IBUPROFEN - ibuprofen capsule, liquid filled Strides Pharma Inc

DRUG FACTS

READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION

Active ingredient (in each capsule)

Solubilized ibuprofen equal to 200 mg ibuprofen (NSAID)*

(Present as the free acid and potassium salt)

*nonsteroidal anti-inflammatory drug

Purpose

Pain reliever/Fever reducer

Uses

- temporarily relieves minor aches and pains due to:
 - headache
 - toothache
 - backache
 - menstrual cramps
 - the common cold
 - muscular aches
 - minor pain of arthritis
- temporarily reduces fever

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 aged 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
- right before or after heart surgery

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

Ask a doctor or pharmacist before use if you are

- under a doctor's care for any serious condition
- taking aspirin for heart attack or stroke, because ibuprofen may decrease this benefit of aspirin
- taking any other drug

When using this product

• 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
- fever gets worse or lasts more than 3 days
- 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
- the smallest effective dose should be used
- adults and children 12 years and over: take 1 capsule every 4 to 6 hours while symptoms persist
- if pain or fever does not respond to 1 capsule, 2 capsules may be used
- do not exceed 6 capsules in 24 hours, unless directed by a doctor
- children under 12 years: ask a doctor

Other information

- each capsule contains: **potassium 17.840 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)

Inactive ingredients

Ibuprofen Capsules

FD&C blue 1, gelatin, gelatin (hydrolyzed), medium chain triglyceride, PEG 600, potassium hydroxide, purified water, sorbital and sorbitan solution.

Printing ink: propylene glycol, shellac resins, sodium lauryl sulphate, titanium dioxide.

Ibuprofen Capsules - Minis

FD&C green no.3, gelatin, gelatin (hydrolyzed), lecithin (Soya Lecithin), medium chain triglyceride, polyethylene Glycol 600, potassium hydroxide, purified water, sorbital and sorbitan solution.

Printing ink: propylene glycol, shellac resins, sodium lauryl sulphate, titanium dioxide.

Questions or comments?

call toll free 1-877-244-9825

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

For most recent product information, visit us at www.strides.com

Revised: 05/2023

Manufactured by:

Strides Pharma Science Limited

Bengaluru - 562106, India

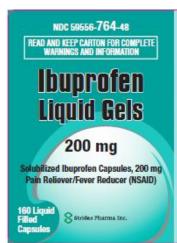
Distributed by:

Strides Pharma Inc.

East Brunswick, NJ 08816

PRINCIPAL DISPLAY PANELS

Ibuprofen Capsules, 200 mg Pain Reliever/Fever Reducer (NSAID) Liquid Filled Capsules



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

- temporarily relieves minor aches and pains due to: headache, muscular aches, menstrual cramps, the common cold, backache, toothache, minor pain of arthritis. . temporarily reduces fever Warnings
- Ask your doctor before use if you are pregnant, under a doctor's care for a serious condition, age 60 or over, taking any other drug Heart attack and stroke warning: NSAIDs, 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 smallest effective dose should be used

reaction to any pain reliever/fever reducer

- Stomach bleeding warning: This product contains a nonsteroidal anti-inflammatory drug (NSAID), which may cause severe stomach bleeding. The chance is higher if you m are age 60 or older m have had stomach ulcers or bleeding problems a take a blood thinning articoagulant) or steroid drug ■ take other drugs containing prescription or nonprescription NSAIDs [aspirin, ibuprofen, naproxen, or others] ■ have 3 or more alcoholic drinks every day Questions or comments?
- while using this product a take more or for a longer time than directed
- 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.
- use this product if you have ever had an allergic and adults and children 12 years and over: take

persist if pain or fever does not respond to 1 capsule, 2 capsules may be used a do not exceed 6 capsules in 24 hours, unless directed by a doctor a children under 12 years; ask a

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Manufactured by: Strides Pharma Science Ltd. Bengaluru - 562106, India.

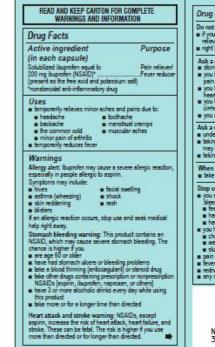
Distributed by: Strides Pharma Inc. East Brunswick, NJ 08816

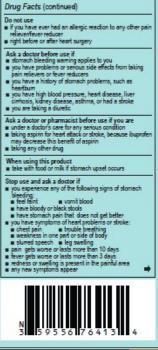
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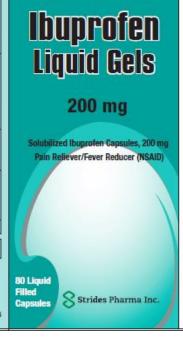


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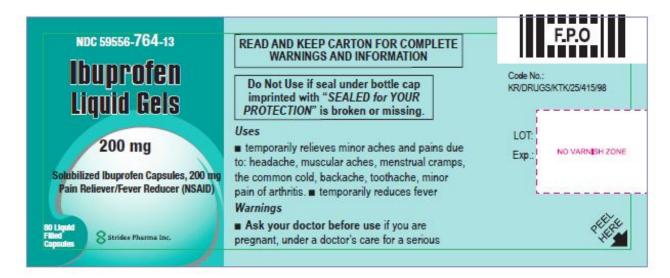








