IBUPROFEN - ibuprofen tablet MARKSANS PHARMA LIMITED

Ibuprofen Tablets 200mg (OTC; Brown Tablets & Caplets)

Active ingredient(s)

Ibuprofen 200 mg (NSAID)*

* nonstreoidal anti-inflammatory drug

Purpose

Pain reliever / fever reducer

Use(s)

- 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 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 NSAID, which may cause severe 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 drugs containing 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

Heart attack and stroke warning: NSAID's except aspirin increases the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or longer than directed.

Do not use

- if you have ever had an allergic reaction to ibuprofen or 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
- The stomach bleeding warning applies to you
- You have a history of stomach problems, such as heartburn
- You have a high blood pressure, heart disease, cirrhosis, kidney disease, as thma or had a stroke
- You are taking a diuretic

Ask a doctor or pharmacist before use if you are

- taking aspirin for heart attack or stroke, because ibuprofen may decrease this benefit of aspirin
- under a doctor's care for any serious condition
- taking any other drug

When using this product

• take with food or milk if stomach upset occurs

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
- you have symptoms of heart problem or stroke:
- chest pain
- trouble breathing
- weakness in one part or side of body
- slurred speech
- leg swelling
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days

- 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 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

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

Inactive ingredients

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

Questions or Comments?

Call 1-877-290-4008

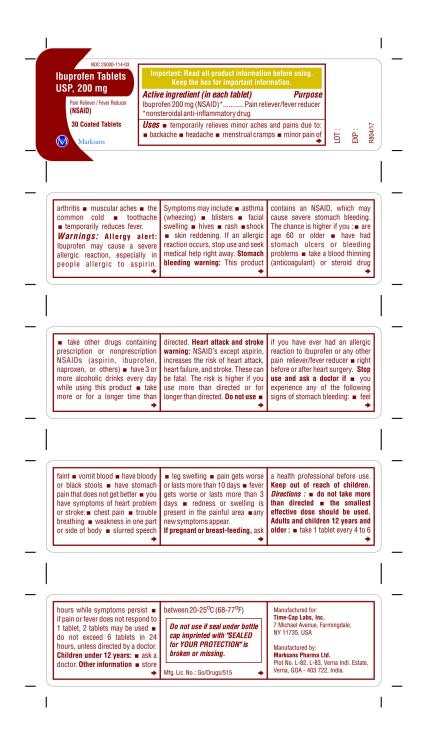
Manufactured for: **Time-Cap Labs, Inc.** 7 Michael Avenue, Farmingdale, NY 11735, USA

Manufactured by: **Marksans Pharma Ltd.** Plot No. L-82, L-83 Verna Industrial Estate Verna, Goa-403722, India

