IBUPROFEN AND DIPHENHYDRAMINE CITRATE- ibuprofen and diphenhydramine citrate tablet
Dr. Reddy's Laboratories Limited

Ibuprofen and Diphenhydramine Citrate Tablets

DRUG FACTS

ACTIVE INGREDIENTS (IN EACH CAPLET)

Diphenhydramine citrate USP, 38 mg

Ibuprofen USP, 200 mg (NSAID)**

* capsule-shaped tablets

**nonsteroidal anti-inflammatory drug

PURPOSES

Nighttime sleep-aid

Pain reliever

USES

- for relief of occasional sleeplessness when associated with minor aches and pains
- helps you fall asleep and stay asleep

WARNINGS

Allergy alert:

Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:

- hives
- facial swelling
- asthma (wheezing)
- shock
- skin reddening
- rash
- blisters

If an allergic reaction occurs, stop use and seek medical help right away.

Stomach bleeding warning:

This product contains an NSAID, which may cause stomach bleeding. The chance is higher if you:

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing an NSAID [aspirin, ibuprofen, naproxen, or others]
- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed

Do not use

- if you have ever had an allergic reaction to any other pain reliever/fever reducer
- unless you have time for a full night's sleep
- in children under 12 years of age
- right before or after heart surgery
- with any other product containing diphenhydramine, even one used on skin
- if you have sleeplessness without pain.

Ask a doctor before use if

- stomach bleeding warning applies to you
- you have problems or serious side effects from taking pain relievers or fever reducers
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, kidney disease, or asthma
- you are taking a diuretic
- you have a breathing problem such as emphysema or chronic bronchitis
- you have glaucoma
- you have trouble urinating due to an enlarged prostate gland

Ask a doctor or pharmacist before use if you are

- taking sedatives or tranquilizers, or any other sleep-aid
- under a doctor’s care for any continuing medical illness
- taking any other antihistamines
- taking aspirin for heart attack or stroke, because ibuprofen may decrease this benefit of aspirin
- taking any other drug

When using this product

- drowsiness will occur
- avoid alcoholic drinks
- do not drive a motor vehicle or operate machinery
- take with food or milk if stomach upset occurs
- the risk of heart attack or stroke may increase if you use more than directed or for longer than directed

Stop use and ask a doctor if

- you experience any of the following signs of stomach bleeding:
- feel faint
- vomit blood
- have bloody or black stools
- have stomach pain that does not get better
- pain gets worse or lasts more than 10 days
- sleeplessness persists continuously for more than 2 weeks. Insomnia may be a symptom of a serious underlying medical illness.
- redness or swelling is present in the painful area
- any new symptoms appear

If pregnant or breast-feeding,

ask a health professional before use. It is especially important not to use ibuprofen during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

Keep out of the reach of children.

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

DIRECTIONS

- **do not take more than directed**
- adults and children 12 years and over: take 2 caplets at bedtime.
- do not take more than 2 caplets in 24 hours

OTHER INFORMATION

- read all warnings and directions before use. Keep carton.
- store at 20-25°C (68-77°F)
- avoid excessive heat above 40°C (104°F)

INACTIVE INGREDIENTS

carnauba wax, corn starch, colloidal silicon dioxide, croscarmellose sodium, FD&C blue no. 2, hypromelllose, microcrystalline cellulose, polydextrose, polyethylene glycol 400, pregelatinized starch, sodium lauryl sulfate, stearic acid, titanium dioxide

QUESTIONS?

Call **1-888-375-3784**

Do Not Use if foil seal under bottle cap imprinted with**"SEALED for YOUR PROTECTION"** is broken or missing.

Manufactured by:

Dr. Reddy's Laboratories Limited

Bachepalli – 502 325 INDIA.

PRINCIPAL DISPLAY PANEL

Container:

taking any other drug or have stomach problems.

■ This product may cause a **severe allergic reaction**, especially in people allergic to aspirin. Symptoms may include; hives, facial swelling, asthma (wheezing), shock, skin reddening, rash, blisters. If an allergic reaction occurs, stop use and seek medical help right away.

