

DOLEX FLEX- ibuprofen capsule, liquid filled
Pharmadel LLC

DOLEX FLEX (HLife)

Drug Facts

Active Ingredient & Purposes

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

Purposes

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 from arthritis
- and to reduce 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 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
- 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

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 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 20 mg**
- store at 20-25°C (68-77°F)
- avoid excessive heat above 40°C (104°F)

Inactive ingredients

FD&C blue no.1, gelatin, pharmaceutical ink, polyethylene glycol, potassium hydroxide, purified water, sorbitol, and sorbitan

Questions or comments?

1-866-359-3478

(M-F) 9 AM - 5 PM EST or www.pharmadel.com

Package Principal Display Panel



DOLEX FLEX

ibuprofen capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55758-014
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
SORBITAN (UNII: 6O92ICV9RU)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
WATER (UNII: 059QF0KO0R)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
SORBITOL (UNII: 506T60A25R)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
GELATIN (UNII: 2G86QN327L)	

Product Characteristics

Color	blue	Score	score with uneven pieces
Shape	OVAL	Size	20mm
Flavor		Imprint Code	IB1
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55758-014-20	1 in 1 CARTON	09/07/2023	
1		20 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:55758-014-99	50 in 1 CARTON	11/01/2023	
2	NDC:55758-014-02	2 in 1 PACKET; Type 0: Not a Combination Product		



Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078682	09/01/2023	

Labeler - Pharmadel LLC (030129680)