IBUPROFEN - ibuprofen tablet, coated
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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

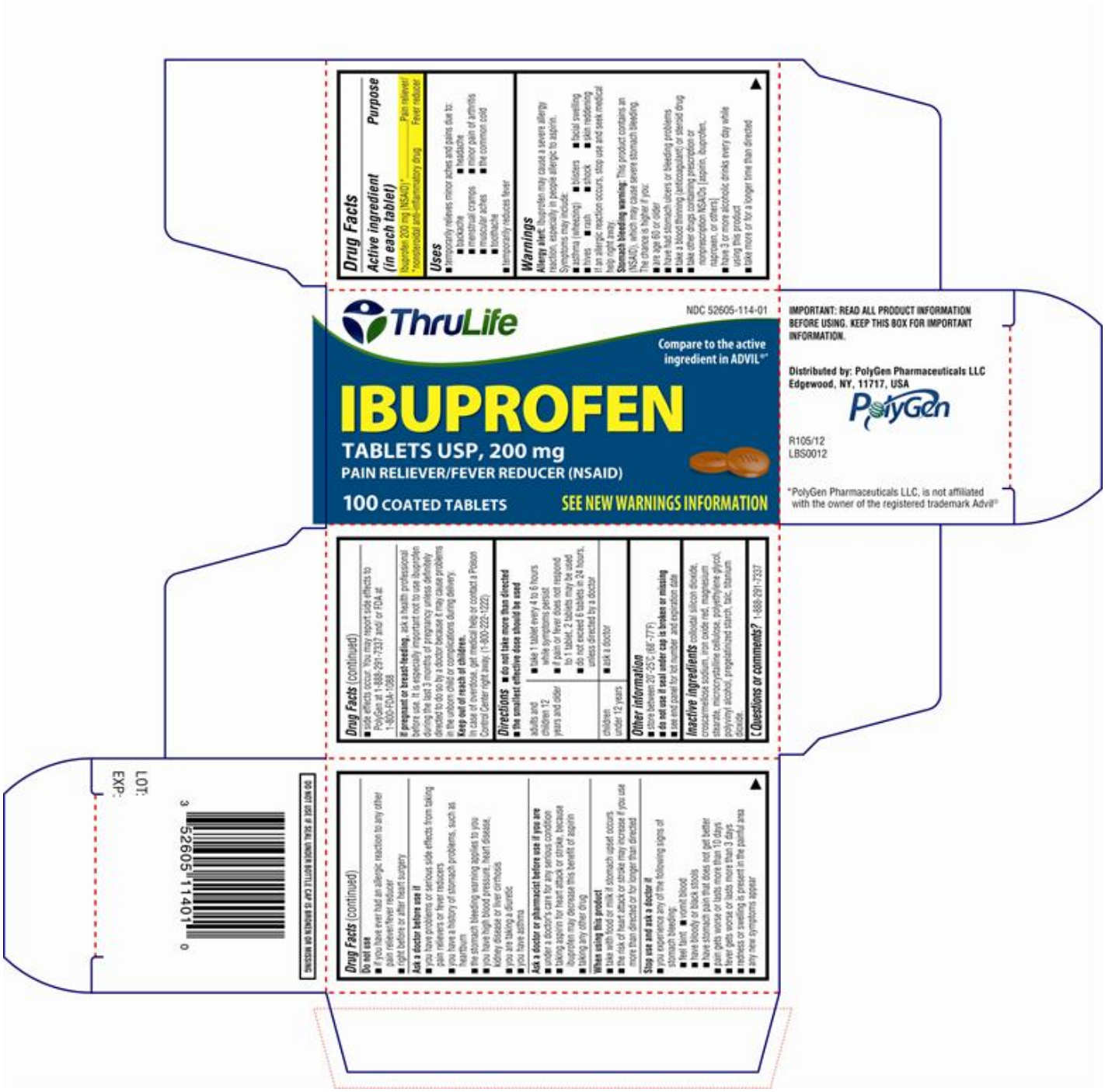
Compare to the active ingredient in Advil®

IBUPROFEN TABLETS, USP 200 mg

PAIN RELIEVER/ FEVER REDUCER (NSAID)

