

IBUPROFEN - ibuprofen tablet, coated
IBUPROFEN - ibuprofen tablet, coated
Polygen Pharmaceuticals LLC

Ibuprofen Tablets, 200 mg

Active ingredient(s)

Ibuprofen 200 mg (NSAID)*

* nonsteroidal anti-inflammatory drug

Purpose

Pain reliever/Fever reducer

Use(s)

temporarily relieves minor aches and pain due to:

- backache
- headache
- menstrual cramps
- minor pain of arthritis
- muscular aches
- the common cold
- toothache
- temporarily reduces fever

Warnings

Allergy alert: Ibuprofen may cause a severe allergy reaction, especially in people allergic to aspirin.

Symptoms may include:

- asthma (wheezing)
- blisters
- facial swelling
- hives
- rash
- shock
- skin reddening

If an allergic reaction occurs, stop use and seek medical help right away.

Stomach bleeding warning: This product contains an NSAID, which may cause 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 non prescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- have 3 or more alcoholic drinks every day while using this product
- the more or for a longer time 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

- you have problems or serious side effects from taking pain relievers or fever reducers
- you have a history of stomach problems such as heartburn
- the stomach bleeding warning applies to you
- you have high blood pressure, heart disease , kidney disease, liver cirrhosis
- you are taking a diuretic
- you have asthma

Ask a doctor or pharmacist before use if

- 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
- the risk of heart attack or stroke may increase if you use more than directed or for longer than directed

Stop use and ask 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
- 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 occur

Side effects occur. You may report side effects to PolyGen at 1-888-291-7337 and/ or FDA at 1-800-FDA-1088

Pregnancy/Breastfeeding

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)

Directions

- **do not take more than directed**
- **the smallest effective dose should be used**

| | |
|--|--|
| adults and children 12 years and older: | · take 1 tablet every 4 to 6 hours while symptoms persist · if pain or fever does not respond to 1 tablet, 2 tablets may be used · do not exceed 6 tablets in 24 hours unless directed by a doctor |
| children under 12 years: | ask a doctor |

other information

- **do not use if seal under cap is broken or missing**
- see end panel for lot number and expiration date

Inactive ingredient

colloidal silicon dioxide, croscarmellose sodium, iron oxide red, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, pregelatinized starch, talc, titanium dioxide

Storage

- store between 20-25 °C (68-77 ° F).

Questions

1-888-291-7337

Principal Display Panel

CARTON LABEL PDP

NDC: 52605-114-01

Compare to the active ingredient in Advil®

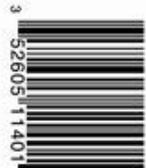
IBUPROFEN TABLETS, USP 200 mg

PAIN RELIEVER/ FEVER REDUCER (NSAID)

