COMTREX COUGH AND COLD DAY/NIGHT- acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride, and chlorpheniramine maleate
Dr. Reddy's Laboratories Inc.

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.

Comtrex® Cough & Cold Day/Night

Drug Facts

Active ingredients (in each caplet) (Cold Multi-Symptom Day)	***Purpose***
Acetaminophen 325 mg	Pain reliever/fever reducer
Dextromethorphan HBr 10 mg	Cough suppressant
Phenylephrine HCl 5 mg	Nasal decongestant

Active ingredients (in each caplet) (Cold Multi-Symptom Night)	***Purpose***
Acetaminophen 325 mg	Pain reliever/fever reducer
Chlorpheniramine maleate 2 mg	Antihistamine
Dextromethorphan HBr 10 mg	Cough suppressant
Phenylephrine HCl 5 mg	Nasal decongestant

Uses

- temporarily relieves these common cold/flu symptoms:
  - headache
  - minor aches and pains
  - nasal congestion
  - sinus congestion and pressure
  - sore throat
  - cough
  - sneezing and runny nose ***(Cold Night only)***
- helps clear nasal passages
- temporarily reduces fever
- promotes nasal and sinus drainage ***(Cold Day only)***
- relieves cough to help you sleep ***(Cold Night only)***

Warnings

Liver warning

This product contains acetaminophen. The maximum daily dose of this product is 10 caplets (3,250 mg acetaminophen) in 24 hours. 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

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 you have

- diabetes
- high blood pressure
- heart disease
- thyroid disease
- liver disease
- 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)
- glaucoma ***(Cold Night only)***
- a breathing problem such as emphysema or chronic bronchitis ***(Cold Night only)***

Ask a doctor or pharmacist before use if you are

- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers ***(Cold Night only)***

When using this product

- **do not exceed recommended dosage**
- avoid alcoholic drinks ***(Cold Night only)***
- marked drowsiness may occur ***(Cold Night only)***
- alcohol, sedatives, and tranquilizers may increase drowsiness ***(Cold Night only)***
- excitability may occur, especially in children ***(Cold Night only)***
- be careful when driving a motor vehicle or operating machinery ***(Cold Night only)***

Stop use and ask a doctor if

- fever gets worse or lasts more than 3 days
- new symptoms occur
- nervousness, dizziness, or sleeplessness occur
- pain, nasal congestion, or cough gets worse or lasts more than 7 days
- a persistent cough may be a sign of a serious condition. If cough persists for more than 1 week, tends to recur, or is accompanied by fever, rash, or persistent headache, consult a doctor.
- redness or swelling is present

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.

Directions

- **do not take more than directed (see overdose warning)**
- adults and children 12 years and over:
  - take 2 caplets every 4 hours
  - swallow whole - do not crush, chew, or dissolve
  - do not take more than 10 caplets in 24 hours
- children under 12 years: ask a doctor

Other information

- **TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN**
- see end flap for expiration date and lot number
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)

Inactive ingredients (Cold Day)

corn starch, croscarmellose sodium, crospovidone, D&C yellow #10 aluminum lake, FD&C yellow #6 aluminum lake, flavor, hypromellose, magnesium stearate, microcrystalline cellulose, polydextrose, polyethylene glycol, povidone, silica gel, stearic acid, sucralose, titanium dioxide, triacetin

Inactive ingredients (Cold Night)

corn starch, crospovidone, FD&C blue #1 aluminum lake, FD&C blue #2 aluminum lake, flavor, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, silica gel, sodium starch glycolate, stearic acid, sucralose, talc, titanium dioxide

Questions or comments?

