

**IBUPROFEN- ibuprofen capsule, liquid filled
DOLGENCORP, INC.**

610T Dollar General 55910-399 Ibuprofen Capsules 200 mg

DRUG FACTS

Active ingredient (in each capsule)

Solubilized ibuprofen equal to
200 mg ibuprofen (NSAID)*
(present as the free acid and potassium salt)
*nonsteroidal anti-inflammatory drug

Purpose

Pain reliever/Fever reducer

Uses

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 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 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
- 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 at 20 weeks or later in 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 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 #3, gelatin, iron oxide black, medium chain triglycerides, polyethylene glycol, potassium hydroxide, propylene glycol, purified water, shellac, sorbitan monooleate, sorbitol sorbitan

Questions or comments?

Call **1-877-290-4008**

DG health

Ibuprofen

Capsules, 200 mg

Pain Reliever/
Fever Reducer (NSAID)

200
mg



200 Softgels*

(*Liquid-Filled Capsules)
Actual Size

Compare to the active ingredient of Advil® Liqui-Gels®††

DO NOT USE IF SEAL UNDER BOTTLE CAP IMPRINTED WITH "SEALED FOR YOUR PROTECTION" IS BROKEN OR MISSING

Drug Facts

Active ingredient (in each capsule)

Solubilized ibuprofen (NSAID)*
200 mg (ibuprofen (NSAID)*
(present as the free acid and potassium salt)
*nonsteroidal anti-inflammatory drug

Purpose

Pain reliever/
Fever reducer

Uses

- 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)
- stomach pain
- 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 under label)

††This product is not manufactured or distributed by GlaxoSmithKline Consumer Healthcare, owner of the registered trademark Advil® and Catalent Pharma Solutions, Inc. owner of the registered trademark Liqui-Gels®.

DISTRIBUTED BY:

OLD EAST MAIN CO.

100 MISSION RIDGE, TN

GOODLETTSVILLE, TN

37072

MADE IN INDIA

6107 0522

4942361 c096 No. G00BRUS515

A1350



3

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Lot No.:

Exp Date:

SEE HERE

Varnish Omit Area

Drug Facts (continued)

Hear 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:

- 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 at 20 weeks or later in 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 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 #3, gelatin, iron oxide black, medium chain triglycerides, polyethylene glycol, potassium hydroxide, propylene glycol, purified water, shellac, sorbitan monooleate, sorbitol sorbitan

Questions or comments? Call 1-877-290-4008

Adhesive Area

DGTM health

Ibuprofen

Capsules, 200 mg
Pain Reliever/
Fever Reducer (NSAID)

80 Softgels[†]

([†]Liquid-Filled Capsules)

DO NOT USE IF SEAL UNDER BOTTLE CAP IMPRINTED WITH "SEALED FOR YOUR PROTECTION" IS BROKEN OR MISSING

READ AND KEEP OUTER CARTON FOR COMPLETE WARNINGS AND INFORMATION

Uses

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

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 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.

If pregnant or breast-feeding, ask a health professional before use.

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 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

each capsule contains: potassium 20 mg

Questions or comments? Call 1-877-290-4008

DISTRIBUTED BY: OLD EAST MAIN CO.
100 MISSION RIDGE, GOODLETTSVILLE, TN 37072
MADE IN INDIA. 610T 0522 40142701 Code No.: 60DRIUGS515

Lot No.:

Exp. Date:

Varnish Omit Area

200 mg



([†]Liquid-Filled Capsules)
Actual Size

120 Softgels[†]

Ibuprofen

Capsules, 200 mg
Pain Reliever/
Fever Reducer (NSAID)

DGTM health

Compare to the active ingredient of Advil[®] Liqui-Gels[®]††

DO NOT USE IF SEAL UNDER BOTTLE CAP IMPRINTED WITH "SEALED FOR YOUR PROTECTION" IS BROKEN OR MISSING

Drug Facts

Active ingredient (in each capsule)

Suspension of ibuprofen (NSAID)^{*} 200 mg (present as the free acid and potassium salt) and nonsteroidal anti-inflammatory drug

Uses

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

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 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 under label)

^{††}This product is not manufactured or distributed by GlaxoSmithKline Consumer Healthcare, owner of the registered trademark Advil[®] and Cabotell[®] Pharma Solutions, Inc. owner of the registered trademark Liqui-Gels[®].

