

IBUPROFEN - ibuprofen capsule, liquid filled
MARKSANS PHARMA LIMITED

ACTIVE INGREDIENT(S)

Solubilized ibuprofen equal to 200 mg ibuprofen
(present as the free acid and potassium salt)

PURPOSE

Pain reliever/Fever reducer

*nonsteroidal anti-inflammatory drug

USE(S)

- temporarily relieves minor aches and pains due to:
- headache
- toothache
- backache
- menstrual cramps
- the common cold
- muscular aches
- minor pain of arthritis
- 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 nonsteroidal anti - inflammatory drug (NSAIDs), 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

- the 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

- 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

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 problems or stroke:
 - chest pain
 - trouble breathing
 - weakness in one part of the body
 - slurred speech
 - leg swelling
 - 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 the painful area
 - any new symptoms appear

OTHER REQUIRED WARNINGS

- each capsule contains: **potassium 20 mg**
- read all warnings and directions before use. Keep carton.

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.

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

INACTIVE INGREDIENTS

Ammonium Hydroxide, FD&C Green No. 3, Gelatin, Iron oxide black, Medium chain triglycerides, Polyethylene glycol, Propylene glycol, Potassium hydroxide, Purified water, Shellac, Sorbitol sorbitan, Sorbitan monooleate.

Questions or comments


Call toll free **1-877-376-4271**

STORAGE

- store at 20-25°C (68-77°F)
- avoid excessive heat above 40°C (104°F)

PRINCIPAL DISPLAY PANEL





Ibuprofen capsules, 200mg
(Liquid filled capsules)
10's bottle label
NDC 25000-133-43

<p>NDC 25000-133-43 SEE NEW WARNINGS INFORMATION</p> <p>Ibuprofen Capsules, 200 mg</p> <p>Pain Reliever / Fever Reducer (NSAID)</p> <p>**Liquid Filled Capsules**</p> <p>10 Softgels**</p> <p> Marksans</p>	<p>READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION</p> <p>Do Not Use if seal under bottle cap imprinted with "SEALED for YOUR PROTECTION" is broken or missing.</p>	<p>Uses</p> <ul style="list-style-type: none"> temporarily relieves minor aches and pains due to: headache, muscular aches, menstrual cramps, the common cold, backache, toothache, minor pain of arthritis. temporarily reduces fever 	<p>LOT : EXP : R408/17</p>
	<p>Warnings</p> <ul style="list-style-type: none"> Ask your doctor before use if you are pregnant, under a doctor's care for a serious condition, age 60 or over, taking any other drug or have stomach problems. This product 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. Do not use this product if you have ever had an allergic reaction to any pain reliever/fever reducer. Stomach bleeding warning: This product contains a nonsteroidal anti-inflammatory drug (NSAID), which may cause severe stomach bleeding. The chance is higher if you are age 60 or older 		

<p>Warnings</p> <ul style="list-style-type: none"> Ask your doctor before use if you are pregnant, under a doctor's care for a serious condition, age 60 or over, taking any other drug or have stomach problems. This product may cause a severe allergic reaction, especially in 	<p>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. Do not use this product if you have ever had an</p>	<p>allergic reaction to any pain reliever/fever reducer. Stomach bleeding warning: This product contains a nonsteroidal anti-inflammatory drug (NSAID), which may cause severe stomach bleeding. The chance is higher if you are age 60 or older</p>
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<p>had stomach ulcers or bleeding problems</p> <ul style="list-style-type: none"> 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 	<p>while using this product</p> <ul style="list-style-type: none"> 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. 	<p>Directions</p> <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 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
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<p>do not exceed 6 capsules in 24 hours, unless directed by a doctor.</p> <ul style="list-style-type: none"> children under 12 years: ask a doctor. <p>Each capsule contains: potassium 20 mg</p>	<p>Questions or comments? call toll free 1-877-376-4271</p> <p>Manufactured for: Time-Cap Labs, Inc. 7 Michael Avenue, Farmingdale, NY 11735, USA</p>	<p>Manufactured by: Marksans Pharma Ltd. Plot No. L-82, L-83, Verna Indl. Estate, Verna, GOA - 403 722, India. Mfg. Lic. No. : GO/Drugs/515</p>
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<p>Description : Ibuprofen Capsules 200 mg Label 10's</p>		<p>Labeling Format Information :</p>	
<p>File # : NDC 25000-133-43</p>	<p>Color scheme :</p> <ul style="list-style-type: none">  PANTONE Process Cyan C  PANTONE 300 C  PANTONE 273 C 	<p>Fonts : Wnd. SW Condensed, Bold, Bold Italic.</p>	
<p>Version : R408/17</p>	<p>Size : 95 x 26 mm</p>	<p>Drug Facts : 8.25 pt.</p> <p>Header : 7.00 pt.</p> <p>Subheader : 6.00 pt.</p> <p>Body Text : 6.00 pt.</p> <p>Drug Facts (Continued) : 7.00 pt.</p>	<p>Leading : 6.00 pt.</p> <p>Header : 5.00 pt.</p> <p>Barlines : 2.50 pt.</p> <p>Hairlines : 0.50 pt.</p>
<p>Date : 17/08/2017</p>	<p></p>	<p>Horizontal Scale : 70%</p>	<p>Average Kerning : 0</p>