100 COATED TABLETS

SEE NEW WARNINGS INFORMATION



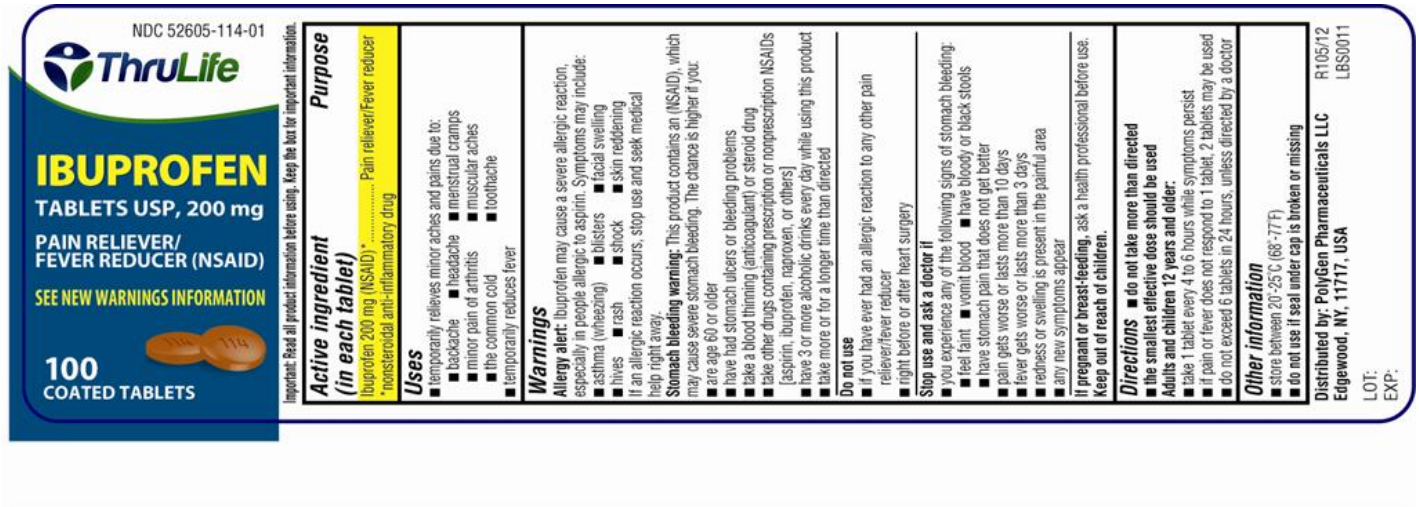
BOTTLE LABEL PDP

NDC: 52605-114-01

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

100 COATED TABLETS

SEE NEW WARNINGS INFORMATION



CARTON LABEL PDP

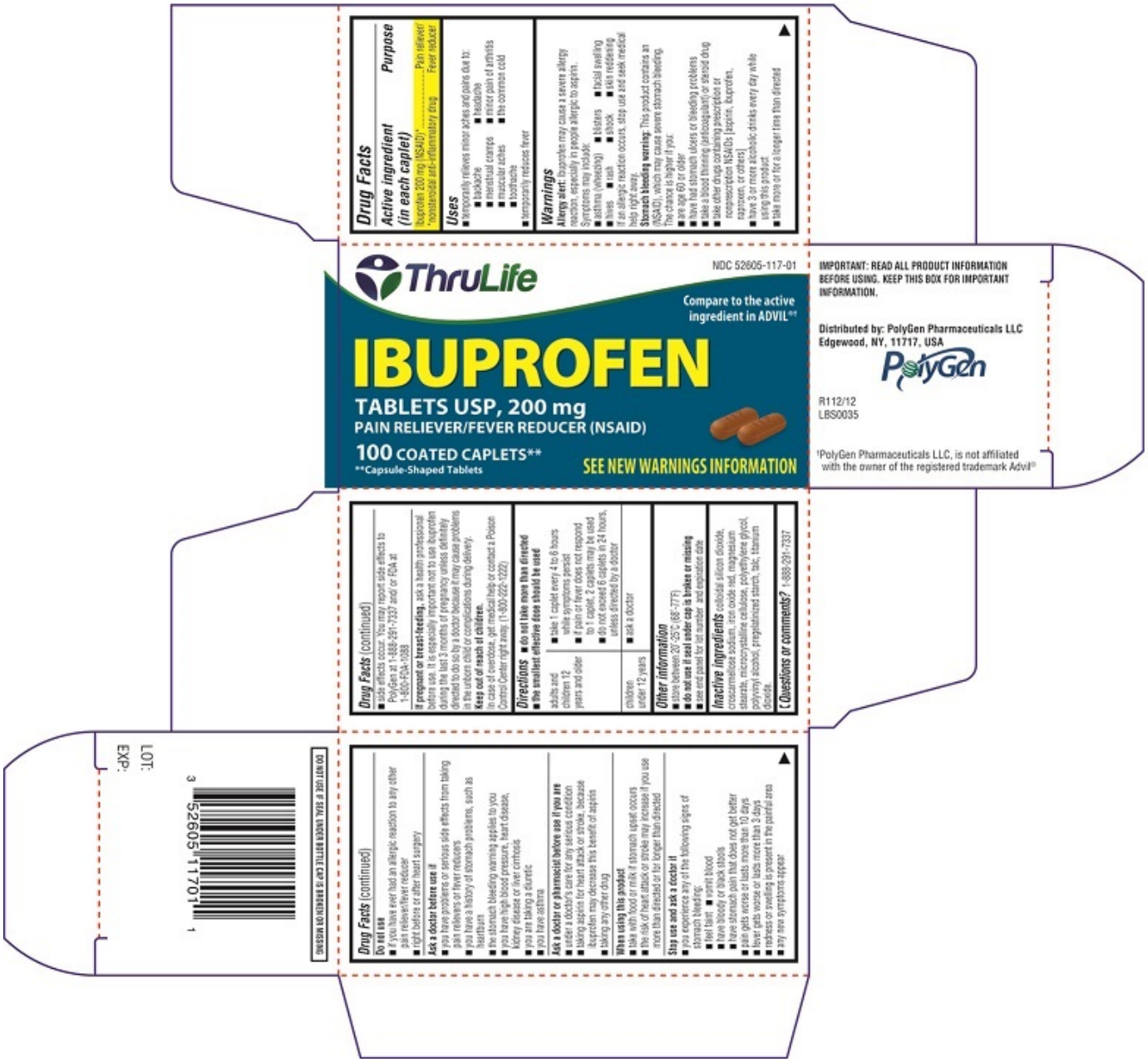
NDC: 52605-117-01

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