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GOODLETTSVILLE, TN
37072
MADE IN INDIA
610T 0522
40142701 Code No.: 60DRIUGS515

Lot No.:

Exp. Date:

Varnish Omit Area

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 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 the 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, any new symptoms appear

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use ibuprofen at 20 weeks or later in 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 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 #3, gelatin, iron oxide black, medium chain triglycerides, polyethylene glycol, potassium hydroxide, propylene glycol, purified water, shellac, sodium monohydroxide, sodium sorbitan

Questions or comments? Call 1-877-290-4008

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
 - 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

Drug Facts (continued)

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
- 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.

Code No.: 60011AR315

Drug Facts (continued)

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

- take with food or milk if stomach upset occurs

Drug Facts (continued)

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
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 - redness or swelling is present in the painful area
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If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use ibuprofen at 20 weeks or later in 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).

DO NOT USE IF SEAL UNDER BOTTLE CAP IMPRINTED WITH "SEALED FOR YOUR PROTECTION" IS BROKEN OR MISSING



A0576

Lot No.: Exp Date:

Drug Facts (continued)

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 #3, gelatin, iron oxide black, medium chain triglycerides, polyethylene glycol, potassium hydroxide,

Drug Facts (continued)

propylene glycol, purified water, shellac, sorbitan monooleate, sorbitol sorbitan

Questions or comments? Call 1-877-290-4008

*This product is not manufactured or distributed by GlaxoSmithKline Consumer Healthcare, owner of the registered trademark Advil® and Catalent Pharma Solutions, Inc. owner of the registered trademark Liqui-Gels®.

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40142201



Compare to the active ingredient of Advil® Liqui-Gels®††

Ibuprofen

Capsules, 200 mg
Pain Reliever/Fever Reducer (NSAID)

200 mg



80 Softgels†
(*Liquid-Filled Capsules)
Actual Size

6011AR3

Adhesive Area

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.

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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

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- do not exceed 6 capsules in 24 hours, unless directed by a doctor
- children under 12 years: ask a doctor

Each capsule contains: **potassium 20 mg**

Questions or comments?
Call 1-877-290-4008

DISTRIBUTED BY:
OLD EAST MAIN CO.
100 MISSION RIDGE
GOODLETTSVILLE, TN 37072
MADE IN INDIA
610T 0522

DGTM health

Ibuprofen

Capsules, 200 mg
Pain Reliever/
Fever Reducer (NSAID)

20 Softgels[†]

([†]Liquid-Filled Capsules)

DO NOT USE IF SEAL UNDER BOTTLE CAP IMPRINTED WITH "SEALED FOR YOUR PROTECTION" IS BROKEN OR MISSING

READ AND KEEP OUTER CARTON FOR COMPLETE WARNINGS AND INFORMATION

Uses

- 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 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,

Drug Facts (continued under label)

