

BACZOL EXPECTORANT- guaifenesin, phenylephrine hcl syrup
Procaps S.A. de C.V.

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.

BACZOL EXPECTORANT (Lex)

Drug Facts

Active ingredients (in each 5 mL tsp.)

Guaifenesin 200 mg

Phenylephrine HCl 5 mg

Purpose

GuaifenesinExpectorant

PhenylephrineNasal Decongestant

Uses • helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes • temporarily relieves nasal congestion due to the common cold.

Warnings: • **Do not exceed recommended dosage** • If nervousness, dizziness, or sleeplessness occurs, discontinue use and consult a doctor.

Do not use this product • for persistent or chronic cough, such as occurs with smoking, asthma, chronic bronchitis, or emphysema, or if cough is accompanied by excessive phlegm (mucus), unless directed by a Doctor • if you are now taking a prescription Monoamineoxidase Inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if you are taking a prescription drug that contains an MAOI, ask a doctor or a pharmacist before taking this product. • if you have heart disease, high blood pressure, thyroid disease, diabetes, or difficulty in urination due to enlargement of the prostate gland unless directed by a Doctor.

Stop use and ask a Doctor • A persistent cough may be a sign of a serious condition; • If cough persists for more than one week, tend to recur, or is accompanied by fever, rash or persistent headache; • if symptoms do not improve within 7 days or are accompanied by fever.

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

Keep out of reach of children.

In case of overdose, contact a physician or Poison Control Center right away.

Directions Do not exceed more than 6 doses for children and adults in a 24 - hour period.

Adults and Children 12 years of age and over	2 teaspoonfuls (10 mL) every 4 hours
Children 6 to under 12 years of age	1 teaspoonful (5 mL) every 4 hours
Children under 6 years of age	Ask a doctor

Other information • Store at room temperature 15°-30°C (59°-86°F).

Tamper evident: Do not use if there is evidence of tampering.

Inactive ingredients: citric acid, glycerin, garpe flavor, methylparaben (as preservative), propylene glycol, propylparaben (as preservative), purified water, sodium citrate, sucralose, xanthan gum

Questions or Comments?

customer.service@lablopez.com.sv

Product Labeling

NDC 76864-209-02

Baczol®
EXPECTORANT

Guaifenesin • Expectorant
Phenylephrine HCl • Nasal Decongestant

Fruit Flavor

- Sugar FREE
- Alcohol FREE

4 fl. oz.

Manufactured For: **Laboratorios López, S.A. de C.V.**
Boulevard del Ejército Nacional, Km. 5 1/2,
Soyapango, San Salvador,, El Salvador, C.A.

Lot:

Rev. 07/2020

Exp. Date:

Carton

Sabor a frutas / Fruit Flavor
 • Libre de azúcar • Libre de alcohol
 • Sin cafeína • Sin colorantes artificiales
 • Sin conservantes artificiales
 • Sin parabenos
 • Sin gluten
 • Sin lactosa
 • Sin soja
 • Sin trigo
 • Sin leche de vaca
 • Sin huevo
 • Sin nueces
 • Sin semillas de sésamo
 • Sin ácidos orgánicos
 • Sin sulfatos
 • Sin fosfatos
 • Sin sales de aluminio
 • Sin sales de sodio
 • Sin sales de calcio
 • Sin sales de magnesio
 • Sin sales de potasio
 • Sin sales de sodio
 • Sin sales de calcio
 • Sin sales de magnesio
 • Sin sales de potasio

Baccol
 EXPECTORANTE

Baccol
 EXPECTORANT

Codeine Hydrochloride + Guaifenesin
 Codeína + Guaifenesina

Fruit Flavor



SHAKE WELL BEFORE USE
 • Sugar FREE
 • Alcohol FREE
 4 fl. oz.

Laboratorios López
 Manufactured For: **Laboratorios López, S.A. de C.V.**
 Boulevard del Ejército Nacional, Km. 5 1/2,
 Soyapango, San Salvador, El Salvador, C.A.

