COMPLETE COLD RELIEF- acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl solution
Belmora LLC

Buckleys 44-005

Active ingredients (in each 20 mL)

Acetaminophen 650 mg
Dextromethorphan HBr 20 mg
Guaifenesin 400 mg
Phenylephrine HCl 10 mg

Purpose

Pain reliever/fever reducer
Cough suppressant
Expectorant
Nasal decongestant

Uses

- temporarily relieves these common cold and flu symptoms:
  - minor aches and pains
  - sinus congestion and pressure
  - stuffy nose
  - nasal congestion
  - sore throat
  - cough
  - headache
- temporarily promotes nasal and/or sinus drainage
- temporarily reduces fever
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive

Warnings

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

- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:

- blisters
- rash

- skin reddening

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 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

- cough that occurs with too much phlegm (mucus)
- liver disease
- thyroid disease
- heart disease
- difficulty in urination due to enlargement of the prostate gland
- high blood pressure
- diabetes
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema

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

- pain, nasal congestion, or cough gets worse or lasts more than 7 days
- new symptoms occur
- nervousness, dizziness, or sleeplessness occur
- fever gets worse or lasts more than 3 days
- cough comes back or occurs with rash or headache that lasts. These could be signs of a serious condition.
- redness or swelling is present

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. 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 take more than directed**
- do not take more than 6 doses in any 24-hour period
- mL = milliliter
- only use the dose cup provided
- dose as follows or as directed by a doctor
- adults and children 12 years and over: 20 mL in dosing cup provided every 4 hours
- children under 12 years: do not use

Other information

- **each 20 mL contains:** sodium 10 mg
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- use by expiration date on package

Inactive ingredients

anhydrous citric acid, FD&C blue #1, FD&C red #40, flavors, glycerin, polyethylene glycol, propylene glycol, purified water, sodium benzoate, sodium citrate dihydrate, sodium metabisulfite, sorbitol, sucralose

Questions or comments?

1-888-779-2877 M-F 9AM-5PM EST

Principal display panel

Belmora LLC

NDC 27854-299-00

MAXIMUM STRENGTH

Buckleys

COMPLETE COLD RELIEF

ACETAMINOPHEN -
PAIN RELIEVER/FEVER REDUCER
DEXTROMETHORPHAN HBr - COUGH SUPPRESSANT
GUAIFENESIN - EXPECTORANT
PHENYLEPHRINE HCl - NASAL DECONGESTANT

RELIEVES:
✓HEADACHE, FEVER & SORE THROAT
✓SINUS PRESSURE AND CONGESTION

✓CONTROLS COUGH, THINS & LOOSENS MUCUS

AGES 12 & OVER

F-005-45 REV A

6 FL OZ (177 mL)

MIXED BERRY FLAVORED

TAMPER EVIDENT: DO NOT USE IF IMPRINTED
SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

PARENTS:
Learn about teen medicine abuse
www.StopMedicineAbuse.org

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Arlington, VA 22201 50844 REV0523A00545

NDC 27854-299-00

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PEEL BACK TAB TO READ COMPLETE DRUG FACTS AND INFORMATION

B-005-45 REV A

Drug Facts

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

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No Print / No Varnish Area
Lot # and Exp. Info

Drug Facts (continued)

■ more than 4,000 mg of acetaminophen in 24 hours
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■ if you have ever had an allergic reaction to this product or any of its ingredients

Ask a doctor before use if you have
■ cough that occurs with too much phlegm (mucus)

HINGE

Drug Facts (continued)

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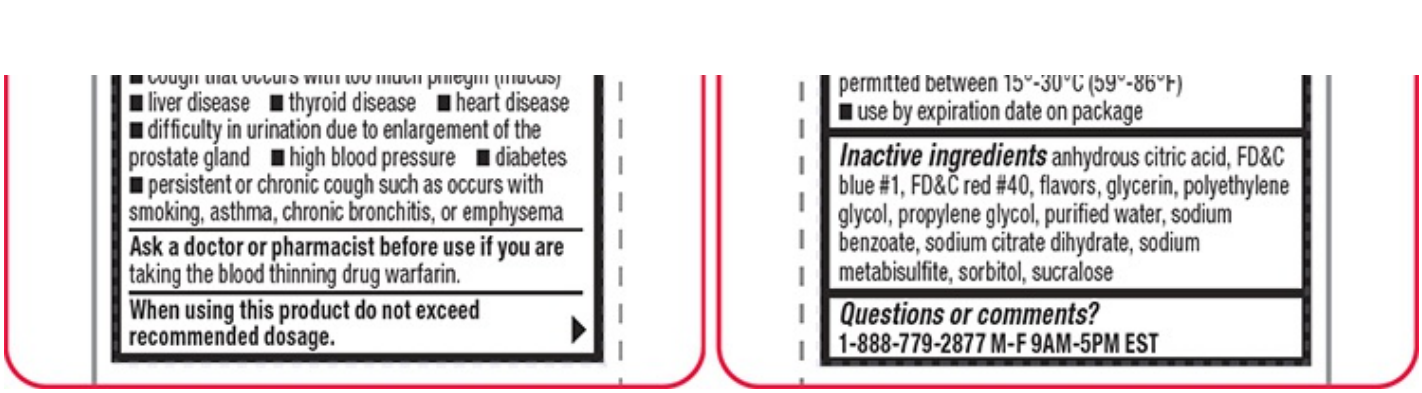
Other information ■ **each 20 mL contains:** sodium 10 mg ■ store at 25°C (77°F); excursions

HINGE



Buckleys 44-005

COMPLETE COLD RELIEF

acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:27854-299
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg in 20 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 20 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	400 mg in 20 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 20 mL

Inactive Ingredients	
Ingredient Name	**Strength**
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics			
Color	blue	**Score**	

Shape		**Size**	
Flavor	BERRY	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:27854-299-00	177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/23/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	02/23/2022	

Labeler - Belmora LLC (112753244)

Revised: 12/2023 Belmora LLC