100 COATED TABLETS

SEE NEW WARNINGS INFORMATION

LOT:
EXP-
3 52605 11401 0



3 52605 11401 0

| | |
|--|--|
| <p>Drug Facts (continued)</p> <p>Do not use</p> <ul style="list-style-type: none">if you have ever had an allergic reaction to any other pain reliever/fever reducerright before or after heart surgery <p>Ask a doctor before use if</p> <ul style="list-style-type: none">you have had stomach side effects from taking pain relievers or fever reducersyou have a history of stomach problems, such as heartburnthe stomach bleeding warning applies to youyou have high blood pressure, heart disease, kidney disease or liver problemsyou are taking a diureticyou have asthma <p>Ask a doctor or pharmacist before use if you are</p> <ul style="list-style-type: none">under a doctor's care for any serious conditiontaking aspirin for heart attack or stroke, because ibuprofen may decrease this benefit of aspirintaking any other drug <p>When using this product</p> <ul style="list-style-type: none">take with food or milk if stomach upset occursthe risk of heart attack or stroke may increase if you use more than directed or for longer than directed <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none">you experience any of the following signs of stomach bleeding:<ul style="list-style-type: none">red stoolvomits bloodhave bloody or black stoolshave stomach pain that does not get betteryour gums bleed or taste more than 10 dayshave persistent sore or sores more than 3 daysnoticed or swelling is present in the painful areaany new symptoms appear | <p>Drug Facts</p> <p>Active ingredient (in each tablet)</p> <p>Ibuprofen 200 mg (NSAID)*. *This is not an essential anti-inflammatory drug. †Fever reducer.</p> <p>Purpose</p> <p>Temporarily relieves minor aches and pains due to:<ul style="list-style-type: none">backacheheadachemenstrual crampsmuscular achestoothache</p> <p>Uses</p> <ul style="list-style-type: none">temporarily reduces fever <p>Warnings</p> <p>Allergy alert: Ibuprofen may cause a severe allergic reaction in people allergic to aspirin.</p> <p>Symptoms may include:<ul style="list-style-type: none">asthma (wheezing)hivesrashswelling of the face, lips, tongue, or throatskin redness or itchingstomach paintrouble breathingtrouble swallowingtrouble talkingtrouble seeingtrouble hearingtrouble sleepingtrouble walkingtrouble standingtrouble sittingtrouble movingtrouble breathingtrouble swallowingtrouble talkingtrouble seeingtrouble hearingtrouble sleepingtrouble walkingtrouble standingtrouble sittingtrouble moving</p> <p>If an allergic reaction occurs, stop use and seek medical help right away.</p> <p>Stomach bleeding warning: This product contains an (NSAID), which may cause severe stomach bleeding. The chance is higher if you:<ul style="list-style-type: none">are age 60 or olderhave had stomach ulcers or bleeding problemstake a blood thinning (anticoagulant) or steroid drugtake other drugs (including prescription or over-the-counter NSAIDs, aspirin, clopidogrel, tacrolimus, or others)have 3 or more alcoholic drinks every day while using this producttake more or for a longer time than directed</p> |
|--|--|



NDC 52605-114-01

Compare to the active ingredient in ADVIL™

IBUPROFEN

TABLETS USP, 200 mg
PAIN RELIEVER/FEVER REDUCER (NSAID)

100 COATED TABLETS **SEE NEW WARNINGS INFORMATION**

IMPORTANT: READ ALL PRODUCT INFORMATION BEFORE USING. KEEP THIS BOX FOR IMPORTANT INFORMATION.

Distributed by: PolyGen Pharmaceuticals LLC
Edgewood, NY, 11717, USA



R105/12
LBS0012

*PolyGen Pharmaceuticals LLC, is not affiliated with the owner of the registered trademark Advil®

NDC: 52605-114-01

**IBUPROFEN TABLETS, USP 200 mg
PAIN RELIEVER/ FEVER REDUCER(NSAID)**

100 COATED TABLETS

SEE NEW WARNINGS INFORMATION

ThruLife
NDC 52605-114-01

IBUPROFEN
TABLETS USP, 200 mg
PAIN RELIEVER/
FEVER REDUCER (NSAID)
SEE NEW WARNINGS INFORMATION

100
COATED TABLETS

Important: Read all product information before using. Keep the box for important information.

Purpose
(in each tablet)
Ibuprofen 200 mg (NSAID)* Pain reliever/fever reducer
*nonsteroidal anti-inflammatory drug

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

Warnings
Allergy alert: Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:
asthma (wheezing) ■ blisters ■ facial swelling
hives ■ rash ■ shock ■ skin reddening
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

Do not use
if you have ever had an allergic reaction to any other pain reliever/fever reducer
right before or after heart surgery

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
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.
Keep out of reach of children.

Directions ■ do not take more than directed
the smallest effective dose should be used
Adults and children 12 years and older:
take 1 tablet every 4 to 6 hours while symptoms persist
if pain or fever does not respond to 1 tablet, 2 tablets may be used
do not exceed 6 tablets in 24 hours, unless directed by a doctor

Other information
store between 20°-25°C (68°-77°F)
do not use if seal under cap is broken or missing

Distributed by: PolyGen Pharmaceuticals LLC
Edgewood, NY, 11717, USA
R105/12
LBS0011

LOT:
EXP:

CARTON LABEL PDP

NDC: 52605-117-01

Compare to the active ingredient in Advil®

**IBUPROFEN TABLETS, USP 200 mg
PAIN RELIEVER/ FEVER REDUCER (NSAID)**

100 COATED CAPLETS

SEE NEW WARNINGS INFORMATION

BOTTLE LABEL PDP

NDC: 52605-117-01

IBUPROFEN TABLETS, USP 200 mg
PAIN RELIEVER/ FEVER REDUCER(NSAID)

