

**COLD PREPARATION FOR COUGH AND SINUS RELIEF- acetaminophen,  
dextromethorphan hydrobromide, phenylephrine hydrochloride liquid  
New Genesis/Monticello Drug 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.*

-----

**Drug Facts**

**Active ingredients (in each 15 mL)**

**Acetaminophen 325 mg**

Dextromethorphan HBr 10 mg

Phenylephrine HCl 5 mg

**Purposes**

**Pain reliever/fever reducer**

Cough suppressant

Nasal decongestant

**Uses**

- temporarily relieves these 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 you take:

- more than 6 doses (180 mL) in 24 hours for adults
- more than 5 doses ( 75 mL) in 24 hours for children 6-12 years old
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks everyday 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, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

**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 non-prescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

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

- liver disease
- heart disease
- thyroid disease
- diabetes
- high blood pressure
- a sodium-restricted diet
- persistent or chronic cough such as occurs with smoking, asthma or emphysema
- cough accompanied by excessive phlegm (mucus)
- 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.

**When using this product,**

**do not exceed recommended dosage.**

**Stop use and ask a doctor if**

- redness or swelling is present
- new symptoms occur
- nervousness, dizziness or sleeplessness occurs
- fever gets worse or lasts more than 3 days
- pain, nasal congestion or cough gets worse or lasts more than 5 days (children) or 7 days (adults)
- cough comes back or occurs, with rash or headache that lasts.

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.**

**Overdose warning:** Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) immediately. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

**Directions**

- **do not take more than directed (see overdose warning)**
  - do not exceed 4 doses in any 24-hour period
  - measure only with dosing cup provided. Do not use any other dosing device.
  - keep dosing cup with product
  - mL=milliliter
-

age	dose
adults and children 12 years and over	30 mL every 4 hours
children 6 to 11 years	15 mL every 4 hours
children 4 to under 6 years	ask a doctor
children under 4 years	do not use

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

#### **Other information**

- **each 15 mL contains:** sodium 12 mg
- store between 20-25°C (68-77°F)
- do not refrigerate

#### **Inactive ingredients**

citric acid, FD&C yellow #6, flavor, glycerin, propylene glycol, purified water, saccharin sodium, sodium benzoate, sodium chloride, sodium citrate, sorbitol, sucralose, xanthan gum

#### **Questions or comments?**

Call us at **904-647-7825** or online at [www.newgenesismonticellodrug.com](http://www.newgenesismonticellodrug.com)

#### **Principal Display Panel**

\*Compare to active ingredients in Vicks® DayQuil®

#### **Cold Preparation**

Acetaminophen

Pain reliever/fever reducer

Dextromethorphan hBr

Cough suppressant

Phenylephrine HCl

Nasal decongestant

For cough and sinus relief

For ages 6 and over

FL OZ (mL)

**TAMPER EVIDENT; DO NOT USE IF PRINTED SAFETY SEAL AROUND DOSAGE CUP OR UNDER CAP IS BROKEN OR MISSING**

\*This product is not manufactured or distributed by The Procter & Gamble Company. Vicks® and DayQuil® are registered trademarks of The Procter & Gamble Company.

Distributed by: New Genesis/Monticello Drug LLC

Jacksonville, FL 32207

#### **Package Label**

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL AROUND DOSAGE CUP OR UNDER CAP IS BROKEN OR MISSING.

\*This product is not manufactured or distributed by The Procter & Gamble Company. Vicks® and DayQuil® are registered trademarks of The Procter & Gamble Company.

**PARENTS:**  
Learn about best medicine abuse  
www.StopMedicineAbuse.org

Distributed by: New Genesis/Monticello Drug LLC,  
Jacksonville, FL 32207



\*Compare to active ingredients in Vicks® DayQuil®

NDC 11868-466-12

# 666® COLD PREPARATION

• **ACETAMINOPHEN**  
PAIN RELIEVER / FEVER REDUCER  
• **DEXTROMETHORPHAN HBr**  
COUGH SUPPRESSANT  
• **PHENYLEPHRINE HCl**  
NASAL DECONGESTANT

**FOR COLD & FLU RELIEF**



FOR AGES 6 YEARS AND OVER  
12 fl oz (355 mL)

### Drug Facts

Active ingredients (in each 15 mL)	Purposes
Acetaminophen 325 mg	Pain reliever/fever reducer
Dextromethorphan HBr 10 mg	Cough suppressant
Phenylephrine HCl 5 mg	Nasal decongestant

### Uses

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

### Warnings

- Liver warning:** This product contains acetaminophen. Severe liver damage may occur if:
- adult takes more than 4 doses (30 mL each) of acetaminophen in 24 hours, which is the maximum daily amount
  - child takes more than 4 doses (15 mL each) in 24 hours
  - 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, 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

**Drug Facts** (continued under label) **PEEL HERE** →

**Drug Facts** (continued)

pharmacist before taking this product.

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

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

**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.**

**Stop use and ask a doctor if**

- nervousness, dizziness, or sleeplessness occur
- pain, nasal congestion, or cough gets worse, or lasts more than 5 days (children) or 7 days (adult)
- 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.

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

**Overdose warning:** Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

**Drug Facts** (continued)

**Directions**

- do not take more than directed (see Overdose warning)
- do not take more than 4 doses in any 24-hour period
- measure only with dosing cup provided. Do not use any other dosing device.
- keep dosing cup with product
- mL = milliliter

adults and children 12 years and over	30 mL every 4 hours
children 6 to under 12 years	15 mL every 4 hours
children 4 to under 6 years	ask a doctor
children under 4 years	do not use

when using other Daytime or Nighttime products, carefully read each label to ensure correct dosing

**Other information**

- each 15 mL contains: sodium 12 mg
- store between 20-25°C (68-77°F). Do not refrigerate.

**Inactive ingredients** citric acid, FD&C yellow #6, flavor, glycerin, propylene glycol, purified water, saccharin sodium, sodium benzoate, sodium chloride, sodium citrate, sorbitol, sucralose, xanthan gum

**Questions or comments?** Call us at 904-647-7825 or online at [www.newgenesiemonticellodrug.com](http://www.newgenesiemonticellodrug.com)

## Monticello Cold Preparation

### COLD PREPARATION FOR COUGH AND SINUS RELIEF

acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride liquid

#### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11868-466
Route of Administration	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg in 15 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 15 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg in 15 mL

**Inactive Ingredients**

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0K00R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11868-466-08	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/30/2015	01/01/2022
2	NDC:11868-466-12	355 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/30/2015	01/01/2022

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	06/30/2015	01/01/2022

**Labeler** - New Genesis/Monticello Drug LLC (079396165)

Revised: 1/2016

New Genesis/Monticello Drug LLC