10's carton label
NDC 25000-133-43



Description : Ibuprofen Capsules 200 mg 10 Carton		Labeling Format Information :	
File # : NDC 25000-133-43	Color scheme : PANTONE Process Cyan C PANTONE 300 C PANTONE 273 C	Fonts : Wnd. SW Condensed, Bold, Bold Italic.	
Version : R408/17		Drug Facts : 8.25 pt.	Leading : 6.00 pt.
Date : 17/08/2017		Header : 7.00 pt.	Header : 5.00 pt.
	Size : 60.00(L) X 90.00(H) X 60.00(W) mm	Subheader : 6.00 pt.	Barlines : 2.50 pt.
		Body Text : 6.00 pt.	Hairlines : 0.50 pt.
		Drug Facts (Continued) : 7.00 pt.	
		Horizontal Scale : 70%	Average Kerning : 0





20's bottle label
NDC 25000-133-01

<p>NDC 25000-133-01 SEE NEW WARNINGS INFORMATION</p> <p>Ibuprofen Capsules, 200 mg</p> <p>Pain Reliever / Fever Reducer (NSAID)</p> <p>**Liquid Filled Capsules</p> <p>20 Softgels**</p> 	<p>READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION</p> <p>Do Not Use if seal under bottle cap imprinted with "SEALED for YOUR PROTECTION" is broken or missing.</p>	<p>Uses</p> <ul style="list-style-type: none"> temporarily relieves minor aches and pains due to: headache, muscular aches, menstrual cramps, the common cold, backache, toothache, minor pain of arthritis. temporarily reduces fever 	<p>LOT : EXP : R408/17</p>
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<p>Warnings</p> <ul style="list-style-type: none"> Ask your doctor before use if you are pregnant, under a doctor's care for a serious condition, age 60 or over, taking any other drug or have stomach problems. This product may cause a severe allergic reaction, especially in 	<p>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. Do not use this product if you have ever had an</p>	<p>allergic reaction to any pain reliever/fever reducer. Stomach bleeding warning: This product contains a nonsteroidal anti-inflammatory drug (NSAID), which may cause severe stomach bleeding. The chance is higher if you</p> <ul style="list-style-type: none"> are age 60 or older have
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<p>had stomach ulcers or bleeding problems</p> <ul style="list-style-type: none"> 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 	<p>while using this product</p> <ul style="list-style-type: none"> take more or for a longer time than directed. <p>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.</p>	<p>Directions</p> <ul style="list-style-type: none"> do not take more than directed the smallest effective dose should be used <p>adults and children 12 years and over: take 1 capsule every 4 to 6 hours while symptoms persist</p> <ul style="list-style-type: none"> if pain or fever does not respond to 1 capsule, 2 capsules may be used
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<p>do not exceed 6 capsules in 24 hours, unless directed by a doctor.</p> <ul style="list-style-type: none"> children under 12 years: ask a doctor. <p>Each capsule contains: potassium 20 mg</p>	<p>Questions or comments? call toll free 1-877-376-4271</p> <p>Manufactured for: Time-Cap Labs, Inc. 7 Michael Avenue, Farmingdale, NY 11735, USA</p>	<p>Manufactured by: Marksans Pharma Ltd. Plot No. L-82, L-83, Verna Indl. Estate, Verna, GOA - 403 722, India. Mfg. Lic. No. : GO/Drugs/515</p>
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<p>Description : Ibuprofen Capsules 200 mg Label 20's</p>		<p>Labeling Format Information :</p>	
<p>File # : NDC 25000-133-01</p>	<p>Color scheme :</p> <ul style="list-style-type: none">  PANTONE Process Magenta C  PANTONE 300 C  PANTONE 273 C 	<p>Fonts : Wnd. SW Condensed, Bold, Bold Italic.</p>	
<p>Version : R408/17</p>	<p>Size : 95 x 26 mm</p>	<p>Drug Facts : 8.25 pt.</p> <p>Header : 7.00 pt.</p> <p>Subheader : 6.00 pt.</p> <p>Body Text : 6.00 pt.</p> <p>Drug Facts (Continued) : 7.00 pt.</p>	<p>Leading : 6.00 pt.</p> <p>Header : 5.00 pt.</p> <p>Barlines : 2.50 pt.</p> <p>Hairlines : 0.50 pt.</p>
		<p>Horizontal Scale : 70%</p>	<p>Average Kerning : 0</p>