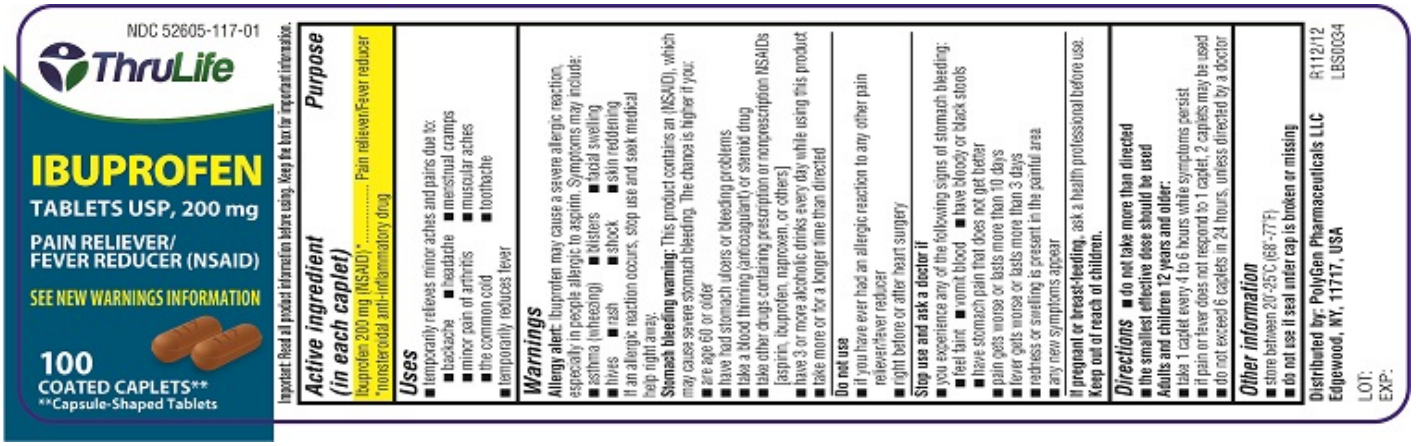
NDC: 52605-117-01

IBUPROFEN TABLETS, USP 200 mg

PAIN RELIEVER/ FEVER REDUCER(NSAID)

100 COATED CAPLETS

SEE NEW WARNINGS INFORMATION



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: 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	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