LOT:
EXP:

3 52605-11701-1

DO NOT USE IF SEAL UNDER BOTTLE CAP IS BROKEN OR MISSING

Drug Facts (continued)

- Do not use if you have had an allergic reaction to any other NSAID.
- Ask a doctor before use if:
 - you are taking aspirin, salicylates, or other heart-surgery-preventing medicines.
 - you have a history of stomach problems, such as heartburn.
 - you have high blood pressure, heart disease, kidney disease or liver cirrhosis.
 - you are taking a diuretic.
 - you have asthma.
- 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 increase this benefit of aspirin.
 - taking any other drug.
- When using this product:
 - do not drink alcohol if stomach upset occurs.
 - do not take other NSAIDs unless your doctor tells you to, because the risk of stomach bleeding is greater if you use more than directed or for longer than directed.
- Stop use and ask a doctor if:
 - any of the following signs of stomach bleeding occur:
 - stomach bleed or pain
 - red heart
 - black stools
 - dark, bloody or black stools
 - stomach pain that does not get better
 - stomach pain that lasts more than 10 days
 - stomach pain that gets worse or lasts more than 3 days
 - nausea or vomiting is present in the painful area
 - any new symptoms appear

Drug Facts
Active ingredient (in each caplet)
Ibuprofen (USP) 200 mg. **Pain reliever/fever reducer and non-steroidal anti-inflammatory drug. Four doses.**

Purpose
Temporarily relieves minor aches and pains due to:

- backache
- headache
- muscular cramps
- muscular aches
- the common cold
- menstrual cramps
- minor pain of arthritis
- the common cold

Warnings
Alert: Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:

- hives
- swelling of the face, lips, tongue, or throat
- difficulty breathing
- skin rash
- itching
- fever
- stomach pain
- diarrhea
- nausea
- vomiting
- dark, bloody or black stools
- stomach pain that does not get better
- stomach pain that lasts more than 10 days
- stomach pain that gets worse or lasts more than 3 days
- nausea or vomiting is present in the painful area
- any new symptoms appear

Directions
Do not take more than directed.
The smallest effective dose should be used.

- Adults and children 12 years and older:
 - Take 1 caplet every 4 to 6 hours.
 - Do not take more than 6 caplets in 24 hours.
 - Do not exceed 6 caplets in 24 hours, unless directed by a doctor.
- Children under 12 years:
 - Do not use if used under cap is broken or missing.
 - Use only as directed.

Other information

- Store between 20°-25°C (68°-77°F).
- Use only as directed.
- Use only as directed.

Inactive ingredients
colloidal silicon dioxide, croscarmellose sodium, iron oxide red, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, propylparacetamol, talc, titanium dioxide.

Questions or comments? 1-888-231-7337

ThruLife

NDC 52605-117-01

Compare to the active ingredient in ADVIL[®]

IBUPROFEN
TABLETS USP, 200 mg
PAIN RELIEVER/FEVER REDUCER (NSAID)

100 COATED CAPLETS**
**Capsule-Shaped Tablets

SEE NEW WARNINGS INFORMATION

IMPORTANT: READ ALL PRODUCT INFORMATION BEFORE USING. KEEP THIS BOX FOR IMPORTANT INFORMATION.

Distributed by: PolyGen Pharmaceuticals LLC
Edgewood, NY, 11717, USA

PolyGen

R112/12
LBS0035

[†]PolyGen Pharmaceuticals LLC, is not affiliated with the owner of the registered trademark Advil[®]

100 COATED CAPLETS

SEE NEW WARNINGS INFORMATION

NDC 52605-117-01



IBUPROFEN
TABLETS USP, 200 mg
PAIN RELIEVER/
FEVER REDUCER (NSAID)
SEE NEW WARNINGS INFORMATION

100
COATED CAPLETS**
**Capsule-Shaped Tablets

Important: Read all product information before using. Keep the box for important information.

