IBUPROFEN - ibuprofen tablet, film coated
Chain Drug Consortium LLC

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 alerts: 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 a nonsteroidal anti-inflammatory drug (NSAID), which may cause stomach bleeding. The chance is higher if you:

- are age 60 or older
- have bad stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drug containing prescription NSAID (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
- stomach problems that last or come back, such as heartburn, upset stomach, or stomach pain
- ulcers
- bleeding problems
- high blood pressure
- heart or kidney disease
- taken a diuretics
- reached age 60 or older

ASK A DOCTOR OR PHARMACIST BEFORE USE IF

you are
- taking any other drugs containg an NSAID (prescription or nonprescription)
- taking a blood thining (anticoagulant) or steriod drug
- under a doctor's care for any serious condition
- taking aspirin for heart attacks 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
- long term continuous use may increase the risk of heart attack or stroke

STOP USE AND ASK DOCTOR IF
- you feel faint, vomit blood, or have bloody or black stools.

  These are signs of stomach bleeding.
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- stomach pain or upset gets worse or lasts
- redness or swelling is present in painful area
- any new symptoms appear

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 a 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 PoisonControlCenter right away.

DIRECTIONS
- do not take more than directed

- the smallest effective dose should be used
- do not take longer than 10 days, unless directed by a doctor (see Warnings)

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

INACTIVE INGREDIENT(S)

Colloidal silicon dioxide, Croscarmellose Sodium, Magnesium stearate, Microcrystalline sodium, Pregelatinised starch, talc.

STORAGE

- store between 20-25 0c (68-77 0 F).
- do not use if seal under bottle cap imprinted with" SEALED for YOUR PROTECTION" is broken or missing.

PRINCIPAL DISPLAY PANEL

Carton Label PDP

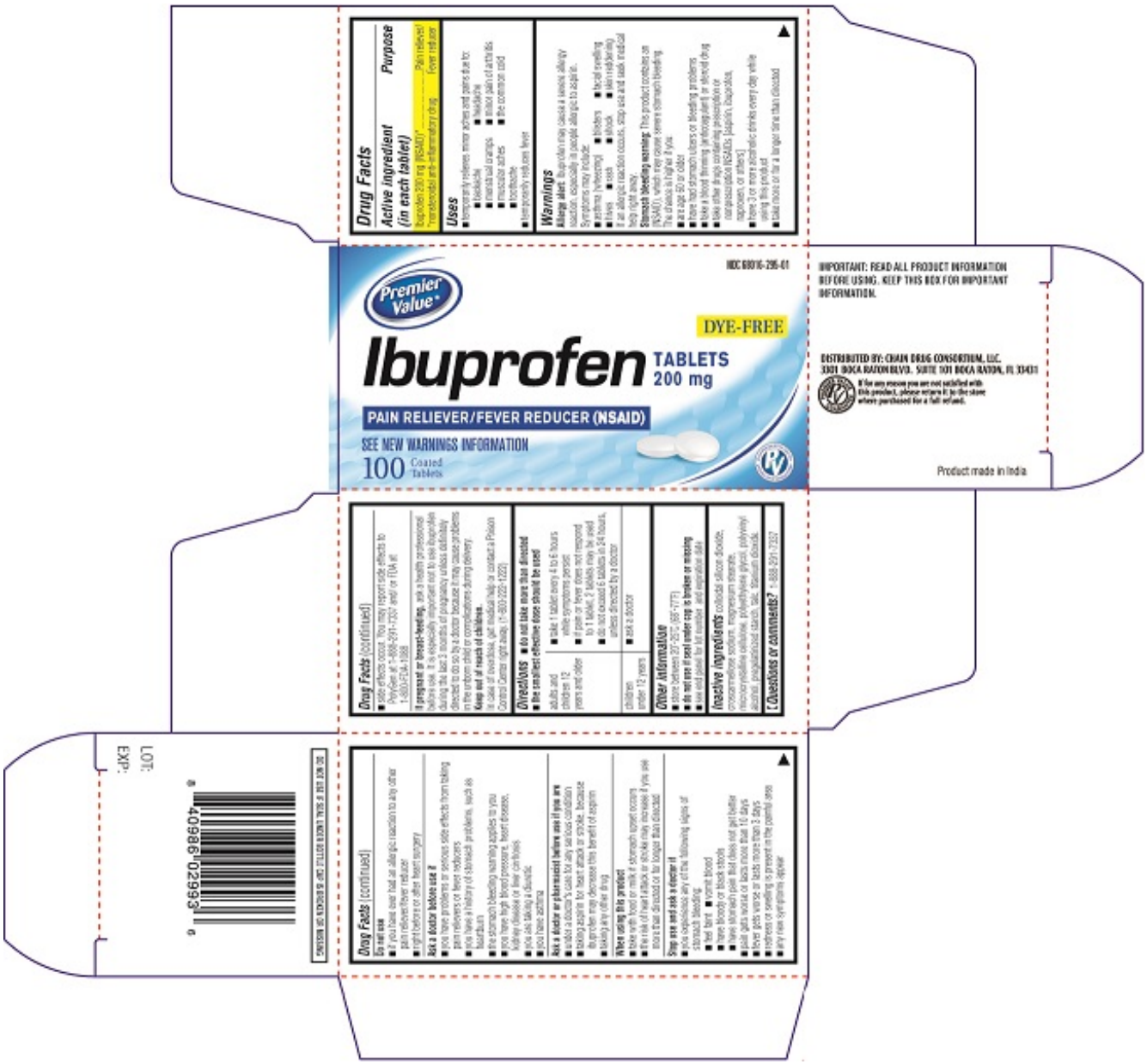
NDC# 68016-295-01

DYE FREE
Ibuprofen Tablets 200 mg

PAIN RELIEVER/FEVER REDUCER (NSAID)

