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

or others]
• have 3 or more alcoholic drinks every day while using this product
• take more or for a longer time than directed
• 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 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 - 562106, India

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

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 64380-732-14
IBUPROFEN and
DIPHENHYDRAMINE HCL
CAPSULES
200 mg/25 mg

16 SOFTGELS**
**Liquid Filled Capsules

NDC 64380-732-14
IBUPROFEN and
DIPHENHYDRAMINE HCL
CAPSULES
200 mg/25 mg

Pain Reliever (NSAID)/Night time Sleep-Aid

Strides Pharma Inc.

16 SOFTGELS**
**Liquid Filled Capsules
See new warnings information

NDC 64380-732-14
IBUPROFEN and
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Visit us at www.stridesshaun.com

16 s label
# IBUPROFEN AND DIPHENHYDRAMINE HCL

**ibuprofen and diphenhydramine hcl capsule, liquid filled**

## Product Information

<table>
<thead>
<tr>
<th>Product Type</th>
<th>Item Code (Source)</th>
<th>NDC:64380-732</th>
</tr>
</thead>
<tbody>
<tr>
<td>HUMAN OTC DRUG</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Route of Administration</td>
<td></td>
<td>ORAL</td>
</tr>
</tbody>
</table>

## Active Ingredient/Active Moiety

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:E8GTS8283M)</td>
<td>DIPHENHYDRAMINE HYDROCHLORIDE</td>
<td>25 mg</td>
</tr>
<tr>
<td>IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)</td>
<td>IBUPROFEN</td>
<td>200 mg</td>
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## Inactive Ingredients

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>D&amp;C RED NO. 33 (UNII: 9DBA0SBB0L)</td>
<td></td>
</tr>
<tr>
<td>FD&amp;C BLUE NO. 1 (UNII: HBR47K3TBDB)</td>
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</tr>
<tr>
<td>GELATIN (UNII: 2G86QN327L)</td>
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</tr>
<tr>
<td>MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)</td>
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</tr>
<tr>
<td>POTASSIUM HYDROXIDE (UNII: WZJBC48M4T)</td>
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</tr>
<tr>
<td>WATER (UNII: 059QF0K00R)</td>
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</tr>
<tr>
<td>SORBITAN (UNII: 6O92ICV9RU)</td>
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<tr>
<td>SORBITOL (UNII: 506T60A25R)</td>
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<tr>
<td>POLYETHYLENE GLYCOL 600 (UNII: NL4J9F21N9)</td>
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## Product Characteristics

<table>
<thead>
<tr>
<th>Color</th>
<th>PURPLE (Bluish purple color)</th>
<th>Score</th>
<th>no score</th>
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<tbody>
<tr>
<td>Shape</td>
<td>OVAL</td>
<td></td>
<td>Size</td>
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<tr>
<td>Flavor</td>
<td>no score</td>
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<td>Imprint Code</td>
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## Packaging

<table>
<thead>
<tr>
<th>#</th>
<th>Item Code</th>
<th>Package Description</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>NDC:64380-732-14</td>
<td>2 in 1 CARTON</td>
<td>03/05/2012</td>
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<tr>
<td>1</td>
<td>NDC:64380-732-15</td>
<td>8 in 1 BLISTER PACK; Type 0: Not a Combination Product</td>
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<tr>
<td>2</td>
<td>NDC:64380-732-20</td>
<td>4 in 1 CARTON</td>
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<tr>
<td>2</td>
<td>NDC:64380-732-19</td>
<td>8 in 1 BLISTER PACK; Type 0: Not a Combination Product</td>
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<tr>
<td>3</td>
<td>NDC:64380-732-20</td>
<td>24 in 1 BOX</td>
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<td>3</td>
<td>NDC:64380-732-19</td>
<td>24 in 1 CARTON</td>
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<tr>
<td>3</td>
<td>NDC:64380-732-20</td>
<td>8 in 1 BLISTER PACK; Type 0: Not a Combination Product</td>
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<tr>
<td>NDC:64380-732-29</td>
<td>1 in 1 CARTON</td>
<td>12/28/2016</td>
<td></td>
<td></td>
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<tr>
<td>------------------</td>
<td>---------------</td>
<td>------------</td>
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</tr>
<tr>
<td>20 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product</td>
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<table>
<thead>
<tr>
<th>NDC:64380-732-12</th>
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<th>12/28/2016</th>
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<td>40 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product</td>
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</table>

<table>
<thead>
<tr>
<th>NDC:64380-732-13</th>
<th>1 in 1 CARTON</th>
<th>12/28/2016</th>
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<tbody>
<tr>
<td>80 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product</td>
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<table>
<thead>
<tr>
<th>NDC:64380-732-11</th>
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<th>12/28/2016</th>
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<tbody>
<tr>
<td>120 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product</td>
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<table>
<thead>
<tr>
<th>NDC:64380-732-18</th>
<th>1 in 1 CARTON</th>
<th>12/28/2016</th>
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</thead>
<tbody>
<tr>
<td>180 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product</td>
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### Marketing Information

<table>
<thead>
<tr>
<th>Marketing Category</th>
<th>Application Number or Monograph Citation</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
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<tbody>
<tr>
<td>ANDA</td>
<td>ANDA200888</td>
<td>03/05/2012</td>
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### Labeler
- Strides Shasun Limited (650738743)

### Registrant
- Strides Shasun Limited (650738743)

### Establishment

<table>
<thead>
<tr>
<th>Name</th>
<th>Address</th>
<th>ID/FEI</th>
<th>Business Operations</th>
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<tbody>
<tr>
<td>Strides Shasun Limited</td>
<td>918513263</td>
<td>ANALYSIS(64380-732) , MANUFACTURE(64380-732)</td>
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Revised: 3/2018