**BACZOL ANTIGRIPAL- acetaminophen, dextromethorphan, guaifenesin, phenylephrine liquid**
**Procaps S.A. de C.V.**

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**BACZOLANTIGRIPAL (G)**

## *Drug Facts*

### *Active ingredients & Purposes*

| ***Active ingredients (in each 10 mL)*** | ***Purposes*** |
|---|---|
| Acetaminophen 325 mg ..... | Pain reliever/ fever reducer |
| Dextromethorphan HBr 10 mg ..... | Cough suppressant |
| Guaifenesin 200 mg..... | Expectorant |
| Phenylephrine HCL 5 mg ..... | Nasal decongestant |

### *Uses*

Temporarily relieves common cold/flu symptoms:

- minor aches and pain
- sore throat
- headache
- stuffy nose
- nasal congestion
- cough due to minor throat and bronchial irritation
- and temporarily reduces fever
- helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive

### *Warnings*

**Liver warning:** This product contains acetaminophen. Severe liver damage may occur if  adults take more than

6 doses in 24 hours, which is the maximum daily amount

- child takes more than 5 doses in 24 hours
- taken with other drugs containing acetaminophen
- adult has 3 or more alcoholic drinks every day while using this product

**Sore throat warning:** If sore throat is severe, persists for more than 2 days, is accompanied, or followed by fever,

headache, rash, nausea, or vomiting, consult a doctor promptly.

**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 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.

**Ask a doctor before use if the user has a**

- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- a cough that is accompanied by excessive
- phlegm (mucus)
- a persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- trouble urinating due to an enlarged
- prostate gland

**Ask a doctor or pharmacist before use if the user is**

- taking the blood thinning drug warfarin

**Ask a doctor before use if the user**

- is a child with pain of arthritis

**When using this product**

- **do not exceed recommended dosage**

**Stop use and ask a doctor if**

- nervousness, dizziness, or sleeplessness occur
- redness or swelling is present
- pain 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
- any new symptoms occur
- a persistent cough or symptoms do not improve within 7 days, tends to recur, or is accompanied by fever, rash, or persistent

headache. 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.**

In case of accidental overdose, get medical help or contact a 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***

- only use the dosing cup provided
- shake well before use
- if you are taking other cold/flu products, read complete labeling before dosing

| | |
|---|---|
| adults & children 12 years of age and older | 20mL every 4 hours, do not exceed **6 doses** per 24 hours |
| children 6 to under 12 years of age | 10mL every 4 hours, do not exceed **5 doses** per 24 hours |
| **children under 6 years of age** | **do not use** |

***Other information***

- each 10 mL contains: **sodium** 10mg
- store between 68-77°F (20-25°C)
- do not refrigerate

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

***Inactive ingredients***

citric acid anhydrous, edetate disodium, FD&C blue #1, FD&C red #40, flavors, glycerin, propylene glycol, propyl gallate, purified water, sodium benzoate, sodium citrate, sorbitol, sucralose, xanthan gum

***Questions or Comments?***

**+1-754-260-6479** (M-F) 9 AM to 5 PM EST or customer.service@sofgenpharma.com

**Mfg. for: & Dist by:**

Mfg. for/ Fdo. para:

**PROCAPS GROUP**

Boulevard de Ejercito Nacional, Km. 5 1/2, Soyapango,

San Salvador, El Salvador, C.A.

