

**IBUPROFEN- ibuprofen tablet
WALGREENS**

Walgreens Ibuprofen 200 MG TABS-(601R) ROUND

Solubilized Ibuprofen equal to

200 mg ibuprofen (NSAID)*

(present as the free acid and potassium salt)

* nonsteroidal anti-inflammatory drug

ibuprofen 200 mg TABLET INACTIVE INGREDIENTS

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

DO NOT TAKE MORE THAN DIRECTED

THE SMALLEST EFFECTIVE DOSE SHOULD BE USED

Adults and children 12 years and over:

- take 1 tablet every 4 to 6 hours while symptoms persist
- If pain 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**

Temporarily relieves minor aches and pain due to :

- headache
- toothache
- backache

- menstrual cramps

- the common cold
- muscular aches
- minor pain of arthritis

Temporarily reduces fever

PAIN RELIEVER/ FEVER REDUCER

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.

**IN CASE OF OVERDOSE, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER
RIGHT AWAY**

IBUPROFEN 200 MG TABLETS 24 COUNT

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

Drug Facts

Active ingredient in each tablet: Ibuprofen 200 mg (NSAID)*. *Non-steroidal 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
 - Temporarily reduces fever.

Warnings:

- Blurred vision, dizziness, or lightheadedness may occur. Stop driving or operating machinery if you experience these symptoms.
- 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 other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
 - take other drugs containing prescription or nonprescription blood thinners (anticoagulants) or steroid drugs (corticosteroids)
 - have 3 or more alcoholic drinks every day while using the product.
 - take more or for a longer time than directed.

Varnish Omit Lot No: Exp. Date:



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Drug Facts (continued)

Heart attack and stroke warning: NSAIDs, such as 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 ibuprofen or any other pain reliever/fever reducer.
- Right before or after heart surgery.

Ask a doctor before use if:

- you have asthma or severe side effects from taking aspirin, ibuprofen, 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:

- taking aspirin for heart attack or stroke, because ibuprofen may decrease the benefit of aspirin.
- taking 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 a doctor if:
 - you experience any of the following signs of stomach bleeding: ● belching ● vomit blood ● have blood or black stools
 - have stomach pain that does not get better
 - you have symptoms of heart problem or stroke: ● chest pain ● trouble breathing

Drug Facts (continued)

Inactive ingredients (continued)

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

Drug Facts (continued)

● weakness in one part or side of the body

- slurred speech
- big 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 you want to stop taking, ask a health professional before use. It is especially important not to use ibuprofen during the last 3 months of pregnancy unless clearly directed to do so by a doctor because it may cause problems in the unborn child or complications during or after birth.

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.
 - 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:**
- Keep out of reach of children.
 - Keep this and all directions before use.
 - Some 6126255-0 (68-777)



Compare to Advil® Tablets active ingredient††

Ibuprofen

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

TABLETS

100 TABLETS

SEE NEW WARNINGS INFORMATION



ACTUAL SIZE

E827

Varnish/Print Omit Area

Varnish Omit

Varnish Omit

ORF00000
RFV-0918
601H

Do not use this product if the caper embossment is cut, torn, broken or missing. Do not use this product if the embossed foil seal over the mouth of the bottle is cut, torn, broken or missing.

Adhesive Area

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 aspirin 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 ■ stomach bleeding warning signs to you ■ you have a history of stomach bleeding ■ you have high blood pressure ■ you have heart disease, liver or kidney disease, diabetes, asthma, or had a stroke ■ you are taking a diuretic

Ask a doctor or pharmacist before use if you are: ■ taking aspirin ■ taking blood thinners ■ taking medicines that may decrease the benefit of aspirin ■ taking other NSAIDs or any serious condition ■ taking any other drug

When using this product

■ Take with food or after a stomach upset occurs

Stop use and ask a doctor if:

- you experience any of the following signs of stomach bleeding:
 - black or bloody stools
 - dark stools
 - stomach pain that does not get better
- you have symptoms of heart problem or stroke:
 - chest pain
 - trouble breathing
 - weakness in one part of side of the body
 - slurred speech
 - eye 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 (1-800-222-1222).