Lot: _____
 Exp. Date: _____

Drug Facts

Active ingredients (in each 5 mL fl. oz.):
 Codeine Hydrochloride 2.5 mg, Guaifenesin 100 mg

Warnings • Do not exceed recommended dosage • If symptoms persist, or if cough is accompanied by excessive phlegm (mucus), when directed by a Doctor • If you are ever taking a prescription Monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or anesthetic conditions or Parkinson's disease), or for 2 weeks after stopping the MAOI drug, if you do not know if you are taking a prescription drug that contains an MAOI, ask a doctor or pharmacist before taking this product • If you have heart disease, high blood pressure, thyroid disease, diabetes, or difficulty in urination due to enlargement of the prostate gland unless directed by a Doctor.

Do not use this product • for persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema, or if cough is accompanied by excessive phlegm (mucus), when directed by a Doctor • if you are ever taking a prescription Monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or anesthetic conditions or Parkinson's disease), or for 2 weeks after stopping the MAOI drug, if you do not know if you are taking a prescription drug that contains an MAOI, ask a doctor or pharmacist before taking this product • if you have heart disease, high blood pressure, thyroid disease, diabetes, or difficulty in urination due to enlargement of the prostate gland unless directed by a Doctor.

Stop use and ask a Doctor • if persistent cough may be a sign of a serious condition, • if cough persists for more than one week, • is accompanied by fever, rash or persistent headache, • if symptoms do not improve within 7 days or are accompanied by fever.

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.

Stop use and ask a Doctor • if persistent cough may be a sign of a serious condition, • if cough persists for more than one week, • is accompanied by fever, rash or persistent headache, • if symptoms do not improve within 7 days or are accompanied by fever.

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.

Baccol is a registered trademark of **Laboratorios López, S.A. de C.V.**

Baccol
 EXPECTORANTE

Codeine Hydrochloride + Guaifenesin
 Codeína + Guaifenesina

Sabor a frutas



AGITAR BIEN ANTES DE USAR
 • Libre de azúcar
 • Libre de alcohol
 120 mL

Laboratorios López
 Manufactured For: **Laboratorios López, S.A. de C.V.**
 Boulevard del Ejército Nacional, Km. 5 1/2,
 Soyapango, San Salvador, El Salvador, C.A.

Drug Facts (continued)

Indicaciones: No exceder más de 5 dosis en niños y adultos en un periodo de 24 horas.

Adultos y niños mayores de 12 años: 2 cucharaditas (10 mL), cada 4 horas.
 Niños de 6 a 12 años: 1 cucharadita (5 mL), cada 4 horas.

Menores de 6 años: Consultar a su médico.

Información adicional • Conserve a temperatura ambiente 15° - 30°C (50°-86°F). **Evidencia de manipulación:** No utilizar si existe esta evidencia de manipulación.

Ingredientes activos: Sabor a frutas, ácido cítrico, extracto de soja, glicerina, metilparabeno (como preservante), propilparabeno, propilparabeno como preservante, agua purificada, xantocena, goma de bencina.

Advertencias: No exceder más de 6 dosis for children and adults in a 24 - hour period.

Children and adults: 2 teaspoons (10 mL), every 4 hours.
 Children 6 to 12 years of age: 1 teaspoon (5 mL), every 4 hours.

Children under 6 years of age: Ask a doctor.

Other information • Store at room temperature 15°-30°C (50°-86°F). **Temporización:** Do not use if there is evidence of tampering.

Inactive ingredients: Citric acid, glycerin, grape flavor, methylparaben (as preservative), propylparaben, propylparaben as preservative, purified water, sodium citrate, sucralose, xanthan gum.

Frecuencia o concentración / Dosis / Dosis o comentarios?
 (consultar www.laboratorioslopez.com)

For sale in the US only. Rev. 11/2020



Bottle

Drug Facts

Active Ingredients (in each 5 mL tsp.) **Purpose**
 Guaifenesin 200 mgExpectorant
 Phenylephrine HCl 5 mg Nasal Decongestant

Uses ■ helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes ■ temporarily relieves nasal congestion due to the common cold.