20's carton label
NDC 25000-133-01



LOT :
EXP :
N
3 2 5 0 0 1 3 3 0 1 9

Drug Facts (continued)

- 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

Drug Facts (continued)

- 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
 - vomit blood
 - have bloody or black stools
 - have stomach pain that does not get better
- you have symptoms of heart problems 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 the painful area
- any new symptoms appear

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.

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

SEE NEW WARNINGS INFORMATION

NDC 25000-133-01

Ibuprofen Capsules, 200 mg

Pain Reliever / Fever Reducer (NSAID)

** Liquid Filled Capsules

20 Softgels**

Marksans

READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION.

Drug Facts

Active ingredient	Purpose
Solubilized ibuprofen equal to 200 mg ibuprofen (NSAID)*	Pain reliever/ Fever reducer
(present as the free acid and potassium salt)	
*nonsteroidal anti-inflammatory drug	

Uses

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

Drug Facts (continued)

Other information

- each capsule contains: potassium 20 mg
- read all warnings and directions before use. Keep carton.
- store at 20-25°C (68-77°F).
- avoid excessive heat above 40°C (104°F)

Inactive ingredients Ammonium hydroxide, FD&C green no. 3, Gelatin, iron oxide black, Medium chain triglycerides, Polyethylene glycol, Propylene glycol, Potassium hydroxide, Purified water, Shellac, Sorbitol sorbitan, Sorbitan monooleate

Questions or comments?
call toll free 1-877-376-4271

Do Not Use if seal under bottle cap imprinted with "SEALED for YOUR PROTECTION" is broken or missing.


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

Manufactured by:
Marksans Pharma Ltd.
Plot No. L-92, L-83, Verna Indl. Estate,
Verna, Goa-403 722, India.
Mfg. Lic. No. - GO/Drugs/515

L180817

Description : Ibuprofen Capsules 200 mg 20 Carton		Labeling Format Information :	
File # : NDC 25000-133-01	Color scheme :	Fonts : Wnd. SW Condensed, Bold, Bold Italic.	
Version : R408/17	<ul style="list-style-type: none"> PANTONE Process Magenta C PANTONE 300 C PANTONE 273 C 	Drug Facts : 8.25 pt.	Leading : 6.00 pt.
Date : 17/08/2017		Header : 7.00 pt.	Header : 5.00 pt.
		Subheader : 6.00 pt.	Barlines : 2.50 pt.
		Body Text : 6.00 pt.	Hairlines : 0.50 pt.
		Drug Facts (Continued) : 7.00 pt.	
	Size : 60.00(L) X 90.00(H) X 60.00(W) mm	Horizontal Scale : 70%	Average Kerning : 0


