

**BACZOL COLD MEDICINE- acetaminophen, dextromethorphan hbr, chlorpheniramine maleate, 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 COLD (Lex)**

**Drug Facts**

**Active ingredients (in each 5 mL tsp.)**

Acetaminophen 250 mg  
Dextromethorphan HBr 10 mg  
Chlorpheniramine Maleate 4 mg  
Phenylephrine HCl 10 mg

**Purpose**

Acetaminophen ..... Analgesic and Antipyretic  
Dextromethorphan HBr .....Cough Suppressant  
Chlorpheniramine Maleate .....Antihistamine  
Phenylephrine HCl ..... Nasal Decongestant

**Uses** • Temporarily relieves runny nose, sneezing, itching of the nose or throat, and itchy, watery eyes due to hay fever • nasal congestion due to the common cold • Calms the cough control center and relieves coughing • minor aches and pains associated with the common cold • temporarily reduces fever.

**Warnings: Liver warning: This product contains acetaminophen**

• Severe liver damage may occur if • adult takes more than 6 doses in 24 hours, which is the maximum daily amount • child takes more than 6 doses in 24 hours • taken with other drugs containing acetaminophen • adult has 3 or more alcoholic drinks every day while using this product • Do not give to children under 3 years of age or use for more than 10 days unless directed by a physician.

**Stop Use and ask a Doctor if** • you have liver disease • pain, cough or nasal congestion gets worse or lasts more than 5 days (children) or 7 days (adults) • fever gets worse or lasts more than 3 days • redness or swelling is present • new symptoms occur • you have a breathing problem such as emphysema or chronic bronchitis • you have glaucoma or difficulty in urination due to enlargement of the prostate gland • you have shortness of breath, asthma, heart disease, high blood pressure, thyroid disease, diabetes.

**Ask a Doctor or pharmacist before use if** you are taking the blood thinning drug warfarin.

**When using this product, do not exceed recommended dosage.** If nervousness, dizziness, or sleeplessness occur, discontinue use and consult a doctor. May cause excitability especially in children. May cause drowsiness; alcohol, sedatives, and tranquilizers may increase the drowsiness effect. Avoid alcoholic beverages while taking this product. Use caution when driving motor vehicle or operating machinery.

**Precaution:** this product contains FD&C Yellow #5 (Tartrazine) as color additive.

**Do Not Use:** 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 your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product • 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 the product • for persistent or chronic cough such as occurs with smoking, asthma, or emphysema, or if cough is accompanied by excessive phlegm (mucus), unless directed by a doctor • if you are taking sedatives or tranquilizers, without first consulting your doctor.

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

**Keep out of reach of children.**

**Overdose Warning:** taking more than recommended dose (overdose) may cause liver damage. In case of accidental overdose, contact a physician or Poison Control Center right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

**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	1 teaspoon (5 mL) every 4 hours
Children 6 to under 12 years of age	1/2 teaspoon (2.5 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** Banana Flavor, cherry flavor, FD&C yellow #5, glycerin, methyl paraben (as preservative), polyethylene glycol 400, propyl paraben (as preservative), purified water, sucralose and Xanthan gum.

**Questions or comments?**

customer.service@lablopez.com.sv 754-260-6479

**Product Labeling**

NDC 76864-208-01

**Baczol**®

**COLD MEDICINE**

**Acetaminophen** • Analgesic and Antipyretic  
Dextromethorphan HBr • Cough Suppressant  
Chlorpheniramine Maleate • Antihistamine  
Phenylephrine HCl • Nasal Decongestant

**Fruit Flavor**

**For sale in the  
US only.**

**SHAKE WELL  
BEFORE USE**

• Sugar FREE • Alcohol FREE

**4 fl.oz. (120 mL)**

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

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

7 69041 04544 8

Lot:

Rev. 05/2020

Exp. Date:

**Drug Facts****Active ingredients (in each 5 mL tsp.)**

Active ingredients (in each 5 mL tsp.)	Purpose
Acetaminophen 250 mg	Analgesic and Antipyretic
Dextromethorphan HBr 10 mg	Cough Suppressant
Chlorpheniramine Maleate 4 mg	Antihistamine
Phenylephrine HCl 10 mg	Nasal Decongestant

**Uses** • Temporarily relieves runny nose, sneezing, itching of the nose or throat, and itchy, watery eyes due to hay fever • nasal congestion due to the common cold • Calms the cough control center and relieves coughing • minor aches and pains associated with the common cold • temporarily reduces fever.