1-800-790-6417

PRINCIPAL DISPLAY PANEL - Kit Carton

NDC 55741-524-24

COMTREX®
COLD & COUGH

DAY

Acetaminophen

- **Pain Reliever**
- **Fever Reducer**

Dextromethorphan HBr

- **Cough Suppressant**

Phenylephrine HCl

- **Nasal Decongestant**

12 COATED CAPLETS

NIGHT

Acetaminophen

- **Pain Reliever**
- **Fever Reducer**

Chlorpheniramine maleate

- **Antihistamine**

Dextromethorphan HBr

- **Cough Suppressant**

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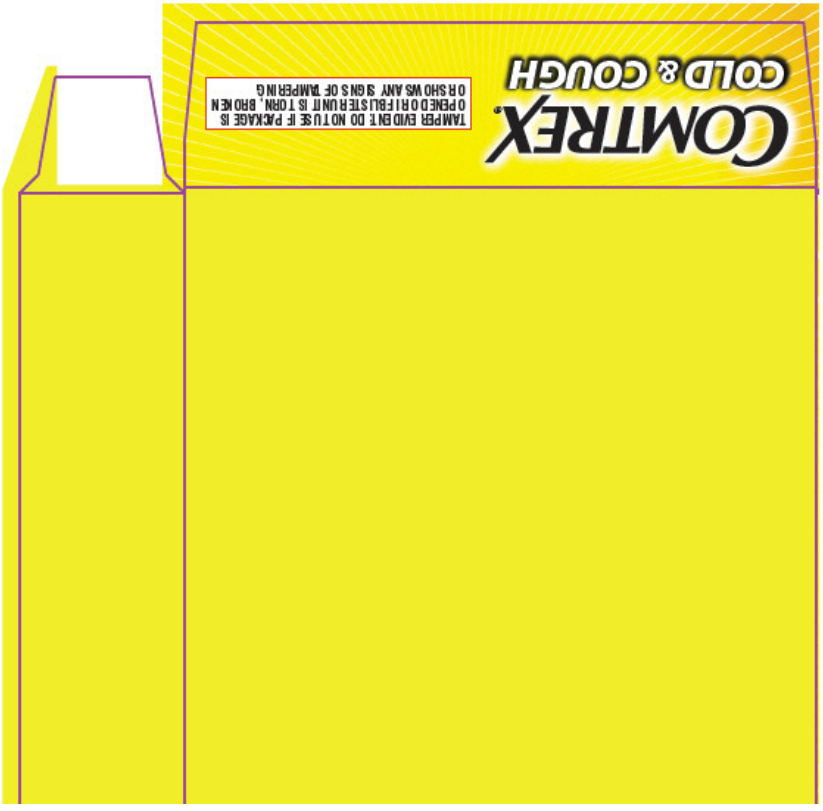
A1700R
8-0385-630631-08
ORG0613.630631O8


COMTREX
COLD & COUGH
TAMPER EVIDENT DO NOT USE IF PACKAGE IS OPENED OR IF BLISTER UNIT IS TORN. BROKEN OR SHOWS ANY SIGNS OF TAMPERING

50844 ORG0613.630/63108

No Print Area
Lot no. & Exp. Date

8 49648 08524 2

KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

Drug Facts

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- temporarily relieves these common cold/flu symptoms: ■ headache ■ minor aches and pains ■ nasal congestion ■ sinus congestion and pressure ■ sore throat ■ cough ■ sneezing and runny nose ***(Cold Night only)***
- helps clear nasal passages ■ temporarily reduces fever
- promotes nasal and sinus drainage ***(Cold Day only)***
- relieves cough to help you sleep ***(Cold Night only)***

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PEEL CORNER TO READ COMPLETE DRUG FACTS ▲

TYPE SAFETY

ADHESIVE AREA

Drug Facts (continued)

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.
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Ask a doctor before use if you have ■ diabetes ■ high blood pressure ■ heart disease ■ thyroid disease ■ liver disease ■ 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) ■ glaucoma ***(Cold Night only)*** ■ a breathing problem such as emphysema or chronic bronchitis ***(Cold Night only)***

Ask a doctor or pharmacist before use if you are

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- taking sedatives or tranquilizers ***(Cold Night only)***

When using this product ■ **do not exceed recommended dosage**

- avoid alcoholic drinks ***(Cold Night only)***
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- alcohol, sedatives, and tranquilizers may increase drowsiness ***(Cold Night only)***
- excitability may occur, especially in children ***(Cold Night only)***
- be careful when driving a motor vehicle or operating machinery ***(Cold Night only)***

Stop use and ask a doctor if

- fever gets worse or lasts more than 3 days
- new symptoms occur ■ nervousness, dizziness, or sleeplessness occur
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These could be signs of a serious condition. ➡

TYPE SAFETY

ADHESIVE AREA

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Drug Facts (continued)

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.