32's bottle label
NDC 25000-133-04

<p>NDC 25000-133-04</p> <p>SEE NEW WARNINGS INFORMATION</p> <p>Ibuprofen Capsules, 200 mg</p> <p>Pain Reliever / Fever Reducer (NSAID)</p> <p>**Liquid Filled Capsules**</p> <p>32 Softgels**</p>  <p>Marksans</p>	<p>READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION</p> <p>Do Not Use if seal under bottle cap imprinted with "SEALED for YOUR PROTECTION" is broken or missing.</p>	<p>Uses</p> <ul style="list-style-type: none"> temporarily relieves minor aches and pains due to: headache, muscular aches, menstrual cramps, the common cold, backache, toothache, minor pain of arthritis. temporarily reduces fever 	<p>LOT : _____</p> <p>EXP : _____</p> <p>R908/17</p>
	<p>Warnings</p> <p>■ Ask your doctor before use if you are pregnant, under a doctor's care for a serious condition, age 60 or over, taking any other drug or have stomach problems. ■ This product may cause a severe allergic reaction, especially in</p> <p>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. Do not use this product if you have ever had an</p> <p>allergic reaction to any pain reliever/fever reducer. ■ Stomach bleeding warning: This product contains a nonsteroidal anti-inflammatory drug (NSAID), which may cause severe stomach bleeding. The chance is higher if you ■ are age 60 or older ■ have</p>		

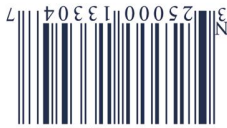
<p>had stomach ulcers or bleeding problems ■ take a blood thinning (anticoagulant) or steroid drug ■ take other drugs containing prescription or nonprescription NSAIDs [aspirin, ibuprofen, naproxen, or others] ■ have 3 or more alcoholic drinks every day</p>	<p>while using this product ■ take more or 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.</p>	<p>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 ■</p>
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<p>do not exceed 6 capsules in 24 hours, unless directed by a doctor. ■ children under 12 years: ask a doctor.</p> <p>Each capsule contains: potassium 20 mg</p>	<p>Questions or comments? call toll free 1-877-376-4271</p> <p>Manufactured for: Time-Cap Labs, Inc. 7 Michael Avenue, Farmingdale, NY 11735, USA</p>	<p>Manufactured by: Marksans Pharma Ltd. Plot No. L-82, L-83, Verna Indl. Estate, Verna, GOA - 403 722, India. Mfg. Lic. No. : GO/Drugs/515</p>
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<p>Description : Ibuprofen Capsules 200 mg 32 label</p>	<p>Color scheme :</p> <ul style="list-style-type: none"> PANTONE 540 C PANTONE 300 C PANTONE 273 C <p>Size : 95 x 26 mm</p>
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<p>File # : NDC 25000-133-04</p> <p>Version : R908/17</p> <p>Date : 17/08/2017</p> 	<p>Labeling Format Information :</p> <p>Fonts : Wnd. SW Condensed, Bold, Bold Italic.</p> <table border="0"> <tr> <td>Drug Facts :</td> <td>8.25 pt.</td> <td>Leading :</td> <td>6.00 pt.</td> </tr> <tr> <td>Header :</td> <td>7.00 pt.</td> <td>Header :</td> <td>5.00 pt.</td> </tr> <tr> <td>Subheader :</td> <td>6.00 pt.</td> <td>Barlines :</td> <td>2.50 pt.</td> </tr> <tr> <td>Body Text :</td> <td>6.00 pt.</td> <td>Hairlines :</td> <td>0.50 pt.</td> </tr> <tr> <td>Drug Facts (Continued) :</td> <td>7.00 pt.</td> <td></td> <td></td> </tr> </table> <p>Horizontal Scale : 70% Average Kerning : 0</p>	Drug Facts :	8.25 pt.	Leading :	6.00 pt.	Header :	7.00 pt.	Header :	5.00 pt.	Subheader :	6.00 pt.	Barlines :	2.50 pt.	Body Text :	6.00 pt.	Hairlines :	0.50 pt.	Drug Facts (Continued) :	7.00 pt.		
Drug Facts :	8.25 pt.	Leading :	6.00 pt.																		
Header :	7.00 pt.	Header :	5.00 pt.																		
Subheader :	6.00 pt.	Barlines :	2.50 pt.																		
Body Text :	6.00 pt.	Hairlines :	0.50 pt.																		
Drug Facts (Continued) :	7.00 pt.																				

32's carton label
NDC 25000-133-04



LOT :
EXP :

Drug Facts (continued)

- 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

Drug Facts (continued)

Other information

- each capsule contains: potassium 20 mg
- read all warnings and directions before use. Keep carton.
- store at 20-25°C (68-77°F).
- avoid excessive heat above 40°C (104°F)

Inactive ingredients Ammonium hydroxide, FD&C green no. 3, Gelatin, Iron oxide black, Medium chain triglycerides, Polyethylene glycol, Propylene glycol, Potassium hydroxide, Purified water, Shellac, Sorbitol sorbitan, Sorbitan monooleate

Questions or comments?

call toll free 1-877-376-4271

Do Not Use if seal under bottle cap imprinted with "SEALED for YOUR PROTECTION" is broken or missing.