**Warnings: Liver warning: This product contains acetaminophen** • Severe liver damage may occur if • adult takes more than 6 doses in 24 hours, which is the maximum daily amount • child takes more than 6 doses in 24 hours • taken with other drugs containing acetaminophen • adult has 3 or more alcoholic drinks every day while using this product • Do not give to children under 3 years of age or use for more than 10 days unless directed by a physician.

**Stop Use and ask a Doctor if** • you have liver disease • pain, cough or nasal congestion gets worse or lasts more than 5 days (children) or 7 days (adults) • fever gets worse or lasts more than 3 days • redness or swelling is present • new symptoms occur • you have a breathing problem such as emphysema or chronic bronchitis • you have glaucoma or difficulty in urination due to enlargement of the prostate gland • you have shortness of breath, asthma, heart disease, high blood pressure, thyroid disease, diabetes.

**Ask a Doctor or pharmacist before use if** you are taking the blood thinning drug warfarin. **When using this product, do not exceed recommended dosage.** If nervousness, dizziness, or sleeplessness occur, discontinue use and consult a doctor. May cause excitability especially in children. May cause drowsiness; alcohol, sedatives, and tranquilizers may increase the drowsiness effect. Avoid alcoholic beverages while taking this product. Use caution when driving motor vehicle or operating machinery.

**Precaution:** this product contains FD&C Yellow #5 (Tartrazine) as color additive.

**Do Not Use:** 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 your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product • 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 the product • for persistent or chronic cough such as occurs with smoking, asthma, or emphysema, or if cough is accompanied by excessive phlegm (mucus), unless directed by a doctor • if you are taking sedatives or tranquilizers, without first consulting your doctor.

NDC 76864-208-01

**Baczol****ANTIGRIPAL  
COLD MEDICINE**

**Acetaminofén • Analgésico y Antipirético.**  
Dextrometorfano - Antitusivo  
Clorfeniramina - Antihistaminico  
Fenilefrina - Descongestionante Nasal

**Acetaminophen • Analgesic and Antipyretic**  
Dextromethorphan HBr • Cough Suppressant  
Chlorpheniramine Maleate • Antihistamine  
Phenylephrine HCl • Nasal Decongestant

Sabor a frutas / Fruit Flavor

For sale in the  
US only.

**AGITAR BIEN  
ANTES DE USAR  
SHAKE WELL  
BEFORE USE**

• Libre de azúcar • Libre de alcohol  
• Sugar FREE • Alcohol FREE

4 fl. oz. (120 mL)

**Drug Facts (continued)**

If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. **Overdose Warning:** taking more than recommended dose (overdose) may cause liver damage. In case of accidental overdose, contact a physician or Poison Control Center right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

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

Adultos y Niños mayores de 12 años	1 cucharadita (5 mL), cada 4 horas
Niños de 6 a 12 años	1/2 cucharadita (2.5 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 banana y cereza, Amaro #5 FD&C, glicerina, metilparaben (como preservante), goma xantán, polietilenglicol 400, propilparaben (como preservante), agua purificada y sucralosa.

**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	1 teaspoon (5 mL) every 4 hours
Children 6 to under 12 years of age	1/2 teaspoon (2.5 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** Banana flavor, cherry flavor, FD&C yellow #5, glycerin, polyethylene glycol 400, methyl paraben (as preservative), xanthan gum, propyl paraben (as preservative), purified water and sucralose.

**Preguntas o comentarios / Questions or comments?**  
customer.service@lablopez.com.sv

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

Lot:  
Exp. Date:

Rev. 05/2020

**Baczol**  
**ANTIGRIPAL**  
**COLD MEDICINE**

Acetaminophen • Analgésico y Antipirético  
 Dextrometorphan Hbr • Antitusivo  
 Chlorpheniramine Maleate • Antihistamínico  
 Phenylephrine HCl • Nasal Decongestant

Sabor a frutas / Fruit Flavor

• Libre de azúcar • Libre de alcohol  
 • Sugar FREE • Alcohol FREE

4 fl. oz. (120 mL)

NDC 018-201-01  
**Baczol**

**COLD MEDICINE**

Acetaminophen • Analgésico y Antipirético  
 Dextrometorphan Hbr • Cough Suppressant  
 Chlorpheniramine Maleate • Antihistamínico  
 Phenylephrine HCl • Nasal Decongestant

Fruit Flavor



**SHAKE WELL BEFORE USE**

- Sugar FREE
- Alcohol FREE

4 fl. oz.

