

REGULAR STRENGTH PAIN RELIEF- acetaminophen capsule, liquid filled

Belmora LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Regular Strength Pain Relief

Drug Facts

Active ingredient (in each softgel)

Acetaminophen 325 mg

Purpose

Pain reliever/fever reducer

Uses

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

Warnings

Liver warning

This product contains acetaminophen. The maximum daily dose of this product is 10 softgels (3,250 mg) in 24 hours for adults or 5 softgels (1,625 mg) in 24 hours for children. Severe liver damage may occur if

- adult takes more than 4,000 mg of acetaminophen in 24 hours
- child takes more than 5 doses in 24 hours, which is the maximum daily amount
- taken with other drugs containing acetaminophen
- adult has 3 or more alcoholic drinks every day while using this product

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters

- rash

If a skin reaction occurs, stop use and seek medical help right away.

Do not use

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- if you are allergic to acetaminophen or any of the inactive ingredients in this product

Ask a doctor before use if the user has liver disease

Ask a doctor or pharmacist before use if the user is taking the blood thinning drug warfarin

Stop use and ask a doctor if

- pain gets worse or lasts more than 10 days in adults
- pain gets worse or lasts more than 5 days in children under 12 years
- fever gets worse or lasts more than 3 days
- new symptoms occur
- redness or swelling is present

These could be signs of a serious condition.

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

Keep out of reach of children.

Overdose warning

In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

- **do not take more than directed (see Overdose warning)**

adults and children 12 years and over	<ul style="list-style-type: none"> • take 2 softgels every 4 to 6 hours while symptoms last • do not take more than 10 softgels in 24 hours • do not use for more than 10 days unless directed by a doctor
children 6 years to under 12 years	<ul style="list-style-type: none"> • take 1 softgel every 4 to 6 hours while symptoms last • do not take more than 5 softgels in 24 hours • do not use for more than 5 days unless directed by a doctor

children under 6 years	ask a doctor
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Other information

- store at 15°-30°C (59°-86°F) and avoid excessive heat.

Inactive ingredients

FD&C red #40, FD&C yellow #6, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol special and white ink

Questions or comments?

Call toll free: **1-888-779-2877**

Monday to Friday 9AM - 5PM EST

PRINCIPAL DISPLAY PANEL - Carton Label

REGULAR STRENGTH Pain Relief

Acetaminophen 325 mg 20 SOFTGELS

NDC 27854-388-01

*Compare to the active ingredient in **TYLENOL®** Regular Strength

*Compare to the active ingredient in **TYLENOL®** Regular Strength
*Comparar con el ingrediente activo en **TYLENOL®** Concentración Regular



NDC 27854-388-01

PARACETAMOL

Pain Reliever/Fever Reducer • Analgésico/Reductor de Fiebre
Acetaminophen 325 mg • Acetaminofén 325 mg

RAPID RELEASE
ALIVIO RÁPIDO DEL DOLOR

Contains no aspirin • No contiene aspirina

RAPID RELEASE
**ALIVIO RÁPIDO
DEL DOLOR**



www.paracetamol.com

PARACETAMOL

Pain Reliever/Fever Reducer • Analgésico/Reductor de Fiebre
Acetaminophen 325 mg • Acetaminofén 325 mg

Contains no aspirin • No contiene aspirina



20 SOFTGELS/CÁPSULAS DE GELATINA

Actual Size/Tamaño Real

Drug Facts

Active ingredient

(in each softgel)

Purpose

Acetaminophen 325 mg... Pain reliever/fever reducer

Uses

temporarily relieves minor aches and pains due to:

- headache
- muscular aches
- backache
- minor pain of arthritis
- the common cold
- toothache
- premenstrual and menstrual cramps
- temporarily reduces fever

Warnings

Liver warning

This product contains acetaminophen. The maximum daily dose of this product is 10 softgels (3,250 mg) in 24 hours for adults or 5 softgels (1,625 mg) in 24 hours for children. Severe liver damage may occur if you take more than 4,000 mg of acetaminophen in 24 hours.

