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

IBUPROFEN AND DIPHENHYDRAMINE HCL 200 mg/25 mg

Drug Facts

Active ingredients (in each capsule)
Purposes

Diphenhydramine hydrochloride 25 mg.....Nighttime sleep-aid

Solubilized ibuprofen equal to ibuprofen 200 mg (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, 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
- 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 at 20 weeks or later in 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 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 20-25°C (68-77°F)
- avoid excessive heat above 40°C (104°F)
- protect from light

Inactive ingredients

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 Pharma Science Limited

Bengaluru - 562106, India

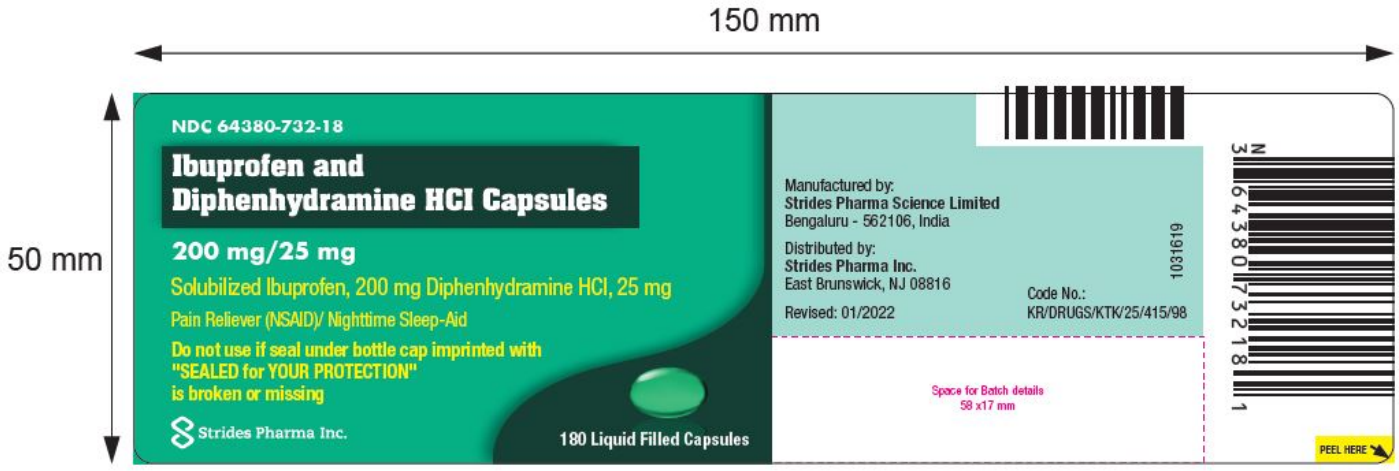
Distributed by:

Strides Pharma Inc.