■ **Do not use** this product if you have ever had an allergic reaction to any pain reliever/fever reducer; unless you have time for a full night's sleep; in children under 12 years or with any other product containing diphenhydramine.

■ This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you

■ are age 60 or older

■ have had stomach ulcers or bleeding problems

■ take a blood thinning (anticoagulant) or steroid drug

■ take other drugs containing prescription or nonprescription NSAIDs [aspirin, ibuprofen, naproxen, or others]

■ have 3 or more alcoholic drinks every day while using this product

■ take more or for a longer time than directed .

■ **When using this product** drowsiness will occur.Do not drive a motor vehicle or operate machinery. Avoid alcoholic drinks.

■ The risk of heart attack or stroke may increase if you use more than directed or for longer than directed.

NDC 55111-565-05

DR.REDDY'S

500 Caplets*

Ibuprofen and Diphenhydramine Citrate Tablets, 200 mg/38 mg

*Pain Reliever **(NSAID)**/Nighttime Sleep-Aid*

*capsule-shaped tablets

READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION

Uses

■ for relief of occasional sleeplessness when associated with minor aches and pains

■ helps you fall asleep and stay asleep

Warnings

■ **Ask your doctor before use** if you are pregnant, under a doctor's care for any continuing medical illness, age 60 or over,

Do Not Use if foil seal under bottle cap imprinted with *"SEALED for YOUR PROTECTION"* is broken or missing.

Directions

■ **do not take more than directed**

■ adults and children 12 years and over; take 2 caplets at bedtime

■ do not take more than 2 caplets in 24 hours

Store at 20-25°C (68-77°F)

Avoid excessive heat above 40°C(104°F)