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

Manufactured by:
Marksans Pharma Ltd.
Plot No. L-82, L-83, Verna Indl. Estate,
Verna, Goa-403 722, India.
Mfg. Lic. No. : GO/Drugs/515

RI00817

Drug Facts (continued)

- 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 ■ vomit blood ■ have bloody or black stools ■ have stomach pain that does not get better
- you have symptoms of heart problems 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 the painful area
- any new symptoms appear

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.

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

NDC 25000-133-04

SEE NEW WARNINGS INFORMATION

Ibuprofen Capsules, 200 mg

Pain Reliever / Fever Reducer (NSAID)

** Liquid Filled Capsules

32 Softgels**

Marksans

READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION.

Drug Facts

Active ingredient (in each capsule)	Purpose
Solubilized ibuprofen equal to 200 mg ibuprofen (NSAID)*	Pain reliever/ Fever reducer
(present as the free acid and potassium salt)	*nonsteroidal anti-inflammatory drug

Uses

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

Description : Ibuprofen Capsules 200 mg 32 Carton

File # : NDC 25000-133-04

Version : R1008/17

Date : 17/08/2017



Color scheme :

- PANTONE 540 C
- PANTONE 300 C
- PANTONE 273 C

Size :

60.00(L) X 90.00(H) X 60.00(W) mm

Labeling Format Information :

Fonts : Wnd. SW Condensed, Bold, Bold Italic.

Drug Facts :	8.25 pt.	Leading :	6.00 pt.
Header :	7.00 pt.	Header :	5.00 pt.
Subheader :	6.00 pt.	Barlines :	2.50 pt.
Body Text :	6.00 pt.	Hairlines :	0.50 pt.
Drug Facts (Continued) :	7.00 pt.		

Horizontal Scale : 70%

Average Kerning : 0

600 Softgels
NDC 25000-133-13

NDC 25000-133-13

SEE NEW WARNINGS INFORMATION

Ibuprofen Capsules, 200 mg

Pain Reliever / Fever Reducer (NSAID)

****Liquid Filled Capsules**

600 Softgels**



Marksans

Drug Facts

Active ingredient (in each capsule)	Purpose
Solubilized ibuprofen equal to 200 mg ibuprofen (NSAID)*	Pain reliever/ Fever reducer (present as the free acid and potassium salt)
*nonsteroidal anti-inflammatory drug	

Uses

- temporarily relieves minor aches and pains due to:
 - headache
 - muscular aches
 - menstrual cramps
 - the common cold
 - backache
 - toothache
 - minor pain of arthritis
- 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.

LOT :

EXP :



Drug Facts (continued)

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

Drug Facts (continued)

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

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
- you have symptoms of heart problems or stroke:
 - chest pain
 - trouble breathing
 - weakness in one part or side of body
 - leg swelling
 - slurred speech
- 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. It is especially important not to use ibuprofen during the last 3 months of

Drug Facts (continued)

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.

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**
- read all warnings and directions before use.
- store at 20-25°C (68-77°F).
- avoid excessive heat above 40°C (104°F)

Inactive ingredients Ammonium hydroxide, FD&C green no. 3, Gelatin, Iron oxide black, Medium chain triglycerides, Polyethylene glycol, Propylene glycol, Potassium hydroxide, Purified water, Shellac, Sorbitol sorbitan, Sorbitan monooleate

Drug Facts (continued)

Questions or comments?

call toll free 1-877-376-4271


Do Not Use if seal under bottle cap imprinted with "SEALED for YOUR PROTECTION" is broken or missing.

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 Indl. Estate,
Verna, GOA - 403 722, India.