Storage

Principal Display Panel

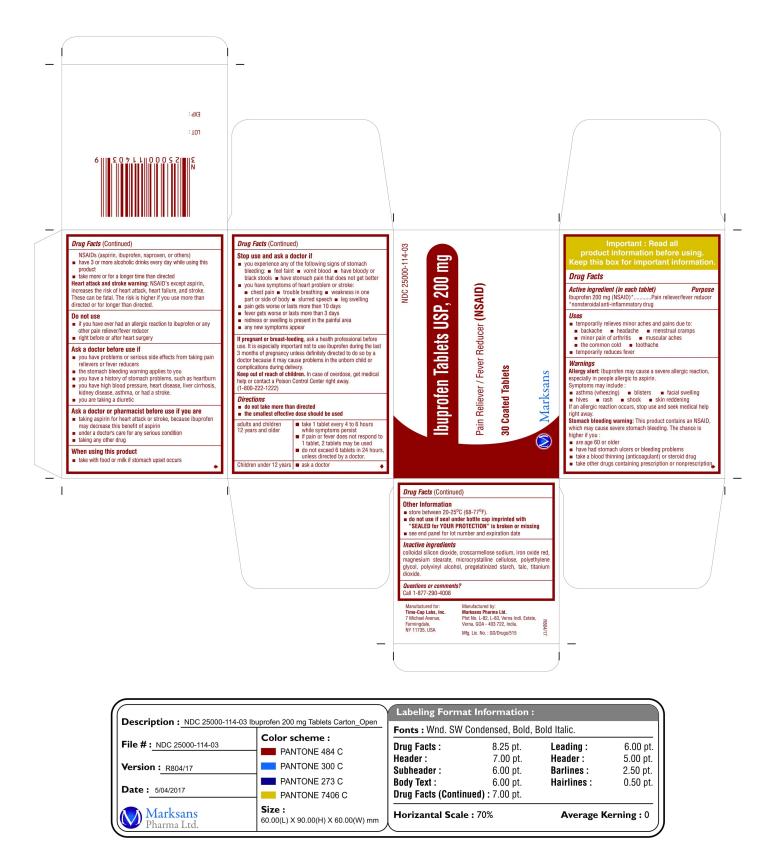
Ibuprofen Tablets USP, 200mg

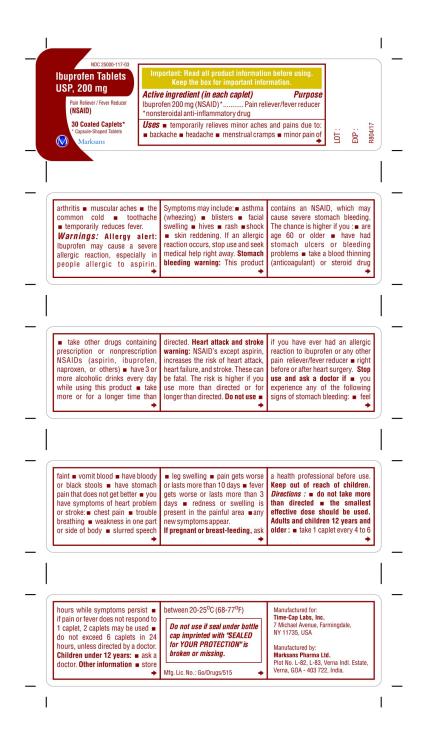


	Ibuprofen 200 mg 30-Tablets Label_Open	Fonts : Wnd. SW	Condensed, Bold,	Bold Italic.	
File #: NDC 25000-114-03	PANTONE 484 C	Drug Facts :	8.25 pt.	Leading :	6.00 pt
Version: R804/17	PANTONE 300 C	Header :	7.00 pt.	Header :	5.00 pt
Version . R804/17	PANTONE 273 C	Subheader : Body Text :	6.00 pt. 6.00 pt.	Barlines : Hairlines :	2.50 pt 0.50 pt
Date: 5/04/2017		Drug Facts (Contin		1141111163.	0.50 pi
Marksans	Size :	Horizantal Scale	, .	Average K	Coming (

