

REVASOL DAYTIME COLD AND FLU- acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride liquid
Rnv LLC

Revasol Daytime Cold & Flu

Active ingredients (in each 30 mL dose cup) Purpose

Acetaminophen 650mg.....Pain reliever-Fever reducer

Dextromethorphan HBr 20 mg.....Cough suppressant

Phenylephrine HCl 10 mg.....Nasal decongestant

Pain reliever/fever reducer

Cough suppressant

Nasal decongestant

Uses

- temporarily relieves common cold/flu symptoms: • minor aches and pains
- headache • sore throat • fever • nasal congestion • cough due to minor throat and bronchial irritation.

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if:

- adults and children over 12 years of age take more than 4 doses (30 mL each in 24 hours, which is the maximum daily amount for this product
- 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.

Sore throat warning: If sore throat is severe, lasts 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.
- if you have ever had an allergic reaction to this product or any of its ingredients.

Ask a doctor before use if you have

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

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

When using this product

- do not use more than directed (see overdose warning)
- avoid alcoholic drinks.

Stop use and ask a doctor if

- you get nervous, dizzy or sleepless • pain, nasal congestion or cough get 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 • cough comes back or occurs with rash or headache that lasts.
- These could be signs of a serious condition.

Keep out of the reach of children. If pregnant or breast-feeding, ask a health professional before use.

Overdose warning:

Taking more than the recommended dose (overdose) could cause serious health problems, including liver damage. In case of accidental overdose, seek professional assistance or contact a Poison Control Center immediately. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

- take only as directed (see overdose warning)
- measure only with dosing cup provided and keep dosage cup with product
- mL=milliliter
- do not exceed 4 doses per 24 hours

| Age | Dose |
|--|---------------------|
| adults and children 12 years of and over | 30 mL every 4 hours |
| children under 12 years | do not use |

- when using Day Time and Night Time products, carefully read each label to ensure correct dosing.

Other information

- **Each 30 mL dose cup contains: sodium 10 mg**

- store at room temperature 15-30°C (59-86°F) and do not refrigerate
- TAMPER-EVIDENT FEATURE:** Do not use if printed safety seal is torn, broken or missing.

Inactive ingredients

citric acid, FD&C Yellow #6, flavor, glycerin, menthol, propylene glycol, purified water, sodium benzoate, sorbitol solution, sucralose, xanthan gum.

Questions or comments 1-888-446-4753

Monday - Friday (9 AM - 5 PM EST)

Hinge

Drug Facts (continued)

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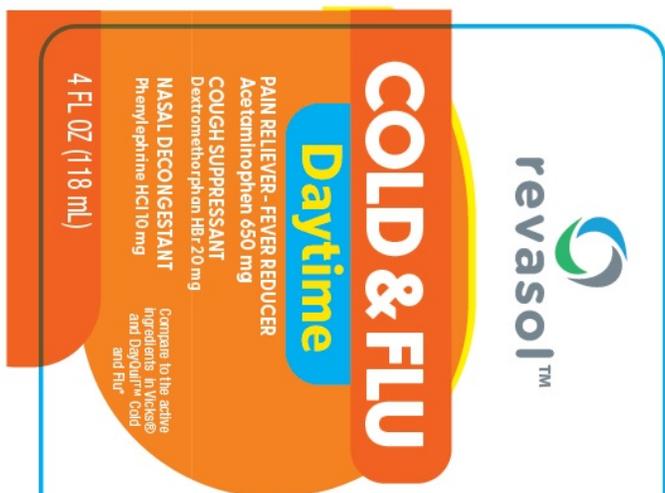
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Made in USA
Distributed by: RNV LLC
14501 NW 60 Ave, Miami Lakes, FL 33014

Rev. 1



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PEEL OFF FOR
DRUG FACTS ▼

Lot:
Exp:

REVASOL DAYTIME COLD AND FLU

acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride liquid

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:84379-275 |
| Route of Administration | ORAL | | |

| Active Ingredient/Active Moiety | | |
|--|-------------------------------|-----------------|
| Ingredient Name | Basis of Strength | Strength |
| PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV) | PHENYLEPHRINE HYDROCHLORIDE | 10 mg in 30 mL |
| DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS) | DEXTROMETHORPHAN HYDROBROMIDE | 20 mg in 30 mL |
| ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D) | ACETAMINOPHEN | 650 mg in 30 mL |

| Inactive Ingredients | |
|---|----------|
| Ingredient Name | Strength |
| WATER (UNII: 059QF0KO0R) | |
| XANTHAN GUM (UNII: TTV12P4NEE) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| SODIUM BENZOATE (UNII: OJ245FE5EU) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| CITRIC ACID (UNII: 2968PHW8QP) | |
| SORBITOL SOLUTION (UNII: 8KW3E207O2) | |
| SUCRALOSE (UNII: 96K6UQ3ZD4) | |
| MENTHOL (UNII: L7T10EIP3A) | |
| FD&C YELLOW NO. 6 (UNII: H77VEI93A8) | |

| Packaging | | | | |
|-----------|------------------|---|----------------------|--------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:84379-275-04 | 118 mL in 1 BOTTLE; Type 0: Not a Combination Product | 02/03/2025 | |

| Marketing Information | | | |
|-----------------------|--|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC Monograph Drug | M012 | 02/03/2025 | |

Labeler - Rnv LLC (118917568)

Registrant - Rnv LLC (118917568)

Establishment

| Name | Address | ID/FEI | Business Operations |
|---------|---------|-----------|------------------------|
| RNV LLC | | 118917568 | manufacture(84379-275) |