SEE NEW WARNINGS INFORMATION

100 COATED TABLETS



Bottle Label PDP

NDC# 68016-295-01

DYE FREE
Ibuprofen Tablets 200 mg

PAIN RELIEVER/FEVER REDUCER (NSAID)

SEE NEW WARNINGS INFORMATION

100 COATED TABLETS

Carton Label PDP

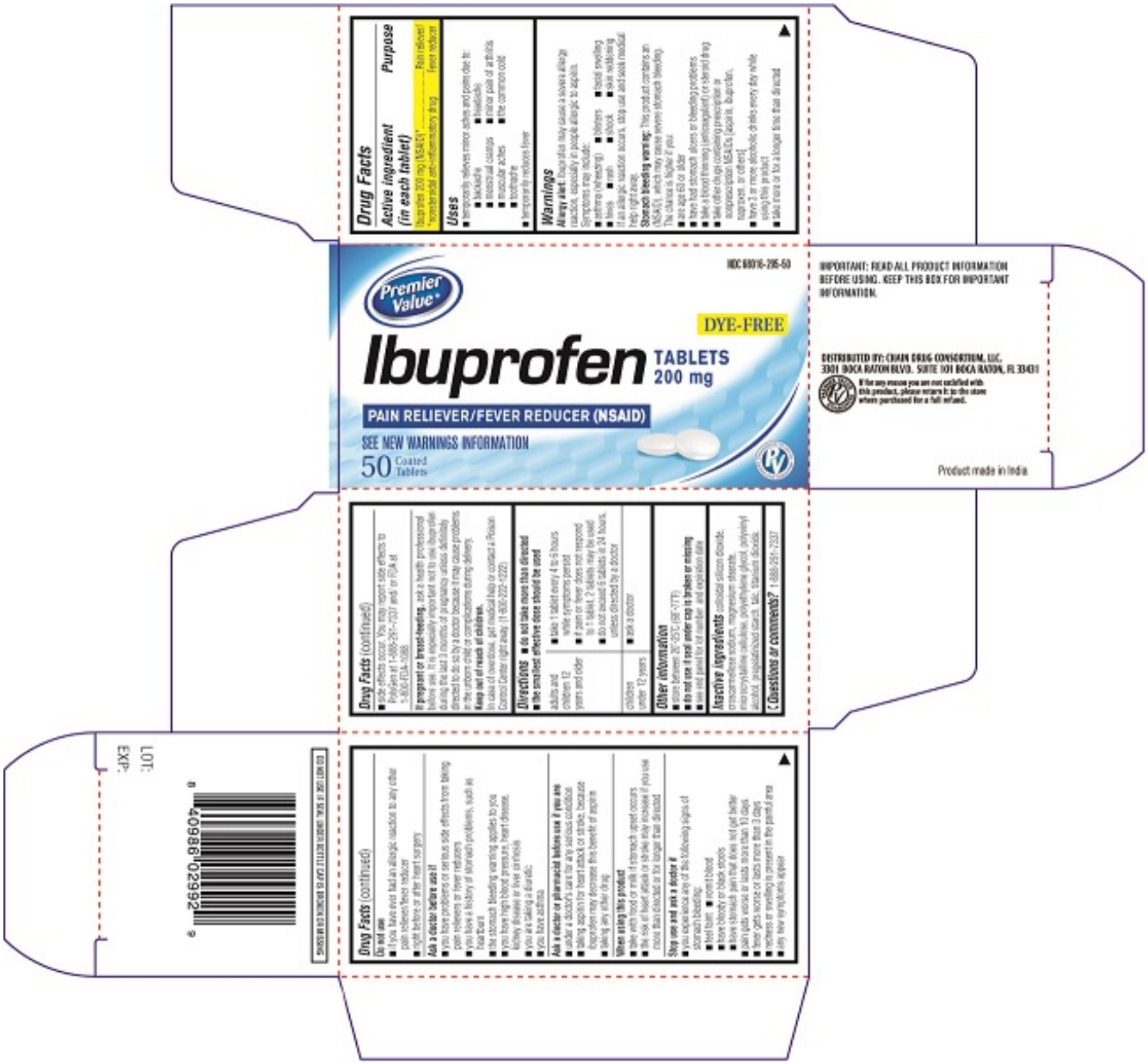
NDC# 68016-295-50

DYE FREE
Ibuprofen Tablets 200 mg

PAIN RELIEVER/FEVER REDUCER (NSAID)

SEE NEW WARNINGS INFORMATION

50 COATED TABLETS



Bottle Label PDP

NDC# 68016-295-50

DYE FREE
Ibuprofen Tablets 200 mg

PAIN RELIEVER/FEVER REDUCER (NSAID)

SEE NEW WARNINGS INFORMATION

50 COATED TABLETS

IBUPROFEN

ibuprofen tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68016-295
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**
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
COLLOIDAL SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

Product Characteristics			
Color	WHITE	**Score**	no score
Shape	ROUND	**Size**	10mm
Flavor		**Imprint Code**	115
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:68016-295-01	1 in 1 CARTON		
1		100 in 1 BOTTLE		
2	NDC:68016-295-50	1 in 1 CARTON		
2		50 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091237	05/07/2013	

Labeler - Chain Drug Consortium LLC (101668460)

Registrant - Chain Drug Consortium LLC (101668460)

Establishment

Name	Address	ID/FEI	Business Operations
Marksans Pharma Limited		925822975	MANUFACTURE(68016-295)

Revised: 4/2013 Chain Drug Consortium LLC