Child takes more than 5 doses in 24 hours, which is the maximum daily amount.

Adult has 3 or more alcoholic drinks every day while using this product.

Adult has 3 or more alcoholic drinks every day while using this product.

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin redness
- hives
- rash
- if a skin reaction occurs, stop use and seek medical help right away.

Drug Facts (continued)

Do not use

with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

If you are allergic to acetaminophen or any of the inactive ingredients in this product.

Ask a doctor before use if the user has liver disease.

Ask a doctor or pharmacist before use if the user is taking the blood thinning drug warfarin.

Stop use and ask a doctor if

pain gets worse or lasts more than 10 days in adults.

pain gets worse or lasts more than 5 days in children under 12 years.

fever gets worse or lasts more than 3 days.

new symptoms occur.

redness or swelling is present.

These could be signs of a serious condition.

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

Keep out of reach of children.

Overdose warning

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Información sobre el medicamento

Ingrediente activo

(en cada cápsula)

Propósito

Acetaminofén 325 mg... Analgésico/antipirético

Usos

alivia temporalmente los dolores y molestias menores debido a:

- dolor de cabeza
- dolores musculares
- dolor de espalda
- dolor menor de artritis
- resfriado común
- dolor de dientes
- calambres premenstruales y menstruales
- reduce temporalmente la fiebre

Advertencias

Advertencia sobre el hígado: Este producto contiene acetaminofén. La dosis máxima de este producto es de 10 cápsulas (3,250 mg) en 24 horas para adultos o 5 cápsulas (1,625 mg) en 24 horas para niños. Se puede presentar daño hepático grave si:

un adulto toma más de 4,000 mg de acetaminofén en 24 horas.

un niño toma más de 5 dosis en 24 horas, que es la cantidad máxima diaria.

se toma con cualquier otro medicamento que contenga acetaminofén.

un adulto toma 3 o más tragos de bebidas alcohólicas diariamente mientras usa este producto.

Alerta de alergia: El acetaminofén puede causar severas reacciones en la piel. Los síntomas pueden incluir:

- enrojecimiento de la piel
- impollas
- erupciones
- Si se produce una reacción cutánea, deje de usarlo y busque atención médica de inmediato.

Información sobre el medicamento (continuación)

No lo use

con otro medicamento que contenga acetaminofén (con receta o sin receta). Si no está seguro de que un medicamento contiene acetaminofén, pregunte a un médico o farmacéutico.

si es alérgico al acetaminofén o a alguno de los ingredientes inactivos en este producto.

Pregunte a un médico antes de usarlo si el usuario padece de enfermedad del hígado.

Pregúntele a un médico o farmacéutico antes de utilizarlo si el usuario:

está tomando el medicamento anticoagulante warfarina.

Deje de usarlo y póngaselo a un médico si:

el dolor empeora o dura más de 10 días en adultos.

el dolor empeora o dura más de 5 días en niños menores de 12 años.

la fiebre empeora o dura más de 3 días.

se presentan nuevos síntomas.

hay enrojecimiento o hinchazón.

Estos podrían ser signos de una condición grave.

Si está embarazada o amamantando, pregúntele a un profesional de la salud antes de usarlo.

Mantener fuera del alcance de los niños.

Advertencia de sobredosis

En caso de sobredosis, busque ayuda médica o póngase en contacto con un Centro de Control de Envenenamientos inmediatamente. (1-800-222-1222)

La atención médica rápida también es crítica para los adultos, así como para los niños, incluso si usted no nota ningún signo o síntoma.

Drug Facts (continued)**Directions** ■ do not take more than directed (see overdose warning)

adults and children 12 years and over	■ take 2 softgels every 4 to 6 hours while symptoms last ■ do not take more than 10 softgels in 24 hours, unless directed by a doctor ■ do not use for more than 10 days unless directed by a doctor
children 6 years to under 12 years	■ take 1 softgel every 4 to 6 hours while symptoms last ■ do not take more than 5 softgels in 24 hours ■ do not use for more than 5 days unless directed by a doctor
children under 6 years	ask a doctor

Other information

■ Store at 15°C-30°C (59°F-86°F) and avoid excessive heat.