Ibuprofen Tablets USP, 200mg

30 counts Carton Label

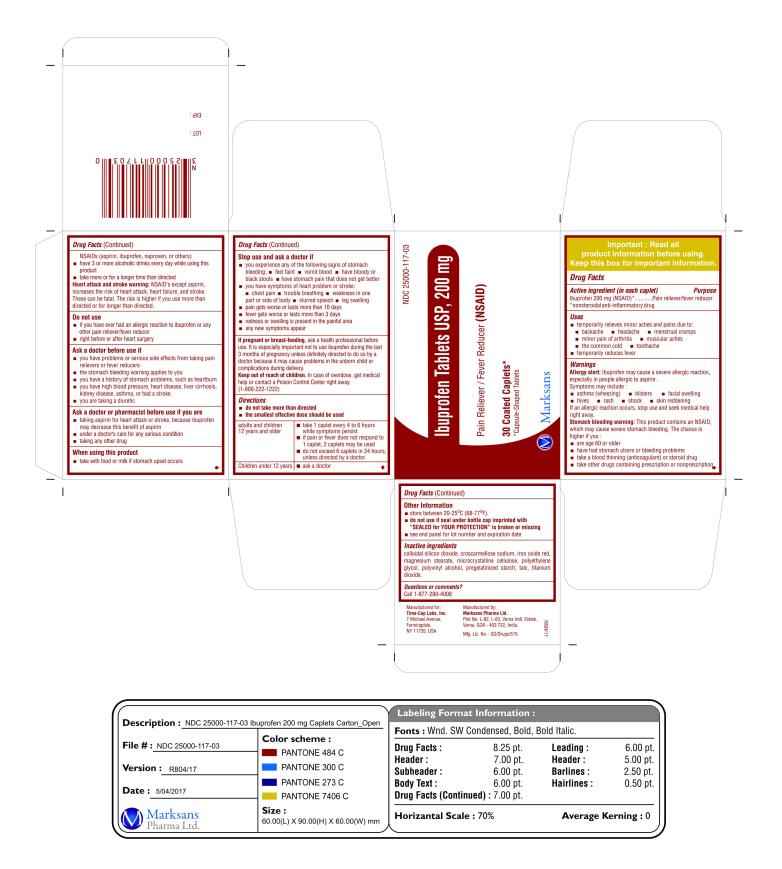




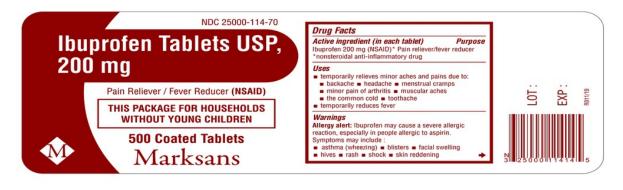
Description : NDC 25000-117-03	Ibuprofen 200 mg 30-Caplets Label_Open	Fonts : Wnd. SW	Condensed, Bold,	Bold Italic.	
File # : NDC 25000-117-03	Color scheme : PANTONE 484 C	Drug Facts :	8.25 pt.	Leading :	6.00 pt
Version : R804/17	PANTONE 300 C	Header : Subheader :	7.00 pt. 6.00 pt.	Header : Barlines :	5.00 pt. 2.50 pt.
Date : 5/04/2017	PANTONE 273 C	Body Text : Drug Facts (Contin	6.00 pt. ued) : 7.00 pt.	Hairlines :	0.50 pt
Marksans Pharma Ltd.	Size : 140.00(L) X 80.00(H) mm	Horizantal Scale	e: 70%	Average K	erning:0

Ibuprofen Tablets USP, 200mg (Caplets)

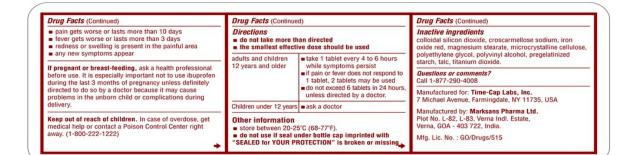
30 counts Carton Label



Ibuprofen Tablets USP, 200mg



Drug Facts (Continued) Drug Facts (Continued) Drug Facts (Continued) These can be fatal. The risk is higher if you use more than If an allergic reaction occurs, stop use and seek medical Ask a doctor or pharmacist before use if you are taking aspirin for heart attack or stroke, becaus ibuprofen may decrease this benefit of aspirin under a doctor's care for any serious condition taking any other drug help right away. Stomach bleeding warning: This product contains an directed or for longer than directed. Do not use NSAID, which may cause severe stomach bleeding NSAID, which may cause severe stomach bleeding. The chance is higher if you : a 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) if you have ever had an allergic reaction to ibuprofen or any other pain reliever/fever reducer right before or after heart surgery When using this product Ask a doctor before use if you have problems or serious side effects from taking pain relievers or fever reducers the stomach bleeding warning applies to you you have a history of stomach problems, such as beethvire take with food or milk if stomach upset occurs Stop use and ask a doctor if you experience any of the following signs of stomach others) have 3 or more alcoholic drinks every day while using this product eding: feel faint = vomit blood = have bloody or black stools heartburn this product take more or for a longer time than directed Heart attack and stroke warning: NSAID's except aspirin, increases the risk of heart attack, heart failure, and stroke you have high blood pressure, heart disease, liver have stomach pain that does not get better you have symptoms of heart problem or stroke cirrhosis, kidney disease, asthma, or had a stroke. you are taking a diuretic • chest pain • trouble breathing • weakness in one part or side of body • slurred speech • leg swelling •



		Labeling Forma	t Information :		
Description : Ibuprofen 200mg 50	Color scheme :	Fonts : Wnd. SW (Condensed, Bold,	Bold Italic.	
File # : NDC 25000-114-70	PANTONE 484 C	Drug Facts :	8.25 pt.	Leading :	6.00 pt.
Manaian a manai		Header :	7.00 pt.	Header :	5.00 pt.
Version : R011/19		Subheader :	6.00 pt.	Barlines :	2.50 pt.
Date : 30/11/2019	Size :	Body Text : Drug Facts (Contin	6.00 pt. u ed) : 7.00 pt.	Hairlines :	0.50 pt.
Marksans Pharma Ltd.	165.00(L) X 57.00(H) mm	Horizantal Scale	: 70%	Average K	erning:0

