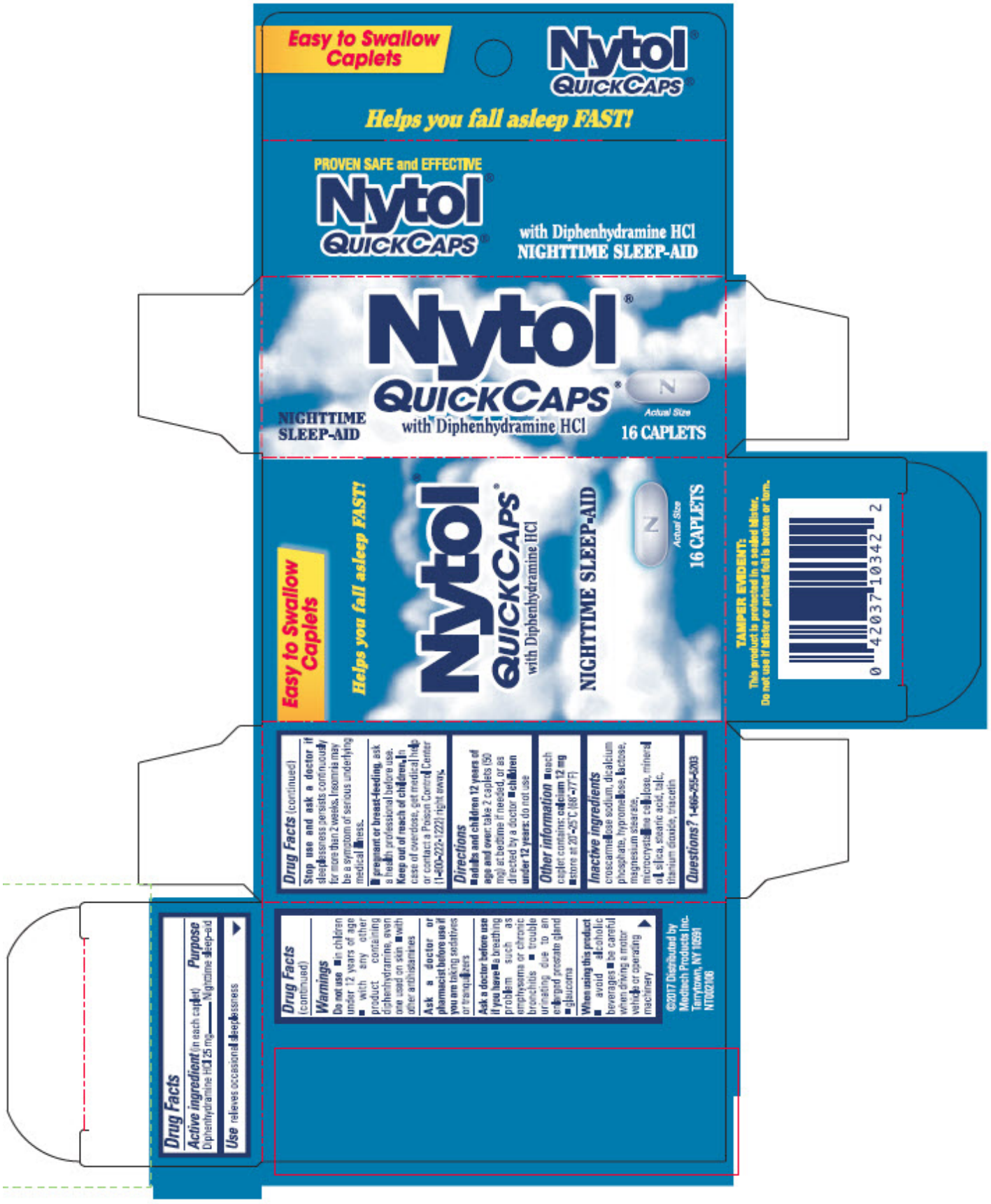


PRINCIPAL DISPLAY PANEL

Nytol QuickCaps with Diphenhydramine HCl

Nighttime Sleep-Aid

16 caplets



NYTOL

diphenhydramine hcl tablet

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63029-211
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg

Inactive Ingredients

Ingredient Name	Strength
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: L11K75P92J)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
LACTOSE, UNSPECIFIED FORM (UNII: J2B2A4N98G)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
MINERAL OIL (UNII: T5L8T28FGP)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	

Product Characteristics

Color	white	**Score**	no score
Shape	OVAL	**Size**	14mm
Flavor		**Imprint Code**	N
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63029-211-01	4 in 1 BOX	06/01/2012	
1		8 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:63029-211-02	2 in 1 BOX	01/16/2013	
2		8 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part338	06/01/2012	

Labeler - Medtech Products Inc. (122715688)