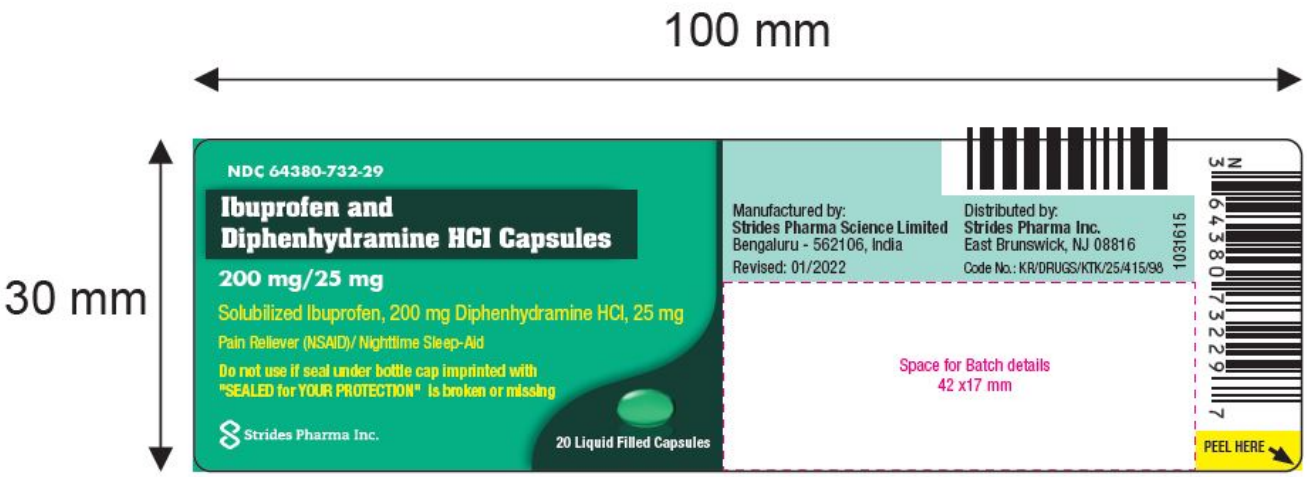
East Brunswick, NJ 08816

Revised: 01/2022

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



180 s count container label



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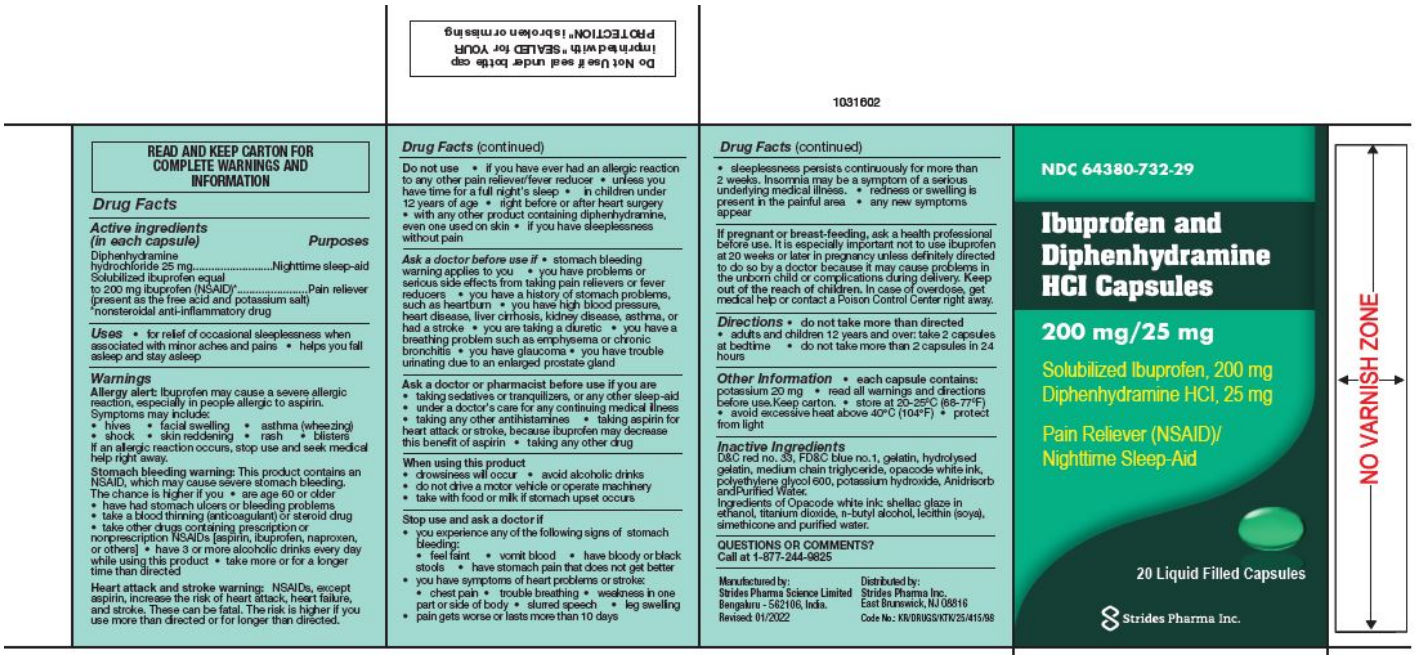
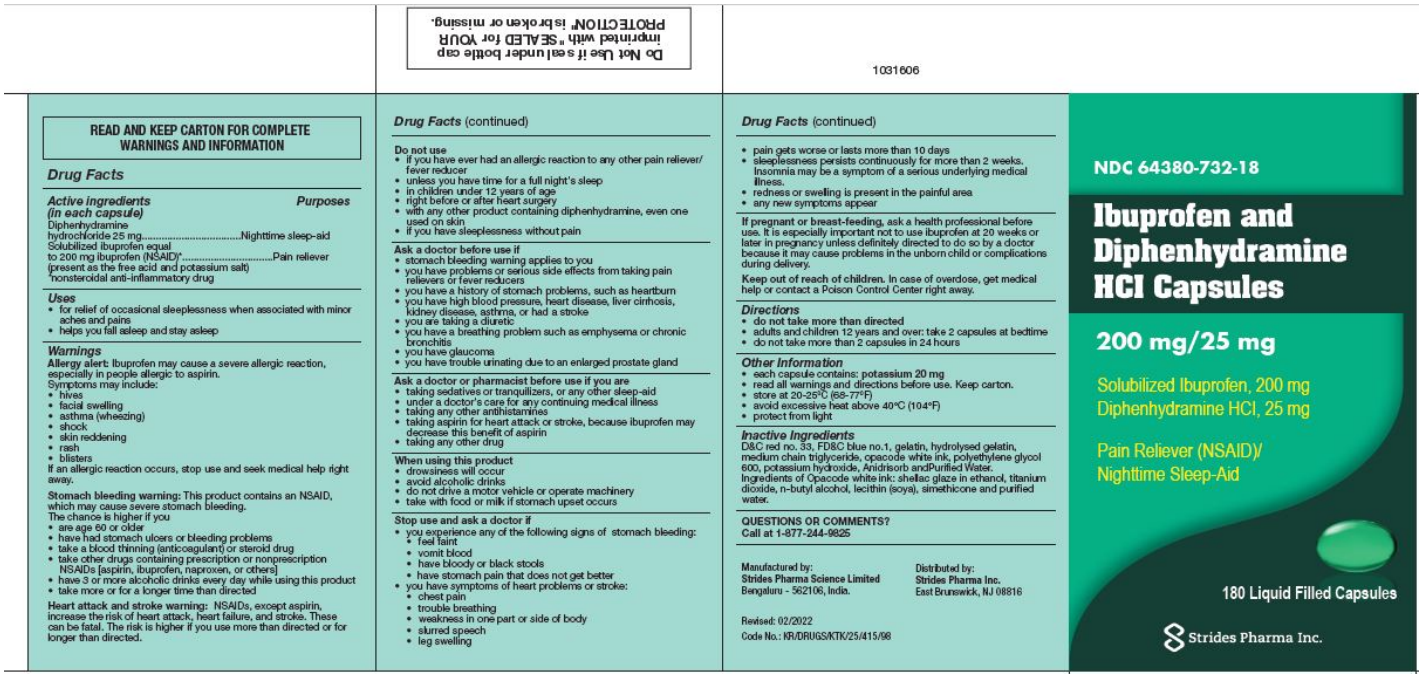


20 s count carton label



180 s carton label

IBUPROFEN AND DIPHENHYDRAMINE HCL

ibuprofen and diphenhydramine hcl capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:64380-732
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
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	200 mg

Inactive Ingredients

Ingredient Name	Strength
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
WATER (UNII: 059QF0KO0R)	
SORBITAN (UNII: 6O92ICV9RU)	
SORBITOL (UNII: 506T60A25R)	
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		
9	NDC:64380-732-92	3000 in 1 BAG; Type 0: Not a Combination Product	11/30/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA200888	03/05/2012	

Labeler - Strides Pharma Science Limited (650738743)

Registrant - Strides Pharma Science Limited (650738743)

Establishment

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

Revised: 2/2022 Strides Pharma Science Limited