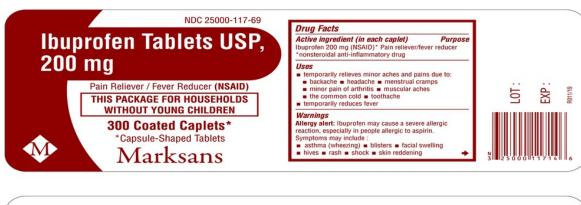
Ibuprofen Tablets USP, 200mg



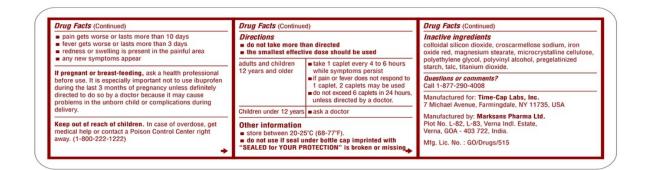
Drug Facts (Continued)	Drug Facts (Continued)	Drug Facts (Continued)
 taking aspirin for heart attack or stroke, because ibuprofen may decrease this benefit of aspirin under a doctor's care for any serious condition taking any other drug 	Directions • do not take more than directed • the smallest effective dose should be used	Manufactured for: Time-Cap Labs, Inc. 7 Michael Avenue, Farmingdale,
When using this product take with food or milk if stomach upset occurs Stop use and ask a doctor if you experience any of the following signs of stomach bleeding: • feel faint womit blood & have bloody or black stools	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.	NY 11735, USA Manufactured by: Marksans Pharma Ltd. Plor No. 1-82, L-83, Verna. Indl. Estate, Verna. GOA - 403 722, India.
have stomach pain that does not get better you have symptoms of heart problem or stroke: chest pain trouble breathing weakness in one part or side of body slurred speech leg swelling pain gets worse or lasts more than 10 days fever gets worse or lasts more than 3 days redness or vealling is present in the painful area	Children under 12 years a sk a doctor Other information = store betwen 20-25°C (68-77°F). = do not use if seal under bottle cap imprinted with "SEALED for YOUR PROTECTION" is broken or missing	verna, GOA - 40 7 722, india. Mfg. Lic. No. : GO/Drugs/515
 any new symptoms appear frpegnant 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 rint away. (1-800-222-1222) 	Inactive ingredients colloidal silicon dioxide, croscarmellose sodium, iron oxide red, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, pregelatinized starch, talc, titanium dioxide. Questions or comments? Call 1-877-290-4008	

Description : Ibuprofen 200mg 10	00 tablets brown label	Labeling Forma			
	Color scheme :	Fonts : Wnd. SW	Condensed, Bold,	Bold Italic.	
File #: NDC 25000-114-71	PANTONE 484 C	Drug Facts :	8.25 pt.	Leading :	6.00 pt
		Header :	7.00 pt.	Header :	5.00 pt
Version: R011/19		Subheader :	6.00 pt.	Barlines :	2.50 pt
-		Body Text :	6.00 pt.	Hairlines :	0.50 pt
Date: 30/11/2019	Size :	Drug Facts (Contin	ued): 7.00 pt.		1
Marksans Pharma Ltd.	229.00(L) X 86.00(H) mm	Horizantal Scale : 70% Average Ker			Cerning:0

Ibuprofen Tablets USP, 200mg (Caplets)



Drug Facts (Continued)	Drug Facts (Continued)	Drug Facts (Continued)
If an allergic reaction occurs, stop use and seek medical help right away.	These can be fatal. The risk is higher if you use more than directed or for longer than directed.	Ask a doctor or pharmacist before use if you are taking aspirin for heart attack or stroke, because
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	Do not use if you have ever had an allergic reaction to ibuprofen or any other pain reliever/fever reducer	 ibuprofen may decrease this benefit of aspirin under a doctor's care for any serious condition taking any other drug
 are age ou or older have had stomach ulcers or bleeding problems take a blood thinning (anticoagulant) or steroid drug 	right before or after heart surgery Ask a doctor before use if	When using this product take with food or milk if stomach upset occurs
 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: NSAID's except aspirin, increases the risk of heart attack, heart failure, and stroke 	 you have problems or serious side effects from taking pain relievers or fever reducers the stomach bleeding warning applies to you 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 	Stop use and ask a doctor if you experience any of the following signs of stomach bleeding: left faint = vomit blood = have bloody or black stools have stomach pain that does not get better you have symptoms of heart problem or stroke: - chest pain = trouble breathing = weakness in one part or side of body = slurred speech = leg swelling