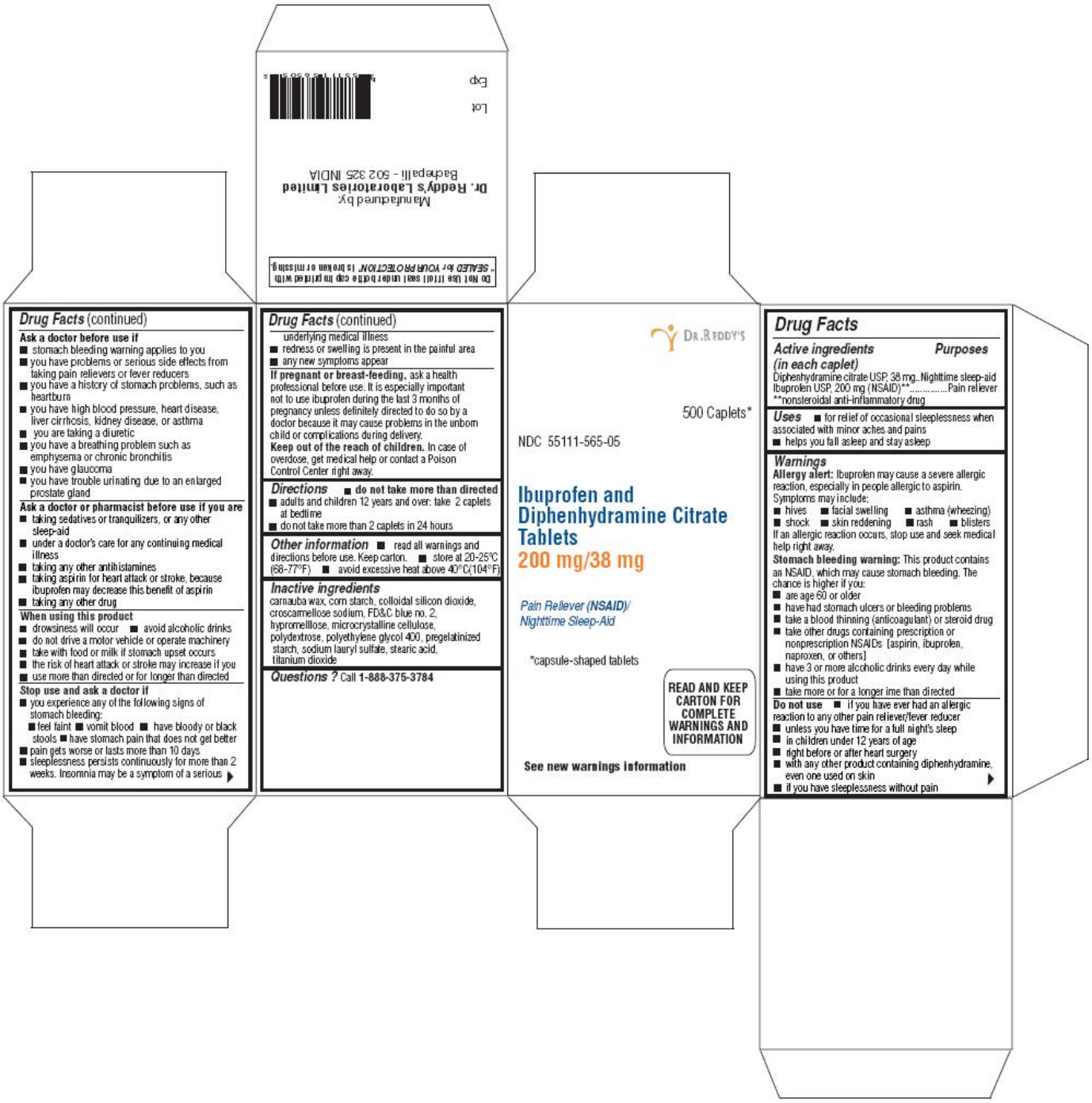
Questions? Call **1-888-375-3784**

Mfg by: **Dr. Reddy's Laboratories Limited**
Bachepalli - 502 325 INDIA

Lot :

Exp:

Container carton



IBUPROFEN AND DIPHENHYDRAMINE CITRATE

ibuprofen and diphenhydramine citrate tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:55111-565
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**

Ibuprofen (UNII: WK2XYI10QM) (Ibuprofen - UNII:WK2XYI10QM)	Ibuprofen	200 mg
Diphenhydramine Citrate (UNII: 4OD433S209) (Diphenhydramine - UNII:8GTS82S83M)	Diphenhydramine Citrate	38 mg

Inactive Ingredients

Ingredient Name	Strength
carnauba wax (UNII: R12CBM0EIZ)	
STARCH, CORN (UNII: O8232NY3SJ)	
Silicon Dioxide (UNII: ETJ7Z6XBU4)	
croscarmellose sodium (UNII: M28OL1HH48)	
FD&C blue no. 2 (UNII: L06K8R7DQK)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
hypromelloses (UNII: 3NXW29V3WO)	
polydextrose (UNII: VH2XOU12IE)	
polyethylene glycol 400 (UNII: B697894SGQ)	
sodium lauryl sulfate (UNII: 368GB5141J)	
stearic acid (UNII: 4ELV7Z65AP)	
titanium dioxide (UNII: 15FIX9V2JP)	

Product Characteristics

Color	BLUE (blue)	**Score**	no score
Shape	CAPSULE (slightly glossy smooth blue film coated)	**Size**	15mm
Flavor		**Imprint Code**	RDY;565
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55111-565-14	1 in 1 CARTON	01/31/2010	
1		20 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:55111-565-30	1 in 1 CARTON	01/31/2010	
2		30 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:55111-565-40	1 in 1 CARTON	01/31/2010	
3		40 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:55111-565-80	1 in 1 CARTON	01/31/2010	
4		80 in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:55111-565-90	1 in 1 CARTON	01/31/2010	
5		90 in 1 BOTTLE; Type 0: Not a Combination Product		
6	NDC:55111-565-18	1 in 1 CARTON	01/31/2010	
6		180 in 1 BOTTLE; Type 0: Not a Combination Product		
7	NDC:55111-565-05	1 in 1 CARTON	01/31/2010	
7		500 in 1 BOTTLE; Type 0: Not a Combination Product		
8	NDC:55111-565-92	2500 in 1 POUCH; Type 0: Not a Combination Product	01/31/2010	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090619	01/31/2010	

Labeler - Dr. Reddy's Laboratories Limited (650562841)

Revised: 12/2018 Dr. Reddy's Laboratories Limited