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

Adults and children 17 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 ■ Read all warnings and directions before use ■ Store at 20-25°C (68-77°F)

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

Questions or comments? call 1-877-298-4008

Drug Facts (continued under label)

This is a Schedule II controlled substance. Abuse may lead to addiction. For more information, see the Schedule II Drug Facts under label. © 2018 Walgreen Co. All rights reserved.

Warnings
Allergy alert: Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:
 ■ hives ■ rash ■ Swelling of the face, lips, tongue, or throat
 ■ difficulty breathing ■ wheezing ■ asthma (wheezing) ■ dizziness ■ blurred vision ■ difficulty seeing ■ skin redness/itching ■ skin rash ■ Stomach pain ■ Stomach bleeding ■ Blood in stool or urine
Stomach bleeding warning: This product contains an NSAID, which may cause stomach bleeding. The chances are 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

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

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ITEM# 1671678 | W003000-000-X
 DISTRIBUTED BY WALGREEN CO.
 100% SATISFACTION GUARANTEED
 walgreens.com © 2018 Walgreen Co.
 MADE IN INDIA
 6018 REV. 8-18
 09030000

Lot No.: **Varnish Omit Area**
 Exp Date:

VALUE SIZE
Walgreens
Compare to Advil® Tablets active ingredient!
NDC 0363-9601-10

Ibuprofen
TABLETS USP, 200 mg / PAIN RELIEVER / FEVER REDUCER (NSAID)
1,000 TABLETS
SEE NEW WARNINGS INFORMATION

Drug Facts
Active ingredient (in each tablet) Purpose
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) hives facial swelling
rash shock skin redness
Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you:
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take a blood-thinning (anticoagulant) or steroid drug
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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.

Drug Facts (continued)
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
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.
Ask a doctor or pharmacist before use if you are:
taking aspirin for heart attack or stroke, because ibuprofen may decrease the benefit of aspirin
under a doctor's care for any serious condition
taking any other drug

Drug Facts (continued)
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: 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 the 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

Drug Facts (continued)
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 (1-800-222-1222).

Directions
Do not take more than directed.
The smallest effective dose should be used.
Adults and children 12 years and over:
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, unless directed by a doctor.
Children under 12 years:
Ask a doctor.

Other information
Read all warnings and directions before use.
Store at 20-25°C (68-77°F).

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

Questions or comments? call 1-877-299-4088

TAMPER EVIDENT: DO NOT USE THIS PRODUCT IF THE IMPRINTED FOIL SEAL OVER THE MOUTH OF THE BOTTLE IS CUT, TORN, BROKEN OR MISSING.

THIS PRODUCT IS REIMBURSED OR OTHERWISE COVERED BY A HEALTH CARE PROGRAM. ©2011 Walgreen Co. All rights reserved. MADE IN INDIA

Lot No.:
Exp. Date:

191720449

Yarnish Omit Area

IBUPROFEN

ibuprofen tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0363-9601
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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELOSE SODIUM (UNII: M28OL1HF48)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
STARCH 1500, PREGELATINIZED (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	brown	Score	no score
Shape	ROUND	Size	10 mm
Flavor		Imprint Code	114
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-9601-42	24 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/11/2018	
2	NDC:0363-9601-05	50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/11/2018	
3	NDC:0363-9601-01	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/11/2018	
4	NDC:0363-9601-15	150 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/11/2018	
5	NDC:0363-9601-50	500 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/11/2018	
6	NDC:0363-9601-10	1000 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/11/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091239	12/11/2018	

Labeler - WALGREENS (008965063)

Registrant - TIME CAP LABORATORIES, INC (037052099)

Establishment

Name	Address	ID/FEI	Business Operations
MARKSANS PHARMA LIMITED		925822975	manufacture(0363-9601)