

ACTROGEL- ibuprofen capsule, liquid filled
Belmora LLC

Actrogel 44-754

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
 - the common cold
 - backache
 - menstrual cramps
 - toothache
 - 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:

- facial swelling
- blisters
- shock
- hives
- skin reddening
- asthma (wheezing)
- rash

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

- have had stomach ulcers or bleeding problems
- take more or for a longer time than directed
- take a blood thinning (anticoagulant) or steroid drug
- have 3 or more alcoholic drinks every day while using this product

- are age 60 or older
- take other drugs containing prescription or nonprescription NSAIDs [aspirin, ibuprofen, naproxen, or others]

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 are taking a diuretic
- you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke

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 a doctor if

- you experience any of the following signs of stomach bleeding:
 - vomit blood
 - have bloody or black stools
 - feel faint
 - have stomach pain that does not get better
- you have symptoms of heart problems or stroke:
 - chest pain
 - trouble breathing
 - leg swelling
 - slurred speech
 - weakness in one part or side of body
- 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

Other information

- **each capsule contains:** potassium 20 mg
- store at 20° to 25°C (68° to 77°F)
- avoid excessive heat above 40°C (104°F). Protect from light.

Inactive ingredients

FD&C blue #1, gelatin, pharmaceutical ink, polyethylene glycol, potassium hydroxide, purified water, sorbitan, sorbitol

Questions or comments?

Call 1-888-779-2877 M-F 9AM-5PM EST

Principal display panel

Belmora LLC

NDC 27854-222-00

**Actrojel
IBUPROFEN**

Solubilized Ibuprofen Capsules, 200 mg
PAIN RELIEVER/FEVER REDUCER
(NSAID)

24
Liquid-filled
CAPSULES

Actual Size

TAMPER EVIDENT: DO NOT USE IF IMPRINTED
SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

Distributed by Belmora LLC
3033 Wilson Blvd.Suite 700
Arlington, VA 22201

24 Liquid-filled CAPSULES /
CÁPSULA llenos de líquido



Belmar LLC

KEEP OUTER PACKAGE FOR COMPLETE
PRODUCT INFORMATION

Drug Facts

Active ingredient (in each capsule) Purpose
Sulbized ibuprofen equal to 200 mg ibuprofen (NSAID) (present as the free acid and potassium salt). Pain reliever/fever reducer

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

Warnings
Allergy alert: Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:
skin swelling, hives, facial swelling, shock, dizziness, rash, skin redness, asthma (wheezing), 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:
have had stomach ulcers or bleeding problems
take more or for a longer time than directed
take a blood thinning (anticoagulant) or steroid drug
have 3 or more alcoholic drinks every day while using this product
are age 60 or older
take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
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 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, if you are taking a diuretic
you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke

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

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, feel faint
have stomach pain that does not get better
you have symptoms of heart problems or stroke: chest pain, trouble breathing, leg swelling, durred speech, weakness in one part or side of body
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.

Información sobre el medicamento

Ingrediente activo
(en cada capsula)
Analgésico de ibuprofeno soluble igual a 200 mg de ibuprofeno (AINE) (presente como el ácido libre y la sal de potasio) analgésico/antiflogístico no esteroideo.

Usos
alivia temporalmente dolores y malestares menores de cabeza, el resaca común, dolor de espalda, calambres menstruales, dolor de muelas, dolores musculares, dolor menor de artritis, reduce temporalmente la fiebre

Advertencias
El ibuprofeno puede causar una reacción grave de alergia, especialmente en personas alérgicas a la aspirina. Los síntomas pueden incluir: hinchazón facial, ampollas, convulsiones, urticaria, enrojecimiento de la piel, asma (sibilancia), erupción cutánea. Si se produce una reacción cutánea, deje de usarlo y busque atención médica de inmediato. Este producto contiene un antiinflamatorio no esteroideo (AINE) que puede causar sangrado estomacal severo. La posibilidad es mayor si usted ha tenido úlceras estomacales o problemas de sangrado, toma más de la dosis indicada o por más tiempo del indicado, toma un medicamento antiinflamatorio no esteroideo (aspirina, ibuprofeno, naproxeno, u otros).

