

150 mm

50 mm

NDC 64380-732-18

Ibuprofen and Diphenhydramine HCl Capsules

200 mg/25 mg

Solubilized Ibuprofen, 200 mg Diphenhydramine HCl, 25 mg

Pain Reliever (NSAID)/ Nighttime Sleep-Aid

Do not use if seal under bottle cap imprinted with "SEALED for YOUR PROTECTION" is broken or missing

Strides Pharma Inc.

180 Liquid Filled Capsules

Manufactured by:
Strides Shasun Limited
Bengaluru - 562106, India

Distributed by:
Strides Pharma Inc.
East Brunswick, NJ 08816

Revised: 03/2018

Code No.:
KR/DRUGS/KTK/25/415/98

Space for Batch details
58 x17 mm

1031619

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643801732181

PEEL HERE

Drug Facts

Active ingredients (in each capsule)	Purposes
Diphenhydramine	Night time sleep-aid
hydrochloride 25 mg.....	Solubilized ibuprofen equal to 200 mg ibuprofen (NSAID)*.....Pain reliever (present as the free acid and potassium salt)
*nonsteroidal anti-inflammatory drug	

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 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

Heart attack and stroke warning
NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer 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, or had a stroke.
- 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

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
- you have symptoms of heart problems or stroke:
 - chest pain
 - trouble breathing
 - weakness in one part or side of body
 - slurred speech
 - leg swelling
- 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 capsules at bedtime
- do not take more than 2 capsules in 24 hours

Other Information

- each capsule contains: potassium 20 mg
- read all warnings and directions before use. Keep carton.
- store at 20° to 25°C (68° to 77°F)
- avoid excessive heat above 40°C (104°F)
- protect from light

Inactive Ingredients
D&C red no. 33, FD&C blue no. 1, gelatin, hydrolysed gelatin, medium chain triglyceride, opacode white ink, polyethylene glycol 600, potassium hydroxide, Anidrisorb and Purified Water.

Ingredients of Opacode white ink: shellac glaze in ethanol, titanium dioxide, n-butyl alcohol, lecithin (soya), simethicone and purified water.

QUESTIONS OR COMMENTS?
Call at 1-877-244-9825

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3046

ARTWORK DETAIL LABEL

GLUE AREA
Do not print

Product	Diphenhydramine + Ibu Capsules 25mg / 200mg			
Buyer/Country	STRIDES PHARMA INC - US	Component	Label	
Dimension	170 x 50 mm	Pack	180's	
New Item Code	1031619	Old Item Code	NA	
Colour Shades	CMYK	No. of Colours	4	
Change Control No.	NA	Artwork Version	1.0	
Design/Style	Self adhesive labels in Roll-form with Rounded Corners.			
Substrate				
Special Instructions	Printing clarity to be clear and sharp. Please use fine screen.			
Autocartanator Requirements	NA			

Caution to the printer: Before processing, please ensure that the ARTWORK received for printing is exactly in line with APPROVED ARTWORK provided to you. In case of any FONTS/DESIGN are Mis-matching with the APPROVED ARTWORK, please inform PDC for further action. **DO NOT MAKE ANY CHANGE TO THE ARTWORK WITHOUT WRITTEN INSTRUCTIONS FROM PDC.**