

DELSYM NIGHT TIME MULTI-SYMPTOM- acetaminophen, dextromethorphan hydrobromide, and doxylamine succinate liquid
Reckitt Benckiser 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.

Delsym®
Night Time
Multi-Symptom

Drug Facts

| <i>Active ingredients</i> <i>(in each 15 mL)</i> | <i>Purpose</i> |
|---|------------------------------------|
| Acetaminophen 325 mg | Pain reliever/Fever reducer |
| Dextromethorphan HBr 15 mg | Cough suppressant |
| Doxylamine Succinate 6.25 mg | Antihistamine |

Uses

temporarily relieves these common cold and flu symptoms:

- cough due to minor throat and bronchial irritation
- runny nose and sneezing
- minor aches and pains
- sore throat
- headache
- fever
- the impulse to cough to help you get to sleep

Warnings

Liver warning

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

- more than 4 doses in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks daily 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.
- to make a child sleepy

- 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
- glaucoma
- trouble urinating due to an enlarged prostate gland
- a breathing problem such as emphysema or chronic bronchitis
- persistent or chronic cough such as occurs with smoking, asthma or emphysema
- cough that occurs with too much phlegm (mucus)
- a sodium restricted diet

Ask a doctor or pharmacist before use if you are

- taking the blood thinning drug warfarin.
- taking sedatives or tranquilizers.

When using this product

- **do not use more than directed**
- excitability may occur, especially in children
- marked drowsiness may occur
- alcohol, sedatives and tranquilizers may increase drowsiness
- avoid alcoholic drinks
- be careful when driving a motor vehicle or operating machinery

Stop use and ask a doctor if

- pain or cough gets worse or lasts more than 7 days
- 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 persistent headache. 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 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)**
- do not take more than 4 doses in any 24-hour period
- measure only with dosing cup provided
- do not use dosing cup with other products
- dose as follows or as directed by a doctor
- mL = milliliter
- **Adults and Children 12 years and older:** 30 mL in dosing cup provided every 6 hours.
- **Children under 12 years of age:** Do not use.

Other information

- each 15 mL contains: **sodium 19 mg**
- dosing cup provided
- store between 20-25°C (68-77°F)
- **Keep carton for full directions for use**

Inactive ingredients

alcohol, anhydrous citric acid, FD&C blue #1, FD&C red #40, flavor, high fructose corn syrup, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sodium citrate

Questions?

1-888-963-3382

You may also report side effects to this phone number.

Dist. by: Reckitt Benckiser
Parsippany, NJ 07054-0224

PRINCIPAL DISPLAY PANEL - 120 mL Bottle Carton

NEW FORMULA – SEE NEW DOSING DIRECTIONS!

NDC 63824-186-64

Delsym®

**NIGHT
TIME**

MULTI-SYMPTOM

Acetaminophen

(Pain Reliever/Fever Reducer)

Dextromethorphan HBr (Cough Suppressant)

Doxylamine succinate (Antihistamine)

- ▣ **Cough**
- ▣ **Fever & Body Aches**
- ▣ **Sore Throat**
- ▣ **Sneezing**
- ▣ **Runny Nose**

10% ALCOHOL

Cherry
Flavored
Liquid

120 mL (4 fl oz)

for Ages 12+

Tamper evident: do not use if printed neckband on bottle cap is broken or missing.

Delsym[®]



NEW FORMULA - SEE NEW DOSING DIRECTIONS!

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- ✓ Cough
- ✓ Fever & Body Aches
- ✓ Sore Throat
- ✓ Sneezing
- ✓ Runny Nose

Delsym[®]



Find the Right
Delsym[®]
for You or Your Child

| | | |
|--------------------------------|--|-----------------|
| ADULT | | CHILDREN |
| COUGH & COLD MULTI-SYMP TOM | | COUGH & COLD |

| | | |
|----------------------|--|----------------------|
| ADULT | | CHILDREN |
| COUGH SUPPRESSANT | | COUGH SUPPRESSANT |

KEEP CARTON FOR FULL DIRECTIONS FOR USE.

Runny Nose

10% ALCOHOL

120 mL (4 fl oz)

Cherry
Flavored
Liquid

for Ages 12+

PARENTS:

Learn about teen medicine abuse

www.StopMedicineAbuse.org



Dosing Cup
Included



3-63824-18364-0



LOT NO.

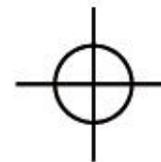
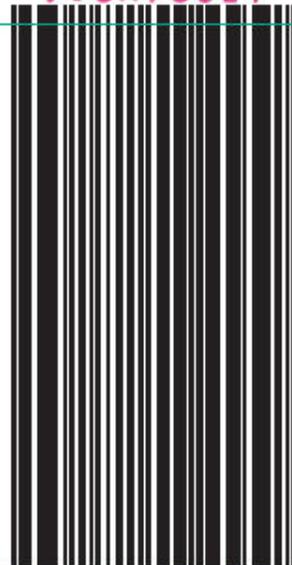
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: 45926 W2 C1

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(in each 15 mL)**

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Dextromethorphan HBr 15 mg Cough suppressant
Doxylamine Succinate 6.25 mg Antihistamine

Uses temporarily relieves these common cold and

Drug Facts (continued)

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Please visit our web site: www.delsym.com



Dist. by: Reckitt Benckiser 060111
Parsippany, NJ 07054-0224 ©RB 2011



45926W2C1

DELSYM NIGHT TIME MULTI-SYMPTOM

acetaminophen, dextromethorphan hydrobromide, and doxylamine succinate liquid

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:63824-186 |
| 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 | 15 mg in 15 mL |
| DOXYLAMINE SUCCINATE (UNII: V9B19B5YI2) (DOXYLAMINE - UNII:95QB77JKPL) | DOXYLAMINE SUCCINATE | 6.25 mg in 15 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| ALCOHOL (UNII: 3K9958V90M) | |
| ANHYDROUS CITRIC ACID (UNII: XF417D3PSL) | |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD) | |
| FD&C RED NO. 40 (UNII: WZB9127XOA) | |
| HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S) | |
| POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| WATER (UNII: 059QF0KO0R) | |
| SACCHARIN SODIUM DIHYDRATE (UNII: SB8ZUX40TY) | |
| SODIUM CITRATE (UNII: 1Q73Q2JULR) | |

Product Characteristics

| | | | |
|-----------------|--------|---------------------|--|
| Color | RED | Score | |
| Shape | | Size | |
| Flavor | CHERRY | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:63824-186-64 | 1 in 1 CARTON | | |
| 1 | | 120 mL in 1 BOTTLE | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC MONOGRAPH FINAL | part341 | 07/01/2011 | |

Labeler - Reckitt Benckiser LLC (094405024)

Revised: 12/2011

Reckitt Benckiser LLC