Alerta de alergia: El ibuprofeno puede causar una reacción grave de alergia, especialmente en personas alérgicas a la aspirina. Los síntomas pueden incluir: hinchazón facial, ampollas, convulsiones, urticaria, enrojecimiento de la piel, asma (sibilancia), erupción cutánea. Si se produce una reacción cutánea, deje de usarlo y busque atención médica de inmediato. Este producto contiene un antiinflamatorio no esteroideo (AINE) que puede causar sangrado estomacal severo. La posibilidad es mayor si usted ha tenido úlceras estomacales o problemas de sangrado, toma más de la dosis indicada o por más tiempo del indicado, toma un medicamento antiinflamatorio no esteroideo (aspirina, ibuprofeno, naproxeno, u otros).

Advertencia de sangrado estomacal: Este producto contiene un antiinflamatorio no esteroideo (AINE) que puede causar sangrado estomacal severo. La posibilidad es mayor si usted ha tenido úlceras estomacales o problemas de sangrado, toma más de la dosis indicada o por más tiempo del indicado, toma un medicamento antiinflamatorio no esteroideo (aspirina, ibuprofeno, naproxeno, u otros).

Pregúntele a un médico antes de usarlo si:
si alguna vez ha tenido una reacción alérgica a cualquier otro analgésico/reductor de fiebre, justo antes o después de una cirugía cardíaca

Pregúntele a un médico o farmacéutico antes de utilizarlo si usted está:
tomando aspirina para un ataque al corazón o una embolia cerebral, porque el ibuprofeno puede disminuir este beneficio de la aspirina, o bajo el cuidado de un médico debido a cualquier condición seria, tomando cualquier otro medicamento

Cuando utilice este producto:
tómelo con alimentos o leche si se presenta malestar estomacal

Ojele de usuario y pregúntele a un médico si:
sufre cualquiera de los siguientes síntomas de sangrado estomacal: vómito sangre, tiene heces con sangre o negras, se siente débil, tiene dolor de estómago que no mejora, tiene síntomas de problemas cardíacos o embolia cerebral, dolor en el pecho, dificultad para respirar

Actrojel

IBUPROFEN / IBUPROFENO



PAIN RELIEVER/FEVER REDUCER(NSAID)
ANALGÉSICO/ REDUCTOR DE FIEBRE (AINE)

NDC 27854-222-00



Actrojel

IBUPROFENO

24

CÁPSULA
llenos de
líquido

Tamaño Real

Cápsulas de Ibuprofeno Solubles, 200 mg
ANALGÉSICO/ REDUCTOR DE FIEBRE
(AINE/NSAID)

NDC 27854-222-00



Actrojel

IBUPROFEN

24

Liquid-filled
CAPSULES

Actual Size

Solubilized Ibuprofen Capsules, 200 mg
PAIN RELIEVER/FEVER REDUCER
(NSAID)

Z FOLD

C8788

B-0099-754-08
ORG022075408

Drug Facts (continued)

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

■ store at 20° to 25°C (68° to 77°F)

■ avoid excessive heat above 40°C (104°F).

■ protect from light.

Inactive ingredients FD&C blue #1, gelatin, potassium hydroxide, purified water, sorbitan, sorbitol

Questions or comments?

Call 1-888-779-2877 M-F 9AM-5PM EST

Drug Facts (continued)

■ **Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away.

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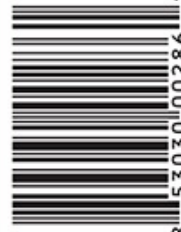
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Inactive ingredients FD&C blue #1, gelatin, potassium hydroxide, purified water, sorbitan, sorbitol

Questions or comments?

Call 1-888-779-2877 M-F 9AM-5PM EST

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING



No print/No varnish
Lot & Exp date

EVIDENCIA DE MANIPULACION: NO USAR SI EL SELLO DE SEGURIDAD ESTÁ ROTO O SI FALTA

Distributed by/Distribuido por Beimora LLC
3033 Wilson Blvd, Suite 700
Arlington, VA 22201



Actrojel 44-754

ACTROGEL

ibuprofen capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:27854-222
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
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ05DW1A)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
WATER (UNII: 059QF0KO0R)	
SORBITAN (UNII: 6O92ICV9RU)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color	blue	Score	no score
Shape	OVAL	Size	20mm
Flavor		Imprint Code	IB1
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:27854-222-00	1 in 1 CARTON	07/06/2022	
1		24 in 1 BOTTLE, PLASTIC; Type 0: Not a		

Combination Product

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078682	07/06/2022	

Labeler - Belmora LLC (112753244)

Revised: 7/2023

Belmora LLC