

DOLEX FLEX- ibuprofen capsule, liquid filled
Pharmadel LLC

DOLEX FLEX (Deactivated)

Drug Facts

Active Ingredient

| | |
|--|-----------------------------|
| Active ingredient (in each capsule) | Purpose |
| Solubilized ibuprofen equal to 200 mg ibuprofen (NSAID)*..... | Pain reliever/fever reducer |

* nonsteroidal anti-inflammatory drug

Uses

Temporarily relieves minor aches and pains due to:

- headache
- muscular aches
- minor pain of arthritis
- toothache
- backache
- the common cold
- menstrual cramps
- 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 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 (1-800-222-1222).

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)
- read all warnings and directions before use
- retain carton for complete product information and warnings

Inactive ingredients

FD&C blue no. 1, FD&C, yellow no.6, gelatin, lecithin (soybean), medium-chain triglycerides, pharmaceutical ink, polyethylene glycol, potassium hydroxide, purified water, sorbitol sobitan.

Questions or comments?

1-866-359-3478

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

Package Principal Display Panel

DOLEX® FLEX

Relief of

MUSCULAR ACHES

Solubilized Ibuprofen Capsules, 200 mg

Pain Reliever / Fever Reducer (NSAID)

20 SOFTGELS**

(**Liquid Filled Capsules)



DOLEX FLEX

ibuprofen capsule, liquid filled

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:55758-310 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|----------|
| IBUPROFEN (UNII: WK2XY10QM) (IBUPROFEN - UNII:WK2XY10QM) | IBUPROFEN | 200 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|------------------------------------|----------|
| SORBITAN (UNII: 6O921CV9RU) | |

| | |
|--|--|
| 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 | green | Score | score with uneven pieces |
| Shape | OVAL | Size | 19mm |
| Flavor | | Imprint Code | AT146 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:55758-310-20 | 1 in 1 CARTON | 10/31/2019 | 04/30/2024 |
| 1 | | 20 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 | ANDA206999 | 10/31/2019 | |

Labeler - Pharmadel LLC (030129680)

Revised: 9/2023

Pharmadel LLC