NDC 59556-764-13



Ibuprofen Capsules, 200 mg Pain Reliever/Fever Reducer (NSAID) Liquid Filled Capsules - Minis



Pain Reliever /Fever Red ucer (NS ALD) Solu bil iz ed l'buprofen Capsules, 200 mg

SOO ING

Liquid Gels **Ibuprofen**

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READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION

Drug Facts

Active ingredient (in each capsule)

Solubilized buprofen equal to 200 mg ibuprofen (NSAID)* ... (present as the free acid and polassium salt) *nonsteroidal anti-inflammatory drug

- Uses:

 lemporantly referves minor aches and pairs due to:

 le headache

 le backache

 le backache

 le to common oold

 le minor pain of arthrits

 lemporantly reduces fever

Warnings

Warnings
Allergy alert. Exporten may cause a severe allergic reaction, especially in people allergic to aspirin.

Symptoms may include:

short to be a spirin.

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Heart attack and stroke warning: NSAIDs, except aspin, increase the risk of heart attack, heart failure, and stroke. These can be fatel. The risk is higher if you use more than directed or for longer than directed.

Drug Facts (continued)

to not use if you have ever had an allergic reaction to any other pain relieventever reducer
inght before or after heart surgery

- Ask a doctor before use if stomach bleeding warning spolles to you you have problems or senous side effects from taking pain relieves or fever reducers s you have a history of stomach problems, such as hearthum so un have high blood pressure, heart disease, liver cathools, kidney disease, asthme, or had a stroke you are taking a disretic

 - Ask a doctor or pharmacist before use if you are a under a doctor's care for any serious condition a taking aspin for heaf attack or stroke, because ibuprofer may decrease this benefit of aspirin a taking any other drug

When using this product

take with food or milk if stomach upset occurs

- It became the second of t



Drug Facts (continued)

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use buprofen 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 defivery.

- Directions

 a do not take more than directed

 a the smallest effective dose should be used

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 every 4 to 6 hours while symptoms persist

 af peri or fever does not respond to 1 capsule, 2 capsules
 may be used

 a do not exceed 6 capsules in 24 hours, unless directed by a
 doctor
- doctor s children under 12 years; ask a doctor

Other information

- each cepsule contains: potassium 17.840 mg
 read all warnings and directions before use. Keep certon
 store at 20-25°C (68-7°F)
 exoid excessive heat above 40°C (104°F)

Inactive ingredients
FDSC blue 1, gelein, gelein (hydrolyzed), medium chain
biglycende, PEG 600, potassum hydroxide, purified water,
sorbial and sorbitan solution.
Parting nic propylere glycd, shellac resins, sodium lauyl
sulphale, thism of coxide.

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For most recent product informati Visit us at www.strides.com

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

Revised: 05/2023 Manufactured by:
Strides Pharma Science Ltd.
Strides Pharma Inc,
Bengaluru - 562106, India.

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

NDC 59556-764-13 lbuprofen **Liquid Gels** 200 mg Solubilized Ibuprofen Capsules, 200 mg Pain Reliever/Fever Reducer (NSAID) 80 Liquid Filled

Strides Pharma Inc.



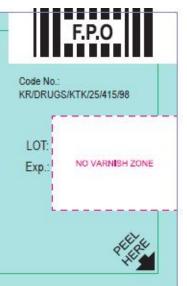
READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION

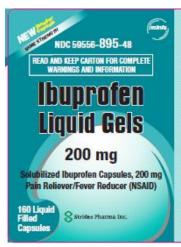
Do Not Use if seal under bottle cap imprinted with "SEALED for YOUR PROTECTION" is broken or missing.

 temporarily relieves minor aches and pains due to: headache, muscular aches, menstrual cramps, the common cold, backache, toothache, minor pain of arthritis.
temporarily reduces fever

Warnings

 Ask your doctor before use if you are pregnant, under a doctor's care for a serious condition,





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

- temporarily relieves minor aches and pains due to: headache, muscular aches, menstrual cramps, the common cold, backache toothache, minor pain of arthritis.

 temporarily reduces fever Warnings
- Ask your doctor before use if you are pregnant, under a doctor's care for a serious condition, age 60 or over, taking any other drug # Heart attack and stroke warning: NSAIDs, 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 and adults and children 12 years and over: take

- reaction to any pain relieven/fever reducer.

 Stomach bleeding warning: This product contains a nonsteroidal anti-inflammatory drug (NSAID), which may cause severe stomach bleeding. The chance is higher if you are age 60 or older m have had stomach ulcers or bleeding problems a take a blood thinning (anticoagulant) or steroid drug . take other drugs containing prescription or nonprescription NSAIDs [aspirin, ibuprofen, naproxen, or others] Each capsule contains: potassium 17.840 mg
- have 3 or more alcoholic drinks every day while using this product a take more or for a longer time than directed
- 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. Directions
- smallest effective dose should be used



1 capsule every 4 to 6 hours while syn persist if pain or fever does not respond to 1 capsule, 2 capsules may be used a do not exceed 6 capsules in 24 hours, unless directed by a doctor a children under 12 years: ask a

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LOT

Ехр.:

Manufactured by: Strides Pharma Science Ltd. Bengaluru - 562106, India.

