

**IBUPROFEN AND DIPHENHYDRAMINE HCL- ibuprofen and diphenhydramine hcl capsule,
liquid filled
Strides Shasun Limited**

IBUPROFEN AND DIPHENHYDRAMINE HCL 200 mg/25 mg

DRUG FACTS

ACTIVE INGREDIENT

Active Ingredient(s)

(In each capsule)

Diphenhydramine hydrochloride 25 mg

Solubilized Ibuprofen equal to Ibuprofen 200 mg (NSAID)* (Present as the free acid and potassium salt)

*nonsteroidal anti-inflammatory drug

PURPOSE

- 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 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

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 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 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 REACH OF CHILDREN

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

DIRECTIONS

1. do not take more than directed
2. adults and children 12 years and over: take 2 capsules at bedtime
3. 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 20-25°C (68-77°F)
- avoid excessive heat above 40°C (104°F)
- protect from light

INACTIVE INGREDIENT

Anidrisorb, D&C red no. 33, FD&C blue no. 1, gelatin, Hydrolyzed gelatin, medium chain triglyceride. Opacode white ink, Polyethylene glycol 600, potassium hydroxide, 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 1877 244 9825

Manufactured by:

Strides Shasun Limited



Bengaluru - 560076, India

Distributed by:






Strides Pharma Inc.

East Brunswick, NJ 08816

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

<p>NDC 64380-732-14</p> <p>IBUPROFEN and DIPHENHYDRAMINE HCL CAPSULES</p> <p>200 mg/25 mg</p>	<p>16 SOFTGELS**</p> <p>**Liquid Filled Capsules</p>
<p>NDC 64380-732-14</p> <p>IBUPROFEN and DIPHENHYDRAMINE HCL CAPSULES</p> <p>200 mg/25 mg</p> <p>Pain Reliever (NSAID)/Night time Sleep-Aid</p> <p> Strides Pharma Inc.</p> <p>16 SOFTGELS**</p> <p>**Liquid Filled Capsules</p> <p>See new warnings information</p>	 <p>3 64380 73214 3</p> <div data-bbox="1130 716 1219 1003" style="border: 1px solid black; padding: 5px;"> <p>Product inside sealed in Plastic blister with foil backing. Do Not Use if plastic blister or foil barrier is broken</p> </div> <p>Code No.: KR/DRUGS/KTK/2541598</p> 
<p>NDC 64380-732-14</p> <p>IBUPROFEN and DIPHENHYDRAMINE HCL CAPSULES</p> <p>200 mg/25 mg</p> <p>Visit us at www.strideshasun.com</p>	<p>Manufactured by: Strides Shasun Limited Bengaluru - 560076, India.</p> <p>Distributed by: Strides Pharma Inc. East Brunswick, NJ 08816</p> <p>Revised: 01/2017</p>

16s label

<p>NDC 64380-732-29</p> <p>Ibuprofen and Diphenhydramine HCl Capsules</p> <p>200 mg/25 mg</p> <p>Solubilized Ibuprofen, 200 mg Diphenhydramine HCl, 25 mg</p> <p>Pain Reliever (NSAID)/ Nighttime Sleep-Aid</p> <p>Do not use if seal under bottle cap imprinted with "SEALED for YOUR PROTECTION" is broken or missing</p> <p> Strides Pharma Inc.</p> <p> 20 Liquid Filled Capsules</p>	 <p>Code No.: KR/DRUGS/KTK/25/415/98</p> <p>Manufactured by: Strides Shasun Limited Bengaluru - 560076, India</p> <p>Distributed by: Strides Pharma Inc. East Brunswick, NJ 08816</p> <p>Revised: 11/2016</p> <p>LOT: EXP:</p> <div data-bbox="987 1707 1312 1812" style="border: 1px dashed red; padding: 5px;"> <p>NO VARNISH ZONE</p> </div> <p>1031615</p>	 <p>3 64380 73229 7</p> <p>PEEL HERE </p>
---	--	---

20s count container label

D&C RED NO. 33 (UNII: 9DBA0SBB0L)
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)
GELATIN (UNII: 2G86QN327L)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
POTASSIUM HYDRO XIDE (UNII: WZH3C48M4T)
WATER (UNII: 059QF0KO0R)
SORBITAN (UNII: 6O92ICV9RU)
SORBITOL (UNII: 506T60A25R)
SHELLAC (UNII: 46N107B71O)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
BUTYL ALCOHOL (UNII: 8PJ61P6TS3)
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)
POLYETHYLENE GLYCOL 600 (UNII: NL4J9F21N9)

Product Characteristics

Color	PURPLE (Bluish purple color)	Score	no score
Shape	OVAL	Size	16mm
Flavor		Imprint Code	1007
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64380-732-14	2 in 1 CARTON	03/05/2012	
1		8 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:64380-732-15	4 in 1 CARTON	03/05/2012	
2		8 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:64380-732-20	24 in 1 BOX	03/05/2012	
3	NDC:64380-732-19	24 in 1 CARTON		
3		8 in 1 BLISTER PACK; Type 0: Not a Combination Product		
4	NDC:64380-732-29	1 in 1 CARTON	12/28/2016	
4		20 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
5	NDC:64380-732-12	1 in 1 CARTON	12/28/2016	
5		40 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
6	NDC:64380-732-13	1 in 1 CARTON	12/28/2016	
6		80 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
7	NDC:64380-732-11	1 in 1 CARTON	12/28/2016	
7		120 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
8	NDC:64380-732-18	1 in 1 CARTON	12/28/2016	

8	180 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA200888	03/05/2012	

Labeler - Strides Shasun Limited (650738743)

Registrant - Strides Shasun Limited (650738743)

Establishment			
Name	Address	ID/FEI	Business Operations
Strides Shasun Limited		918513263	ANALYSIS(64380-732) , MANUFACTURE(64380-732)

Revised: 12/2016

Strides Shasun Limited