

CREOMULSION FOR CHILDREN- dextromethorphan hydrobromide syrup
Summit Industries, 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.

Creomulsion For Children Soothing Cough Syrup Drug Facts

Active Ingredient

In one teaspoon (5 ml) Dextromethorphan HBr, USP 5 mg

Purpose

Cough Suppressant

Uses

- Temporarily relieves cough due to minor throat and bronchial irritation as may occur with a cold.

Warnings

Do not use if you are now taking 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 a pharmacist before taking the product.

Ask a doctor before use if you

- have cough that occurs with too much phlegm (mucus)
- have cough that lasts or is chronic such as occurs with smoking, asthma, chronic bronchitis, or emphysema.

Stop use and ask a doctor if

- cough lasts more than 7 days comes back, or is accompanied by fever, 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. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- Do not take more than 6 doses in any 24 period. Use enclosed dose cup.

Children under 4 years	do not use
Children 4 years to under 6 years	5ml (1tsp) every 4 hours
Children 6 years to under 12 years	10ml (2tsp) every 4 hours
Children 12 years and over	20ml (4tsp) every 4 hours

Other Information

- store at 20-25°C (68-77°F)
- packaged with tamper evident seal around cap
- contains no alcohol

Inactive Ingredients

caramel, citric acid, corn syrup, FD and C Red No. 40, flavor, menthol, potassium sorbate, purified water, sodium benzoate, sucrose

Questions or Comments

Call 8am - 4pm Est. Mon - Thurs 1-800-241-6996

Money Back Guarantee

Guaranteed to give desired results or your money back.

Send carton top, reason for dissatisfaction, sales receipt, lot number, and your phone number to Summit Industries, Inc.

P.O. Box 7329, Marietta, GA 30065

How Creomulsion For Children Works?

Gentle Creomulsion For Children is specially formulated for a child's delicate system. It contains the most effective cough suppressant available without a prescription. It calms the urge to cough, while Creomulsion's smooth consistency soothes your child's throat.

Summit Industries, Inc.

P.O. Box 7329

Marietta, GA 30065

www.creomulsion.com

Image of Carton and Label

CreomulsionChildren.jpg

Creomulsion

For Children

Drug Facts (continued)

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Creomulsion

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For Adult coughs and colds...

Creomulsion Cough Medicine

Adult Formula

Fast effective relief from coughs due to colds or other bronchial irritations.



SUMMIT INDUSTRIES, INC.
 P. O. BOX 7329
 MARIETTA, GA 30065
 creomulsion.com

Instrucciones en español dentro del envase

Creomulsion®

Great Cherry Taste

For Children



Soothing Cough Syrup

Cough Suppressant

Alcohol-Free
 4 FL OZ (118 mL)

Creomulsion

For Children

Drug Facts

Active ingredient Purpose

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 Dextromethorphan Cough
 HBr, USP 5 mg Suppressant

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- have cough that lasts or is chronic such as occurs with smoking, asthma, chronic bronchitis, or emphysema.

Stop use and ask a doctor if

- cough lasts more than 7 days, comes back, or is accompanied by fever, rash, or persistent headache. These could be signs of a serious condition. →

Creomulsion®

Warnings: 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 a fever, rash, or persistent headache, consult a doctor. Do not take this product for persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, emphysema, or if cough is accompanied by excessive phlegm (mucus) unless directed by a doctor. As with any drug, women who are pregnant or nursing a baby should seek the advice of a health professional before using this product.
Drug Interaction Precaution: Do not take this product 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 are uncertain whether your prescription drug contains an MAOI, consult a health professional before taking this product. In case of accidental overdose, seek professional assistance or contact a poison control center immediately.

KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN. STORE AT 20-25°C (68-77°F)
 SUMMIT INDUSTRIES, INC., P.O. BOX 7329,
 MARIETTA, GA 30065 800-241-6996

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CreomulsionChildrenBackLabel.jpg

CREOMULSION FOR CHILDREN

dextromethorphan hydrobromide syrup

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:12090-0015
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	5 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
CARAMEL (UNII: T9D99G2B1R)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
CORN SYRUP (UNII: 9G5L16BK6N)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
MENTHOL (UNII: L7T10EIP3A)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SUCROSE (UNII: C151H8M554)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:12090-0015-0	1 in 1 CARTON	12/30/2009	12/31/2019
1	NDC:12090-0015-1	118 mL in 1 BOTTLE; Type 6: Drug/Biologic Combination		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	12/30/2009	12/31/2019

Labeler - Summit Industries, Inc. (079868223)

Revised: 8/2016

Summit Industries, Inc.