**Laboratorios López**

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

**Drug Facts**

**Active ingredients (in each 5 mL tsp.) Purpose**  
 Acetaminophen 250 mg Analgesic and Antipyretic  
 Dextrometorphan Hbr 10 mg Cough Suppressant  
 Chlorpheniramine Maleate 4 mg Antihistamine  
 Phenylephrine HCl 10 mg Nasal Decongestant

**Uses** • Temporarily relieves runny nose, sneezing, itching of the nose or throat, and itchy, watery eyes due to hay fever • nasal congestion due to the common cold • Calms the cough control center and relieves coughing • minor aches and pains associated with the common cold • Temporarily reduces fever.

**Warnings: Liver warning: This product contains acetaminophen**

- Severe liver damage may occur if • adult takes more than 6 doses in 24 hours, which is the maximum daily amount • child takes more than 6 doses in 24 hours • taken with other drugs containing acetaminophen • adult has 3 or more alcoholic drinks every day while using this product • Do not give to children under 3 years of age or use for more than 10 days unless directed by a physician.

**Stop Use and ask a doctor if** • you have liver disease • pain, cough or nasal congestion gets worse or lasts more than 5 days (children) or 7 days (adults) • fever gets worse or lasts more than 3 days • redness or swelling is present • new symptoms occur • you have a breathing problem such as emphysema or chronic bronchitis • you have a tumor or difficulty in urination due to enlargement of the prostate gland • you have shortness of breath, asthma, heart disease, high blood pressure, thyroid disease, diabetes.

**Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin.**

**When using this product, do not exceed recommended dosage.** • If nervousness, dizziness, or sleepiness occur, discontinue use and consult a doctor. May cause drowsiness especially in children. May cause drowsiness, alcohol, sedatives, and tranquilizers may increase the drowsiness effect. Avoid alcoholic beverages while taking this product. Use caution when driving motor vehicle or operating machinery.

**Precaution:** this product contains FD&C Yellow #5 (Tartrazine) as color additive.

**Do Not Use:** 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 your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product • 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 the product • for persistent or chronic cough such as occurs with smoking, asthma, or emphysema, or if cough is accompanied by excessive phlegm (mucus), unless directed by a doctor • if you are taking sedatives or tranquilizers, without first consulting your doctor.

**Baczol** is registered trademark of **Laboratorios López, S.A. de C.F.**

NDC 76864-208-01  
**Baczol**

**ANTIGRIPAL**

Acetaminofén • Analgésico y Antipirético.  
 Dextrometorfan • Antitusivo  
 Clorfeniramina • Antihistamínico  
 Fenilefrina • Descongestionante Nasal

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.F.**  
 Boulevard del Ejército Nacional, Km. 5 1/2,  
 Soyapango, San Salvador, El Salvador, C.A.

**Drug Facts (continued)**

If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. **Overdose Warning:** Taking more than recommended dose (overdose) may cause liver damage. In case of accidental overdose, contact a physician or Poison Control Center right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

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

Adultos y Niños mayores de 12 años	1 cucharadita (5 mL), cada 4 horas
Niños de 6 a 12 años	1/2 cucharadita (2.5 mL), cada 4 horas
Niños menores de 6 años:	Consulte a su médico

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

**Ingresantes inactivos:** Sabor banana y cereza, Amarillo #5 FD&C, glicerina, metilparaben (como preservante), polietilenglicol 400, propilparaben (como preservante), agua purificada, sucralosa y goma de Xantano.

**Directives:** 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	1 teaspoon (5 mL), every 4 hours
Children 6 to under 12 years of age	1/2 teaspoon (2.5 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). **Temper evident:** Do not use if there is evidence of tampering.

**Inactive ingredients:** Banana flavor, cherry flavor, FD&C yellow #5, glycerin, methyl paraben (as preservative), polyethylene glycol 400, propyl paraben (as preservative), purified water, sucralose and Xanthan gum.

**Preguntas o comentarios / Questions or comments?**  
 customer\_service@lablopez.com.sv 754-201-9470

For sale in the US only.

Rev. 05/2020

Lot:  
 Exp. Date:

res

**BACZOL COLD MEDICINE**

acetaminophen, dextromethorphan hbr, chlorpheniramine maleate, phenylephrine hcl syrup

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:76864-208
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	250 mg in 5 mL
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 5 mL
<b>CHLORPHENIRAMINE MALEATE</b> (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	4 mg in 5 mL
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 5 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>FD&amp;C YELLOW NO. 5</b> (UNII: I753WB2F1M)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)	
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	

### Product Characteristics

<b>Color</b>	yellow	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	BANANA (BANANA, CHERRY)	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76864-208-01	1 in 1 CARTON	05/25/2020	
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	05/25/2020	

Revised: 8/2023

Procaps S.A. de C.V.