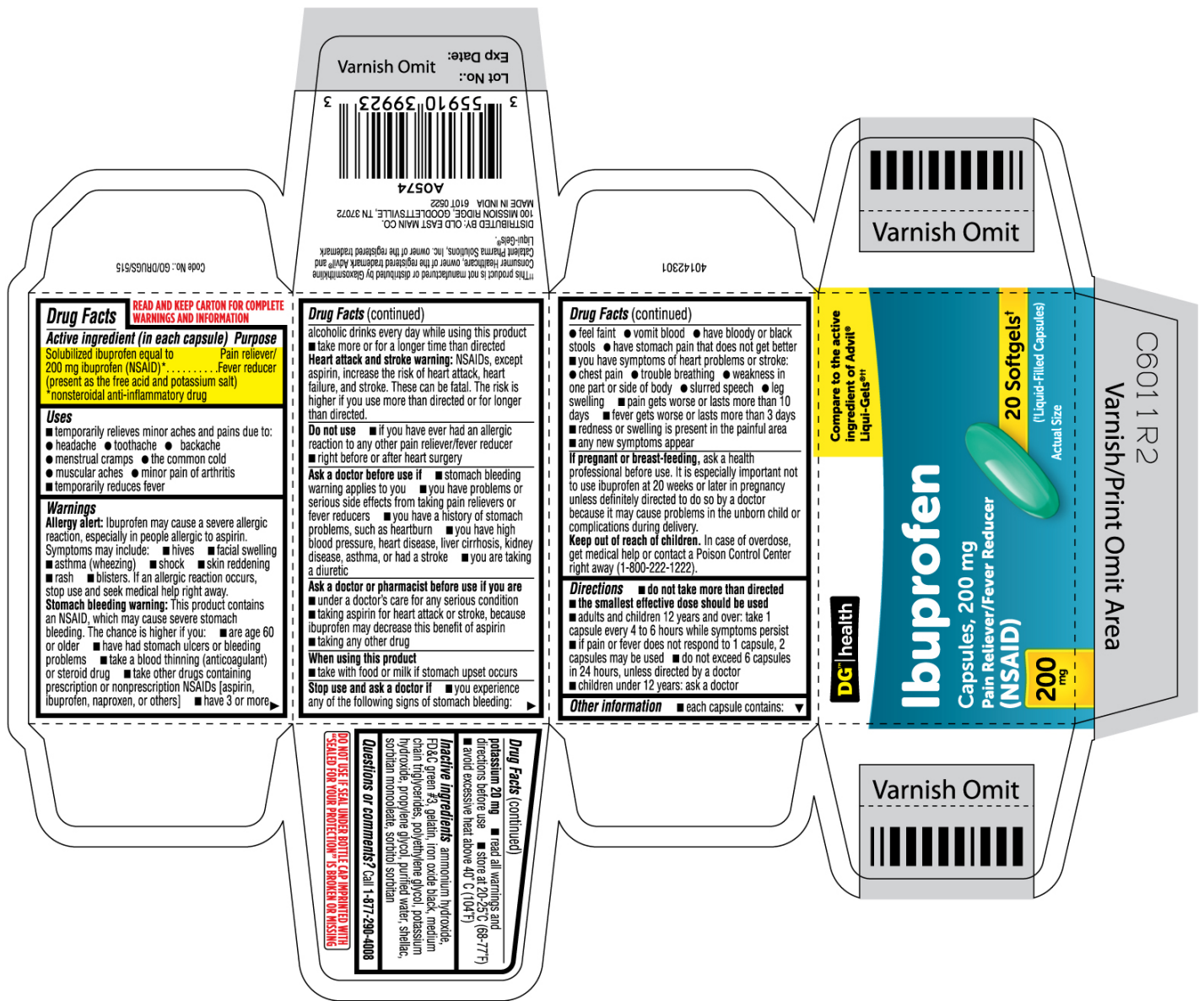
40142601 Code No.: 60DRUGS515

Lot No.:

Exp. Date:

Varnish Omit Area

PEEL HERE



IBUPROFEN

ibuprofen capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55910-399
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
IBUPROFEN (UNII: WK2XY110QM) (IBUPROFEN - UNII:WK2XY110QM)	IBUPROFEN	200 mg

Inactive Ingredients

Ingredient Name	Strength
GELATIN (UNII: 2G86QN327L)	

POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)
FERROSO FERRIC OXIDE (UNII: XM0M87F357)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
WATER (UNII: 059QF0KO0R)
SHELLAC (UNII: 46N107B71O)
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)
AMMONIA (UNII: 5138Q19F1X)
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
SORBITOL (UNII: 506T60A25R)

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:55910-399-23	1 in 1 CARTON	07/12/2022	
1		20 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:55910-399-80	1 in 1 CARTON	07/12/2022	
2		80 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:55910-399-12	120 in 1 BOTTLE; Type 0: Not a Combination Product	07/12/2022	
4	NDC:55910-399-20	200 in 1 BOTTLE; Type 0: Not a Combination Product	07/12/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA079205	07/12/2022	

Labeler - DOLGENCORP, INC. (068331990)

Registrant - TIME CAP LABORATORIES, INC. (037052099)

Establishment

Name	Address	ID/FEI	Business Operations
Marksans Pharma Ltd		925822975	manufacture(55910-399)

Revised: 7/2022

DOLGENCORP, INC.