

**PALAGRIP- acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl liquid**  
**All Pharma, 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.*

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<b>Active ingredients: (in 10 ml)</b>	<b>Purpose</b>
Acetaminophen 200 mg .....	Analgesic
Dextromethorphan HBr 13.33 mg .....	Cough Suppressant
Guaifenesin 200 mg .....	Expectorant
Phenylephrine HCl 5 mg .....	Decongestant

**Purpose**

- Analgesic
- Cough Suppressant
- Expectorant
- Decongestant

**Uses**

- For temporary relief of bronchial and nasal congestion
- Help loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes and make cough more productive.
- Temporarily relieves cough due to minor throat and bronchial irritation as may occur with the common cold

**Warnings**

**Do not exceed recommended dosage**

**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 5 doses in 24 hours
- Taken with other drugs containing Acetaminophen
- Adult has 3 or more alcoholic drinks everyday 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

**Do not use**

- If you are now taking a prescription monoamine oxidase inhibitor (MAOI)( certain drugs for depression , psychiatric conditions, or Parkinson’s disease) or for 2 weeks after stopping the MAOI drug.
- if you do not know if your prescription drug contains on MAOI ask your doctor or pharmacist before taking this product
- if you have a chronic pulmonary disease or shortness of breath unless directed by a

doctor

- avoid alcoholic beverages while you are taking this product
- 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 a pharmacist.

**Ask the doctor before use if you have**

- cough that occurs with too much phlegm (mucus)
- cough that lasts or is chronic such as occurs with smoking, asthma, chronic bronchitis or emphysema
- heart disease, high blood pressure, thyroid disease, or difficulty in urination due to the enlargement of prostate gland.
- The user has liver disease
- The user is taking the blood thinning drug Warfarin.

**Stop use and ask the doctor if**

- Nervousness, dizziness or sleeplessness occurs.
- Cough persists for more than 1 week, tends to recur, or accompanied by fever, rash or persistent headache. A persistent cough may be sign of a serious condition

**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.

**Directions**

- Do not take more than 6 doses in any 24-hour period

**Age**

**Dose**

Adults and children 12 years and over

10 mL (2 tsps) every 6 hours

Children 6 to under 12 years of age.

5 mL (1 tsps) every 6 hours

**Children under 6 years of age**

**Do not use**

**Inactive ingredients**

Aloe vera, citric acid, disodium EDTA, FD&C Red #40, hydroxyethyl cellulose, natural strawberry flavor, propylene glycol, water, sodium benzoate, sorbitol 70%, sucralose

**Palagrip (ACETAMINOPHEN, DEXTROMETHORPHAN HBR, GUAIFENESIN, PHENYLEPHRINE HCL) LIQUID**

**Drug Facts**

**Active Ingredients: (in each 10ml)**

Acetaminophen 250 mg.....	Analggesic
Dextromethorphan Hydrobromide 13.33 mg.....	Cough Suppressant
Guaifenesin USP 200 mg.....	Expectorant
Phenylephrine HCl 5 mg.....	Decongestant

**Uses**

- For temporary relief of Bronchial and Nasal congestion
- Helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes and make cough more productive.
- Temporarily relieves cough due to minor throat and bronchial irritation as may occur with the common cold.

**Warnings**

**Do not exceed recommended dosage.**

**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 5 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
- Do not use if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric conditions, or Parkinson's disease) or for 2 weeks after stopping MAOI drug.
- If you do not know if your prescription drug contains MAOI as your doctor or pharmacist before taking this product.
- If you have a chronic pulmonary disease or shortness of breath unless directed by a doctor.
- Avoid alcoholic beverage while taking this product.
- 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

**Ask doctor before use if you have**

- Cough that occurs with too much phlegm(mucus)
- Cough that last or is a chronic such as occurs with smoking, asthma, chronic bronchitis or emphysema.
- Heart disease, high blood pressure, thyroid disease, or difficulty in urination due enlargement of prostate gland.
- The user has Liver diseases
- The user is taking the blood thinning drug Warfarin



**Palagrip**  
**MULTI-SINTOMAS**

- TOS
- REDUCE FIEBRE
- DOLOR
- CONGESTION NASAL
- GRIPE
- RESFRIADO

**Net. Wt. 6 fl. Oz (177 ml)**

**Stop use and ask a doctor if**

- Nervousness, dizziness or sleeplessness occurs.
- Cough persists more than 1 week, tends to recur or is accompanied by a fever, rash or persistent headache. A persistent cough may be signficant condition.

**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.

Avoid alcoholic beverages while you taking this product.

**Directions**

- Do not exceed 6 doses in any 24-hour period.

Age	Dose
Adults and Children 12 years and over	10ml (2 tps) every 6 hours
Children 6 to under 12 years of age	5ml (1 tsp) every 6 hours
Children under 6 years of age	Do not use

**Other information**

- Each 5 ml contains: Sodium 7 mg
- Store Between 15°-30°C (59°-86°F)
- Tamper Evident Feature: Do not use if seal under cap is torn, broken or missing.

**Inactive ingredients**

Aloe Vera, Citric Acid, Disodium EDTA, FDC Red #40, Hydroxyethyl Cellulose, Natural Strawberry Flavor, Potassium Sorbate, Polyene Glycol USP, Purified Water, Sodium Benzoate, Sorbitol 70% USP, Sucralose.

**Questions or comments?**

Call Weekdays from 9:30 AM to 5 PM EST at Tel 305 2618762

Distributed by: **LABOTICA**  
6003 Bellaire Blvd., Houston, Tx, 77081

Lot #  
Exp. Date:

## PALAGRIP

acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:53149-2001
<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 10 mL
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	13.33 mg in 10 mL
<b>GUAIFENESIN</b> (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg in 10 mL
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg in 10 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>ALOE VERA WHOLE</b> (UNII: KIZ4X2EHYX)	
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>HYDROXYMETHYL CELLULOSE</b> (UNII: 273FM27VK1)	
<b>WATER</b> (UNII: 059QF0KO0R)	

<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53149-2001-6	1 in 1 BOX	01/01/2019	
1		177 mL 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 final	part341	01/01/2019	

**Labeler** - All Pharma, LLC (117605075)

### Establishment

Name	Address	ID/FEI	Business Operations
All Pharma, LLC		117605075	MANUFACTURE(53149-2001)

Revised: 6/2019

All Pharma, LLC