Directions ■ do not take more than directed (see overdose warning)

- adults and children 12 years and over: ■ take 2 caplets every 4 hours ■ swallow whole - do not crush, chew, or dissolve ■ do not take more than 10 caplets in 24 hours
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Other information

- **TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN** ■ see end flap for expiration date and lot number
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Inactive ingredients (Cold Day)

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Inactive ingredients (Cold Night)

corn starch, crospovidone, FD&C blue #1 aluminum lake, FD&C blue #2 aluminum lake, flavor, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, silica gel, sodium starch glycolate, stearic acid, sucralose, talc, titanium dioxide

Questions or comments? 1-800-790-6417

TYPE SAFETY 50844 ORG0613.630/63108

ADHESIVE AREA

COMTREX COUGH AND COLD DAY/NIGHT

acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride, and chlorpheniramine maleate kit

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:55741-524

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:55741-524-24	1 in 1 CARTON; Type 0: Not a Combination Product	05/24/2016	

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	1 BLISTER PACK	12
Part 2	1 BLISTER PACK	12

Part 1 of 2

COMTREX COLD MULTI-SYMPTOM DAY CAPLET

acetaminophen, dextromethorphan hydrobromide, and phenylephrine hydrochloride tablet, coated

Product Information	
Route of Administration	ORAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Acetaminophen (UNII: 362O9ITL9D) (Acetaminophen - UNII:362O9ITL9D)	Acetaminophen	325 mg
Dextromethorphan Hydrobromide (UNII: 9D2RTI9KYH) (Dextromethorphan - UNII:7355X3ROTS)	Dextromethorphan Hydrobromide	10 mg
Phenylephrine Hydrochloride (UNII: 04JA59TNSJ) (Phenylephrine - UNII:1WS297W6MV)	Phenylephrine Hydrochloride	5 mg

Inactive Ingredients	
Ingredient Name	**Strength**
starch, corn (UNII: O8232NY3SJ)	
croscarmellose sodium (UNII: M28OL1HH48)	
crospovidone (UNII: 68401960MK)	
D&C yellow no. 10 (UNII: 35SW5USQ3G)	
FD&C yellow no. 6 (UNII: H77VEI93A8)	
aluminum oxide (UNII: LMI26O6933)	
hypromelloses (UNII: 3NXW29V3WO)	

magnesium stearate (UNII: 70097M6I30)	
cellulose, microcrystalline (UNII: OP1R32D61U)	
polydextrose (UNII: VH2XOU12IE)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
silicon dioxide (UNII: ETJ7Z6XBU4)	
stearic acid (UNII: 4ELV7Z65AP)	
sucralose (UNII: 96K6UQ3ZD4)	
titanium dioxide (UNII: 15FIX9V2JP)	
triacetin (UNII: XHX3C3X673)	

Product Characteristics

Color	YELLOW	**Score**	no score
Shape	OVAL (oblong)	**Size**	16mm
Flavor		**Imprint Code**	Cx
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		12 in 1 BLISTER PACK; 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	05/24/2015	

Part 2 of 2

COMTREX COLD MULTI-SYMPTOM NIGHT CAPLET

acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride, and chlorpheniramine maleate tablet, coated

Product Information

Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Acetaminophen (UNII: 362O9ITL9D) (Acetaminophen - UNII:362O9ITL9D)	Acetaminophen	325 mg
Dextromethorphan Hydrobromide (UNII: 9D2RTI9KYH) (Dextromethorphan - UNII:7355X3ROTS)	Dextromethorphan Hydrobromide	10 mg
Phenylephrine Hydrochloride (UNII: 04JA59TNSJ) (Phenylephrine - UNII:1WS297W6MV)	Phenylephrine Hydrochloride	5 mg
Chlorpheniramine Maleate (UNII: V1Q0O9OJ9Z) (Chlorpheniramine -	Chlorpheniramine Maleate	2 mg

UNII:3U6IO1965U)	Chlorpheniramine Maleate	2 mg

Inactive Ingredients	
Ingredient Name	**Strength**
starch, corn (UNII: O8232NY3SJ)	
crospovidone (UNII: 68401960MK)	
FD&C blue no. 1 (UNII: H3R47K3TBD)	
FD&C blue no. 2 (UNII: L06K8R7DQK)	
aluminum oxide (UNII: LMI26O6933)	
magnesium stearate (UNII: 70097M6I30)	
cellulose, microcrystalline (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
polyvinyl alcohol (UNII: 532B59J990)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
silicon dioxide (UNII: ETJ7Z6XBU4)	
sodium starch glycolate Type A corn (UNII: AG9B65PV6B)	
stearic acid (UNII: 4ELV7Z65AP)	
sucralose (UNII: 96K6UQ3ZD4)	
talc (UNII: 7SEV7J4R1U)	
titanium dioxide (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	BLUE	**Score**	no score
Shape	OVAL (oblong)	**Size**	16mm
Flavor		**Imprint Code**	Cx
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

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OTC monograph final	part341	05/24/2016	

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Labeler - Dr. Reddy's Laboratories Inc. (802315887)