		Labeling Forma	t Information :		
Description : Ibuprofen 200mg ca	Color scheme :	Fonts : Wnd. SW	Condensed, Bold,	Bold Italic.	
File # : NDC 25000-117-69	PANTONE 484 C	Drug Facts :	8.25 pt.	Leading :	6.00 pt.
		Header :	7.00 pt.	Header :	5.00 pt.
Version: R011/19		Subheader :	6.00 pt.	Barlines :	2.50 pt.
Deter commence		Body Text :	6.00 pt.	Hairlines :	0.50 pt.
Date : 30/11/2019	Size :	Drug Facts (Contin	ued): 7.00 pt.		
Marksans Pharma Ltd.	165.00(L) X 57.00(H) mm	Horizantal Scale	e:70%	Average K	erning:0

IBUPROFEN ibuprofen tablet			
Product Information Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:25000-114

Route	of Administration	
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	t/Activ	e Moiety				
		Ingredient Name		Basis of S	trength	Strength
IBUPROFEN (UNII: W	K2XYI10(QM) (IBUPROFEN - UNII:WI	K2XYI10OM	IBUPROFEN		200 mg
				DOINOILIN		200 mg
Inactive Ingredie	ents					
		Ingredient	Name			Strength
SILICON DIOXIDE (U	NII: ETJ7	Z6XBU4)				
CROSCARMELLOSE	SODIUM	II (UNII: M280L1HH48)				
FERRIC OXIDE RED (UNII: 1K)9F3G675)				
MAGNESIUM STEAR	ATE (UN	II: 70097M6I30)				
CELLULOSE, MICRO	CRYST	ALLINE (UNII: OP1R32D61	U)			
TALC (UNII: 7SEV7J4)	R1U)					
TITANIUM DIO XIDE	(UNII: 151	FIX9V2JP)				
STARCH, PREGELAT	INIZED	C ORN (UNII: O8232NY3SJ))			
POLYVINYL ALCOH	OL (UNI	I: 532B59J990)				
POLYETHYLENE GL	YCOL (U	JNII: 3WJQ0SDW1A)				
Product Charact	eristics					
Color		BROWN	Score		no score	
Shape		ROUND	Size		10 mm	
Flavor						
			Imprint Code		114	
Contains			Imprint Code		114	
Contains			Imprint Code		114	
Contains			Imprint Code		114	
			Imprint Code		114	
Packaging		Package Descrij		Marketing Start Date		ing End Dat
Packaging # Item Code	30 in 11	Package Descrij 30TTLE; Type 0: Not a Col	ption	Marketing Start Date		ing End Dat
Packaging H Item Code NDC:25000-114-03		3OTTLE; Type 0: Not a Co	ption mbination Product			ing End Dat
Feature State Sta		3OTTLE; Type 0: Not a Co 1 BOTTLE; Type 0: Not a C	ption mbination Product	07/25/2011		ing End Dat
Fraging Item Code 1 NDC:25000-114-03 2 NDC:25000-114-14 3 NDC:25000-114-24	1000 in 4 in 1 B	3OTTLE; Type 0: Not a Co 1 BOTTLE; Type 0: Not a C	ption mbination Product Combination Product	07/25/2011 07/25/2011		ing End Dat
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First state ing Item Code Item Code NDC:25000-114-03 NDC:25000-114-14 Item Code Item Code <td>1000 in 4 in 1 B 6500 in 6 in 1 B</td> <td>30TTLE; Type 0: Not a Con 1 BOTTLE; Type 0: Not a C DX 1 BAG; Type 0: Not a Com OX</td> <td>ption mbination Product Combination Product bination Product</td> <td>07/25/2011 07/25/2011</td> <td></td> <td>ing End Dat</td>	1000 in 4 in 1 B 6500 in 6 in 1 B	30TTLE; Type 0: Not a Con 1 BOTTLE; Type 0: Not a C DX 1 BAG; Type 0: Not a Com OX	ption mbination Product Combination Product bination Product	07/25/2011 07/25/2011		ing End Dat