Mfg. Lic. No. : GO/Drugs/515

R100817

Description : Ibuprofen Capsules 200 mg 600 label		Labeling Format Information :	
File # : NDC 25000-133-13	Color scheme :	Fonts : Wnd. SW Condensed, Bold, Bold Italic.	
Version : R1008/17	■ PANTONE 540 C	Drug Facts : 8.25 pt.	Leading : 6.00 pt.
Date : 17/08/2017	■ PANTONE 300 C	Header : 7.00 pt.	Header : 5.00 pt.
	■ PANTONE 273 C	Subheader : 6.00 pt.	Barlines : 2.50 pt.
	Size : 140.00(L) X 80.00(H)	Body Text : 6.00 pt.	Hairlines : 0.50 pt.
		Drug Facts (Continued) : 7.00 pt.	
		Horizontal Scale : 70%	Average Kerning : 0

300's bottle label
NDC 25000-133-69

NDC 25000-133-69
SEE NEW WARNINGS INFORMATION

Ibuprofen Capsules, 200 mg

Pain Reliever / Fever Reducer (NSAID)

****Liquid Filled Capsules**

300 Softgels**

Marksans



Drug Facts

Active ingredient (in each capsule)	Purpose
Solubilized ibuprofen equal to 200 mg ibuprofen (NSAID)*.....	Pain reliever/ Fever reducer (present as the free acid and potassium salt)
*nonsteroidal anti-inflammatory drug	

Uses

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

Warnings

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

Symptoms may include:

LOT :
EXP :



Drug Facts (continued)

- 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

Drug Facts (continued)

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

Drug Facts (continued)

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

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
- you have symptoms of heart problems 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 the painful area

Drug Facts (continued)

- any new symptoms appear

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.

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

Drug Facts (continued)

- 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**
- read all warnings and directions before use.
- store at 20-25°C (68-77°F).
- avoid excessive heat above 40°C (104°F)

Inactive ingredients Ammonium hydroxide, FD&C green no. 3, Gelatin, Iron oxide black, Medium chain triglycerides, Polyethylene glycol, Propylene glycol, Potassium hydroxide, Purified water, Shellac, Sorbitol sorbitan, Sorbitan monooleate

Questions or comments?

call toll free 1-877-376-4271

Drug Facts (continued)

Do Not Use if seal under bottle cap imprinted with "SEALED for YOUR PROTECTION" is broken or missing.

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 Indl. Estate,
Verna, GOA - 403 722, India.

Mfg. Lic. No. : GO/Drugs/515

R011/19

Description : Ibuprofen capsules 200mg (liquid filled capsules) (300's) dark blue label

File # : NDC 25000-133-69

Version : R011/19

Color scheme :

■ PANTONE 540 C

Labeling Format Information :

Fonts : Wnd. SW Condensed, Bold, Bold Italic.

Drug Facts :	8.25 pt.	Leading :	6.00 pt.
Header :	8.00 pt.	Header :	5.00 pt.
Subheader :	7.00 pt.	Barlines :	2.50 pt.
Body Text :	7.00 pt.	Hairlines :	0.50 pt.

Date : 30/11/2019

Marksans
Pharma Ltd.

Size : 181.00(L) X 72.00(H)

Drug Facts (Continued) : 7.00 pt.

Horizontal Scale : 70%

Average Kerning : 0

IBUPROFEN

ibuprofen capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:25000-133
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
AMMONIA (UNII: 5138Q19F1X)	
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0K00R)	
SHELLAC (UNII: 46N107B71O)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
FERROUS OXIDE (UNII: G7036X8B5H)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	

Product Characteristics

Color	GREEN	Score	no score
Shape	CAPSULE	Size	19mm
Flavor		Imprint Code	133
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:25000-133-23	5 in 1 DRUM	09/01/2017	

1		2000 in 1 BAG; Type 0: Not a Combination Product		
2	NDC:25000-133-18	4 in 1 BOX	09/01/2017	
2		2500 in 1 BAG; Type 0: Not a Combination Product		
3	NDC:25000-133-04	1 in 1 CARTON	09/01/2017	
3		32 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:25000-133-13	1 in 1 BOX	09/01/2017	
4		600 in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:25000-133-43	1 in 1 CARTON	09/01/2017	
5		10 in 1 BOTTLE; Type 0: Not a Combination Product		
6	NDC:25000-133-01	1 in 1 CARTON	09/01/2017	
6		20 in 1 BOTTLE; Type 0: Not a Combination Product		
7	NDC:25000-133-69	300 in 1 BOTTLE; Type 0: Not a Combination Product	09/01/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA079205	09/01/2017	

Labeler - MARKSANS PHARMA LIMITED (925822975)

Establishment

Name	Address	ID/FEI	Business Operations
MARKSANS PHARMA LIMITED		925822975	MANUFACTURE(25000-133)

Revised: 3/2020

MARKSANS PHARMA LIMITED