| | |
|---|--|
| Purpose (in each caplet) Ibuprofen, 200 mg (NSAID)* *nonsteroidal anti-inflammatory drug | Uses <ul style="list-style-type: none"> ■ temporarily relieves minor aches and pains due to: <ul style="list-style-type: none"> ■ headache ■ muscle aches ■ menstrual cramps ■ minor pain of arthritis ■ muscular aches ■ the common cold ■ temporarily reduces fever |
| Warnings Allergy alert: Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include: <ul style="list-style-type: none"> ■ asthma (wheezing) ■ hives ■ rash ■ shock ■ skin redness 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: <ul style="list-style-type: none"> ■ are age 60 or older ■ have had stomach ulcers or bleeding problems ■ take a blood thinner (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 |
| Do not use <ul style="list-style-type: none"> ■ if you have ever had an allergic reaction to any other pain reliever/fever reducer ■ right before or after heart surgery | Stop use and ask a doctor if <ul style="list-style-type: none"> ■ you experience any of the following signs of stomach bleeding: <ul style="list-style-type: none"> ■ feel faint ■ vomit blood ■ have bloody or black stools ■ have stomach pain that does not get better ■ 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. Keep out of reach of children. | Directions <ul style="list-style-type: none"> ■ do not take more than directed ■ the smallest effective dose should be used Adults and children 12 years and older: <ul style="list-style-type: none"> ■ take 1 caplet every 4 to 6 hours while symptoms persist ■ if pain or fever does not respond to 1 caplet, 2 caplets may be used ■ do not exceed 6 caplets in 24 hours, unless directed by a doctor |
| Other information <ul style="list-style-type: none"> ■ store between 20°-25° C (68°-77°F) ■ do not use if seal under cap is broken or missing | Distributed by: Polycem Pharmaceuticals LLC Edgewood, NY, 11717, USA R112/112 LBS0034 LOT: EXP: |

IBUPROFEN

ibuprofen tablet, coated

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:52605-114 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|----------|
| IBUPROFEN (UNII: WK2XY110QM) (IBUPROFEN - UNII:WK2XY110QM) | IBUPROFEN | 200 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| CROSCARMELOSE SODIUM (UNII: M28OL1HF48) | |
| COLLOIDAL SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| FERRIC OXIDE RED (UNII: 1K09F3G675) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U) | |
| POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A) | |
| TALC (UNII: 7SEV7J4R1U) | |

| | |
|--------------------------------------|--|
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |
| STARCH, CORN (UNII: O8232NY3SJ) | |
| POLYVINYL ALCOHOL (UNII: 532B59J990) | |

Product Characteristics

| | | | |
|----------|-------|--------------|----------|
| Color | BROWN | Score | no score |
| Shape | ROUND | Size | 10mm |
| Flavor | | Imprint Code | 114 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:52605-114-01 | 1 in 1 CARTON | | |
| 1 | | 100 in 1 BOTTLE | | |
| 2 | NDC:52605-114-10 | 1000 in 1 BOTTLE | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| ANDA | ANDA091239 | 06/05/2012 | |

IBUPROFEN

ibuprofen tablet, coated

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:52605-117 |
| 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 |
|--|----------|
| CROSCARMELLOSE SODIUM (UNII: M28OL1HH48) | |
| COLLOIDAL SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| FERRIC OXIDE RED (UNII: 1K09F3G675) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U) | |
| POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A) | |
| TALC (UNII: 7SEV7J4R1U) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |

STARCH, CORN (UNII: O8232NY3SJ)

POLYVINYL ALCOHOL (UNII: 532B59J990)

Product Characteristics

| | | | |
|-----------------|---------|---------------------|----------|
| Color | BROWN | Score | no score |
| Shape | CAPSULE | Size | 15mm |
| Flavor | | Imprint Code | 117 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:52605-117-01 | 1 in 1 CARTON | | |
| 1 | | 100 in 1 BOTTLE | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| ANDA | ANDA091239 | 06/05/2012 | |

Labeler - Polygen Pharmaceuticals LLC (962415720)

Registrant - Polygen Pharmaceuticals LLC (962415720)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------|---------|-----------|------------------------|
| Marksans Pharma Limited | | 925822975 | MANUFACTURE(52605-117) |

Revised: 6/2013

Polygen Pharmaceuticals LLC