Inactive ingredients FD&C red #40, FD&C yellow #6, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan solution and white ink**Questions or Comments?**Call toll free: 1-888-779-2877
Monday to Friday 9AM - 5PM ESTDistributed by/Distribuido por
Bedmora LLC, 3033 Wilson Blvd., #700 Arlington, VA 22201

Made in China/Hecho en China

Información sobre el Medicamento (continuación)**Direcciones** ■ no tome más de lo indicado (consulte la advertencia de sobredosis)

adultos y niños de 12 años y mayores	■ tomar 2 cápsulas cada 4 a 6 horas mientras duran los síntomas ■ no tomar más de 10 cápsulas en 24 horas, a menos que lo indique un médico ■ no usar por más de 10 días a menos que lo indique un médico
niños de 6 años a mayores de 12 años	■ tomar 1 cápsula cada 4 a 6 horas mientras duran los síntomas ■ no tomar más de 5 cápsulas en 24 horas ■ no usar por más de 5 días a menos que lo indique un médico
niños mayores de 6 años	consultar a un médico

Otra Información

■ Almacene a 15°C-30°C (59°F-86°F) y evite el calor excesivo.

Ingredientes Inactivos FD&C rojo #40, FD&C amarillo #6, gelatina, glicerina, polietilenglicol, povidona, propilenglicol, agua purificada, solución de sorbitol sorbitán y tinta blanca**¿Preguntas o comentarios?**Llame a nuestra línea gratuita: 1-888-779-2877
De Lunes a Viernes de 9AM - 5PM ESTDO NOT USE IF PRINTED SEAL UNDER
CAP IS BROKEN OR MISSINGNO LO USE SI EL SELLO IMPRESO DEBAJO
DE LA TAPA ESTÁ ROTO O FALTANTE**PRINCIPAL DISPLAY PANEL - Bottle Label**

REGULAR STRENGTH Pain Relief

Acetaminophen 325 mg 20 SOFTGELS

NDC 27854-388-01

NDC 27854-388-01

Regular Strength • Concentración Regular

PARACETAMOL

Pain Reliever/Fever Reducer

Acetaminophen 325 mg

Analgésico/Reductor de Fiebre

Acetaminofén 325 mg

20 SOFTGELS/
CÁPSULAS DE GELATINA

Contains no aspirin • No contiene aspirina

TAMPER EVIDENT: DO NOT USE IF IMPRINTED
SEAL UNDER CAP IS BROKEN OR MISSING.KEEP OUTER CARTON FOR COMPLETE
WARNINGS AND PRODUCT INFORMATION**Warnings****Liver warning:** This product contains acetaminophen.

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Allergy alert: acetaminophen may cause severe skin reactions. Symptoms may include:

■ hives ■ rash ■ if a skin reaction occurs, stop use and seek medical help right away.

Directions ■ do not take more than directed (see overdose warning)

■ adults and children 12 years and over:

■ take 2 softgels every 4 to 6 hours while symptoms last

■ do not take more than 10 softgels in 24 hours, unless directed by a doctor ■ do not use for more than 10 days unless directed by a doctor

■ children 6 years to under 12 years:

■ take 1 softgel every 4 to 6 hours while symptoms last

■ do not take more than 5 softgels in 24 hours

■ do not use for more than 5 days unless directed by a doctor

■ children under 6 years: ask a doctor

Questions/Comments?

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

Distributed by: Bedmora LLC

3033 Wilson Blvd., #700 Arlington, VA 22201

Made in China

LOT NO: EXP DATE:

CMB07-01

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:27854-388-01	1 in 1 CARTON	01/05/2022	
1		20 in 1 BOTTLE; Type 0: Not a Combination Product		
Marketing Information				
	Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
	OTC monograph not final	part343	01/05/2022	

Labeler - Belmora LLC (112753244)

Revised: 1/2022

Belmora LLC