Warnings ■ **Do not exceed recommended dosage** ■ If nervousness, dizziness, or sleeplessness occurs, discontinue use and consult a doctor.

Do not use this product ■ for persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema, or if cough is accompanied by excessive phlegm (mucus), unless directed by a doctor ■ if you are now taking a prescription Monoamine oxidase Inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions or Parkinson's disease), or for 2 weeks after stopping the MAOI drug; if you do not know if you are taking a prescription drug that contains an MAOI, ask a doctor or pharmacist before taking this product ■ if you have heart disease, high blood pressure, thyroid disease, diabetes, or difficulty in urination due to enlargement of the prostate gland unless directed by a Doctor.

Stop use and ask a Doctor ■ A persistent cough may be a sign of a serious condition; ■ If cough persist for more than one week, tend to recur, or is accompanied by fever, rash or persistent headache; ■ if symptoms do not improve within 7 days or are accompanied by fever.

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.

Baczol® is registered trade mark of **Laboratorios López, S.A. de C.V.**

Manufactured For: **Laboratorios López, S.A. de C.V.**
 Boulevard del Ejército Nacional, Km. 5 1/2, Soyapango, San Salvador,
 El Salvador, C.A.

NDC 76864-209-02

Baczol®

EXPECTORANTE EXPECTORANT

Guaifenesina • Expectorante
 Fenilefrina • Descongestionante Nasal
 Guaifenesina • Expectorant
 Phenylephrine HCl • Nasal Decongestant
 Sabor a frutas / Fruit Flavor



• Shake well before using • Agitar bien antes de usar
 • Libre de azúcar • Libre de alcohol
 • Sugar FREE • Alcohol FREE

4 fl. oz. (120 mL)

Laboratorios López

Drug Facts (continued)

Indicaciones: No exceder más de 6 dosis en niños y adultos en un periodo de 24 horas.

Adultos y niños mayores de 12 años	2 cucharaditas (10 mL), cada 4 horas
Niños de 6 a 12 años	1 cucharadita (5 mL), cada 4 horas
Niños menores de 6 años	Consulte a su médico

Información adicional ■ Conserve a temperatura ambiente 15°-30°C (59°-86°F). **Evidencia de manipulación:** No utilizar si existe clara evidencia de manipulación.

Ingredientes inactivos: Sabor uva, ácido cítrico, citrato de sodio, glicerina, metilparabeno (como preservante), propilenglicol, propilparabeno (como preservante), agua purificada, sucralosa goma de xantano.

Directions Do not exceed more than 6 doses for children and adults in a 24 - hour period.

Adults and children 12 years of age and over	2 teaspoonfuls (10 mL), every 4 hours
Children 6 to under 12 years of age	1 teaspoonful (5 mL), every 4 hours
Children under 6 years of age	Ask a doctor

Other information ■ Store at room temperature 15°-30°C (59°-86°F). **Tamper evident:** Do not use if there is evidence of tampering.

Inactive ingredients: citric acid, glycerin, grape flavor, methylparaben (as preservative), propylene glycol, propylparaben (as preservative), purified water, sodium citrate, sucralose, xanthan gum.

Preguntas o comentarios / Questions or comments?
 customer.service@lablopez.com.sv 754-260-6479

Lot: _____
 Exp. Date: _____
 Rev. 07/2020

res

BACZOL EXPECTORANT

guaifenesin, phenylephrine hcl syrup

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76864-209
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg in 5 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE	5 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

XANTHAN GUM (UNII: TTV12P4NEE)

Product Characteristics

Color		Score	
Shape		Size	
Flavor	GRAPE	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76864-209-02	1 in 1 CARTON	06/03/2021	
1		120 mL 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
OTC monograph final	part341	06/03/2021	

Labeler - Procaps S.A. de C.V. (851259341)

Revised: 8/2023

Procaps S.A. de C.V.