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

NO VARNISH ZONE

IBUPROFEN

ibuprofen capsule, liquid filled

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:59556-764

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM) **IBUPROFEN** 200 mg

Inactive Ingredients Ingredient Name Strength POTASSIUM HYDROXIDE (UNII: WZH3C48M4T) POLYETHYLENE GLYCOL 600 (UNII: NL4|9F21N9) WATER (UNII: 059QF0KO0R) GELATIN (UNII: 2G86QN327L) SORBITOL (UNII: 506T60A25R) SORBITAN (UNII: 6092ICV9RU) FD&C BLUE NO. 1 (UNII: H3R47K3TBD) MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U) PROPYLENE GLYCOL (UNII: 6DC9Q167V3) **SHELLAC** (UNII: 46N107B710) **SODIUM LAURYL SULFATE (UNII: 368GB5141J) TITANIUM DIOXIDE** (UNII: 15FIX9V2JP)

Product Characteristics				
Color	GREEN (transparent green to bluish green)	Score	no score	
Shape	OVAL (oblong shaped)	Size	8mm	
Flavor		Imprint Code		
Contains				

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:59556-764- 29	1 in 1 CARTON	11/16/2022		
1		20 in 1 BOTTLE; Type 0: Not a Combination Product			
2	NDC:59556-764- 12	1 in 1 CARTON	11/16/2022		
2		40 in 1 BOTTLE; Type 0: Not a Combination Product			
3	NDC:59556-764- 13	1 in 1 CARTON	11/16/2022		
3		80 in 1 BOTTLE; Type 0: Not a Combination Product			
4	NDC:59556-764- 11	1 in 1 CARTON	11/16/2022		
4		120 in 1 BOTTLE; Type 0: Not a Combination Product			
5	NDC:59556-764- 48	1 in 1 CARTON	11/16/2022		
5		160 in 1 BOTTLE; Type 0: Not a Combination Product			
6	NDC:59556-764- 49	1 in 1 CARTON	11/16/2022		
6		200 in 1 BOTTLE; Type 0: Not a Combination Product			
7	NDC:59556-764- 50	1 in 1 CARTON	11/16/2022		
7		300 in 1 BOTTLE; Type 0: Not a Combination Product			
8	NDC:59556-764- 18	1 in 1 CARTON	11/16/2022		
8		180 in 1 BOTTLE; Type 0: Not a Combination Product			
9	NDC:59556-764- 92	3000 in 1 BAG; Type 0: Not a Combination Product	11/16/2022		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA204469	11/16/2022		

IBUPROFEN

ibuprofen capsule, liquid filled

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59556-895	
Route of Administration	ORAL			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	200 mg		

Inactive Ingredients	
Ingredient Name	Strength
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
POLYETHYLENE GLYCOL 600 (UNII: NL4J9F21N9)	
WATER (UNII: 059QF0KO0R)	
GELATIN (UNII: 2G86QN327L)	
SORBITOL (UNII: 506T60A25R)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B710)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
SORBITAN (UNII: 6092ICV9RU)	

Product Characteristics					
Color	GREEN (transparent green to bluish green)	Score	no score		
Shape	OVAL	Size	8mm		
Flavor		Imprint Code	469		
Contains					

Pa	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:59556-895- 29	1 in 1 CARTON	11/16/2022		
1		20 in 1 BOTTLE; Type 0: Not a Combination Product			
2	NDC:59556-895- 13	1 in 1 CARTON	11/16/2022		
2		80 in 1 BOTTLE; Type 0: Not a Combination Product			
3	NDC:59556-895- 48	1 in 1 CARTON	11/16/2022		
3		160 in 1 BOTTLE; Type 0: Not a Combination Product			
4	NDC:59556-895- 50	1 in 1 CARTON	11/16/2022		
4		300 in 1 BOTTLE; Type 0: Not a Combination Product			
5	NDC:59556-895- 79	7000 in 1 BAG; Type 0: Not a Combination Product	11/16/2022		

6	NDC:59556-895- 85	1 in 1 CARTON	11/16/2022	
6		80 in 1 BOTTLE; Type 0: Not a Combination Product		
7	NDC:59556-895- 86	1 in 1 CARTON	11/16/2022	
7		120 in 1 BOTTLE; Type 0: Not a Combination Product		
8	NDC:59556-895- 87	1 in 1 CARTON	11/16/2022	
8		160 in 1 BOTTLE; Type 0: Not a Combination Product		
9	NDC:59556-895- 39	1 in 1 CARTON	11/16/2022	
9		200 in 1 BOTTLE; Type 0: Not a Combination Product		
10	NDC:59556-895- 88	1 in 1 CARTON	11/16/2022	
10		300 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA204469	11/16/2022		

Labeler - Strides Pharma Inc (078868278)

Revised: 4/2024 Strides Pharma Inc