

COLD-FLU RELIEF MULTI SYMPTOM- acetaminophen, dextromethorphan hbr, phenylephrine hcl tablet, coated
Salado Sales, Inc.

CVP 44-560

Active ingredients (in each gelcap)

Acetaminophen 325 mg
Dextromethorphan HBr 10 mg
Phenylephrine HCl 5 mg

Purpose

Pain reliever/fever reducer
Cough suppressant
Nasal decongestant

Uses

- temporarily relieves these common cold and flu symptoms:
 - headache
 - cough
 - sinus congestion and pressure
 - sore throat
 - nasal congestion
 - minor aches and pains
- helps clear nasal passages
- promotes nasal and sinus drainage
- temporarily reduces fever

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:

- 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 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

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

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 7 days
- new symptoms occur
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- 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.

In case of accidental overdose, get medical help or contact a Poison Control Center (1-800-222-1222) 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**
- adults and children 12 years and over
 - take 2 gelcaps every 4 hours
 - do not take more than 10 gelcaps in 24 hours
- children under 12 years: ask a doctor

Other information

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

Inactive ingredients

croscarmellose sodium, crospovidone, D&C red #28, FD&C blue #1, FD&C red #40, gelatin, hydroxypropyl cellulose, hypromellose, iron oxide black, iron oxide red, iron oxide yellow, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, propylene glycol, shellac glaze, silicon dioxide, stearic acid, titanium dioxide

Questions or comments?

1-800-426-9391

Principal Display Panel

**COMPARE TO
TYLENOL® COLD MAX
DAY ACTIVE INGREDIENTS***

**CVP®
HEALTH**

DAY • NON-DROWSY

COLD-FLU

RELIEF

MULTI-SYMP TOM

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

RELIEVES:

FEVER, HEADACHE,
SORE THROAT,
COUGHING & NASAL
CONGESTION

12 GELCAPS
RAPID RELEASE

PSEUDOEPHEDRINE FREE

NON-ASPIRIN

**TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED
OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS
ANY SIGNS OF TAMPERING**

*This product is not manufactured or distributed by Johnson & Johnson Corporation,
owner of the registered
trademark Tylenol® COLD MAX Day.

50844 REV0216D56002

Distributed by Consumer Value Products, Inc.

P.O. Box 6115, Temple, Texas 76502

CVPproducts.com



DAY • NON-DROWSY COLD-FLU RELIEF MULTI-SYMPTOM

- ACETAMINOPHEN - PAIN RELIEVER/
FEVER REDUCER
- DEXTROMETHORPHAN HBr - COUGH SUPPRESSANT
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P.O. Box 6115, Temple, Texas 76503
www.CVPproducts.com

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ANY SIGNS OF TAMPERING

Drug Facts (continued)
KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

Active Ingredients (in each gelcap) Purpose
Acetaminophen 325 mg... Pain reliever/fever reducer
Dextromethorphan HBr 10 mg... Cough suppressant
Phenylephrine HCl 5 mg... Nasal decongestant

Uses ■ Temporarily relieves these common cold and flu symptoms: ■ headache ■ cough ■ sinus congestion and pressure ■ sore throat ■ nasal congestion ■ minor aches and pains ■ helps clear nasal passages

Drug Facts (continued)
TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN ■ avoid high humidity ■ see end flap for expiration date and lot number

Inactive ingredients croscarmellose sodium, pregelatinized starch, propylene glycol, shellac glaze, cellulose, polyethylene glycol, povidone, oxide yellow, magnesium stearate, microcrystalline hypromellose, iron oxide black, iron oxide red, iron red #40, gelatin, hydroxypropyl cellulose, croscarmellose, D&C red #28, FD&C blue #1, FD&C

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 ■ diabetes ■ cough that occurs with too much phlegm (mucus)

Directions ■ do not take more than directed ■ adults and children 12 years and over ■ take 2 gelcaps every 4 hours ■ do not take more than 10 gelcaps in 24 hours ■ children under 12 years: ask a doctor

Other information ■ store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)

Keep out of reach of children. In case of accidental overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Warnings ■ do not take more than directed ■ persistent headache ■ If pregnant or breast-feeding, ask a health professional before use. ■ These could be signs of a serious condition.

Drug Facts (continued)
silica gel, stearic acid, titanium dioxide

Questions or comments? 1-800-426-9391

No print/No varnish
Lot & Exp date



B-0226-560-02-RR
REV0216D56002

No Print Area
Glue Area



CVP 44-560

COLD-FLU RELIEF MULTI SYMPTOM

acetaminophen, dextromethorphan hbr, phenylephrine hcl tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57243-560
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
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
CROSPVIDONE (UNII: 2S7830E561)	
D&C RED NO. 28 (UNII: 7671P0Y5NH)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
MAGNESIUM STEARATE (UNII: 70097M6130)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	

POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	red, purple	Score	no score
Shape	OVAL	Size	19mm
Flavor		Imprint Code	L;0
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57243-560-02	1 in 1 CARTON	03/29/2008	
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 Drug	M012	03/29/2008	

Labeler - Salado Sales, Inc. (009830555)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	pack(57243-560)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(57243-560)

Revised: 7/2023

Salado Sales, Inc.