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Provide State Sta	1000 in 4 in 1 B 6500 in 6 in 1 B 6500 in 1 in 1 B 34065 i 1 in 1 B 37470 in 500 in 1 1000 in	BOTTLE; Type 0: Not a Con 1 BOTTLE; Type 0: Not a Con 2 BAG; Type 0: Not a Com 0 X 1 BAG; Type 0: Not a Com 0 X n 1 BAG; Type 0: Not a Com 0 X n 1 BAG; Type 0: Not a Com 0 X n 1 BAG; Type 0: Not a Com 1 BOTTLE; Type 0: Not a Com	ption mbination Product Combination Product bination Product bination Product nbination Product nbination Product	07/25/2011 07/25/2011 07/25/2011 07/25/2011 07/25/2011 07/25/2011 07/25/2011		ing End Dat
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IBUPROFEN ibuprofen tablet							
Product Informa	tion						
Product Type		HUMAN OTC DRUC	G Ite	m Code (Sou	rce)	NDC:250	00-117
Route of Administra	ation	ORAL					
Active Ingredien	t/Active Mo	biety					
	In	gredient Name			Basis of St	rength	Strength
IBUPROFEN (UNII: W	K2XYI10QM) (I	BUPROFEN - UNII:WK2	2XYI10QM)		IBUPRO FEN		200 mg
Inactive Ingredie	ents						
	INIII. ETTITICAT	Ingredient M	Name				Strength
SILICON DIO XIDE (U							
CROSCARMELLOSE							
FERRIC O XIDE RED MAGNESIUM STEAR							
		WE (UNII: OP1R32D6 1U))				
TALC (UNII: 7SEV7J4)				
TITANIUM DIO XIDE		2 IP)					
STARCH, PREGELAT							
POLYVINYL ALCOH							
POLYETHYLENE GL							
	×						
Product Charact	eristics						
Color	BROW	/N	Score			no score	
Shape	CAPS	ULE	Size			15mm	
Flavor			Imprint Cod	e		117	
Contains							
Packaging							
00		Package Descript	tion	Market	ing Start Date	Market	ing End Dat
# Item Code	30 in 1 BOTT	Package Descript LE; Type 0: Not a Com			0	Market	ing End Dat
Item Code NDC:25000-117-03			bination Product	07/25/20	11	Market	ing End Dat
 # Item Code 1 NDC:25000-117-03 2 NDC:25000-117-14 		LE; Type 0: Not a Com	bination Product	07/25/20	11 11	Market	ing End Dat
 # Item Code 1 NDC:25000-117-03 2 NDC:25000-117-14 3 NDC:25000-117-20 	1000 in 1 BO 4 in 1 BOX	LE; Type 0: Not a Com	bination Product ombination Produ	07/25/20 nct 07/25/20	11 11	Market	ing End Dat
 # Item Code 1 NDC:25000-117-03 2 NDC:25000-117-14 3 NDC:25000-117-20 3 	1000 in 1 BO 4 in 1 BOX	LE; Type 0: Not a Com ITLE; Type 0: Not a Co	bination Product ombination Produ	07/25/20 nct 07/25/20	11 11 11	Market	ing End Dat
 # Item Code 1 NDC:25000-117-03 2 NDC:25000-117-14 3 NDC:25000-117-20 3 4 NDC:25000-117-30 	1000 in 1 BOX 4 in 1 BOX 6500 in 1 BAC 6 in 1 BOX	LE; Type 0: Not a Com ITLE; Type 0: Not a Co	bination Product ombination Produ ination Product	07/25/20 act 07/25/20 07/25/20	11 11 11	Market	ing End Dat
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 NDC:25000-117-03 NDC:25000-117-14 NDC:25000-117-20 NDC:25000-117-30 NDC:25000-117-30 	1000 in 1 BOX 4 in 1 BOX 6500 in 1 BAX 6 in 1 BOX 6500 in 1 BAX 1 in 1 BOX	LE; Type 0: Not a Com ITLE; Type 0: Not a Co G; Type 0: Not a Combi	bination Product ombination Produ ination Product ination Product	07/25/20 101 07/25/20 07/25/20 07/25/20	11 11 11 11	Market	ing End Dat

7 NDC:25000-117-69	300 in 1 BOTTLE; Type 0: Not a Combination Product	07/25/2011				
Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
ANDA	ANDA091239	07/25/2011				

Labeler - MARKSANS PHARMA LIMITED (925822975)

Establishment				
Name	Address	ID/FEI	Business Operations	
MARKSANS PHARMA LIMITED		925822975	LABEL(25000-117), MANUFACTURE(25000-114, 25000-117)	

Revised: 12/2019

MARKSANS PHARMA LIMITED