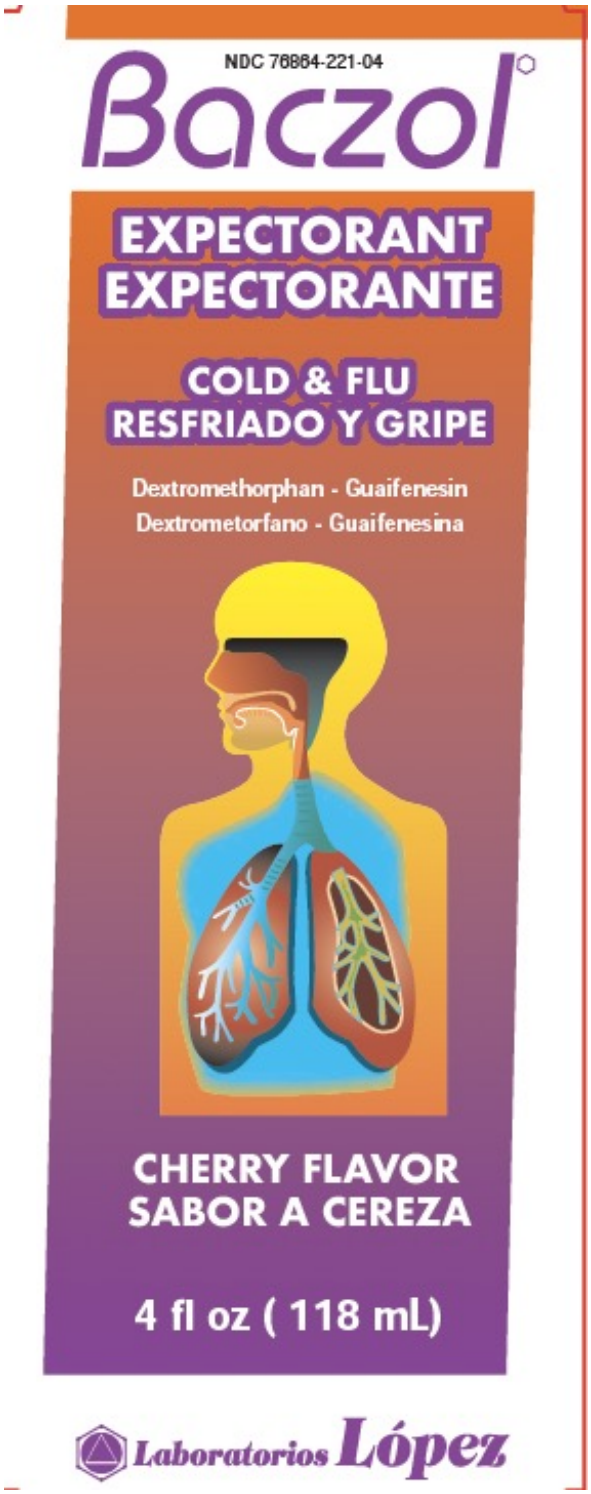
**Baczol®** is a registered trademark of Procaps S.A. De C.V.

Dist. by/ por:

**Sofgen Pharmaceuticals LLC**

21500 Biscayne Boulevard Ste. 600, Aventura, FL 33180

## Principal Display Panel




# BACZOL ANTIGRIPAL

acetaminophen, dextromethorphan, guaifenesin, phenylephrine liquid

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:76864-220 |
| **Route of Administration** | ORAL | | |

## Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **PHENYLEPHRINE HYDROCHLORIDE, (+/-)-** (UNII: O2VT86KV7E) (PHENYLEPHRINE HYDROCHLORIDE, (+/-)- - UNII:O2VT86KV7E) | PHENYLEPHRINE HYDROCHLORIDE, (+/-)- | 5 mg in 10 mL |
| **GUAIFENESIN** (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ) | GUAIFENESIN | 200 mg in 10 mL |
| **DEXTROMETHORPHAN HYDROBROMIDE** (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS) | DEXTROMETHORPHAN HYDROBROMIDE | 10 mg in 10 mL |
| **ACETAMINOPHEN** (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D) | ACETAMINOPHEN | 325 mg in 10 mL |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **SORBITOL** (UNII: 506T60A25R) | |
| **FD&C BLUE NO. 1** (UNII: H3R47K3TBD) | |
| **FD&C RED NO. 40** (UNII: WZB9127XOA) | |
| **ANHYDROUS CITRIC ACID** (UNII: XF417D3PSL) | |
| **GLYCERIN** (UNII: PDC6A3C0OX) | |
| **EDETATE DISODIUM** (UNII: 7FLD91C86K) | |
| **PROPYLENE GLYCOL** (UNII: 6DC9Q167V3) | |
| **PROPYL GALLATE** (UNII: 8D4SNN7V92) | |
| **WATER** (UNII: 059QF0KO0R) | |
| **SODIUM BENZOATE** (UNII: OJ245FE5EU) | |
| **SUCRALOSE** (UNII: 96K6UQ3ZD4) | |
| **XANTHAN GUM** (UNII: TTV12P4NEE) | |
| **SODIUM CITRATE** (UNII: 1Q73Q2JULR) | |

## Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | | **Score** | |
| **Shape** | | **Size** | |
| **Flavor** | BERRY | **Imprint Code** | |
| **Contains** | | | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:76864-220-04 | 1 in 1 CARTON | 01/11/2023 | |
| **1** | | 118 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 Drug | M012 | 01/11/2023 | |

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

Revised: 2/2024 Procaps S.A. de C.V.