EMETROL CHILDREN MIXED BERRY- phosphorated carbohydrate solution WellSpring Pharmaceutical Corporation

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Emetrol

Active ingredients

Phosphorated carbohydrate solution*

- *each 5 mL contains:
- 1.87 g Dextrose (glucose)
- 1.87 g Levulose (fructose)
- 21.5 mg Phosphoric acid

Purpose

Upset Stomach Reliever

Uses

For relief of upset stomach associated with nausea

Warnings

• This product contains fructose and should not be taken by children with hereditary fructose intolerance (HFI).

Do not use if the child has

• allergic reactions to any of the ingredients in this product

Ask a doctor before use if the child has

diabetes

Stop use and ask a doctor if

• symptoms persist, return or get worse

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away

Directions

- for maximum effectiveness never dilute or drink fluids of any kind immediately before or after taking this product
- repeat dose every 15 minutes or until distress subsides

- Child should not take more than 5 doses in 1 hour without consulting a doctor
- measure only with dosing cup provided. Dosing cup to be used with Emetrol only. Do not use with other products. mL= milliliter
- children under 2 years Do not use
- children 2 to under 12 years of age 5 mL or 10mL
- children 12 years of age and over 15 mL or 30 mL

Other information

- Store between 20-25°C (68-77°F) away from heat and direct light; keep from freezing
- Do not use if printed foil seal under bottle cap is broken or missing

Inactive ingredients

FD&C red no. 40, flavors, glycerin, methylparaben, and purified water.

Questions or Comments?

call 1-844-241-5454 or www.emetrol.com

Distributed By

WellSpring Pharmaceutical Corporation Sarasota, FL 34243 USA (c) WellSpring 2023

Money Back Guarantee

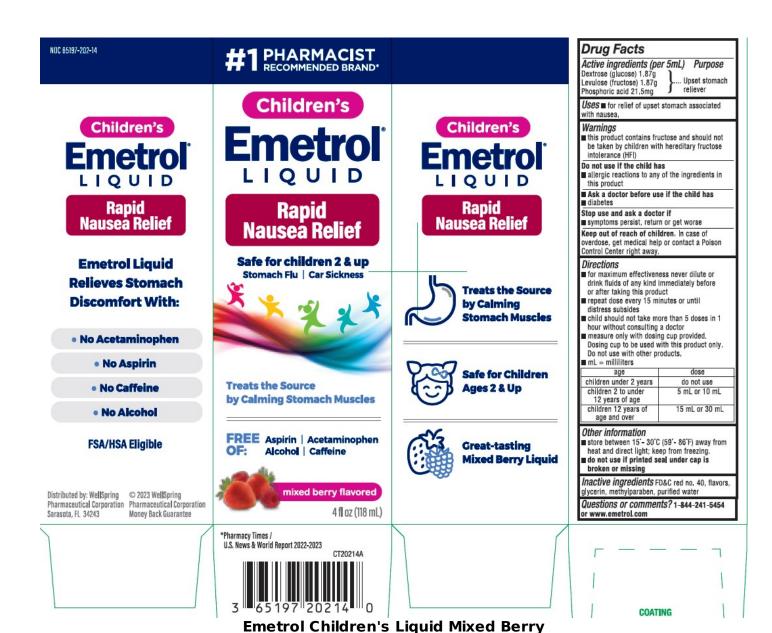
PACKAGE LABEL

Treats the source by Calming Stomach Muscles

Safe for children Ages 2 & Up

Great-tasting Mixed Berry Liquid

Free of: Aspirin | Acetaminophen | Alcohol | Caffeine



EMETROL CHILDREN MIXED BERRY

phosphorated carbohydrate solution

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65197-202
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
DEXTROSE (UNII: IY9XDZ 35W2) (DEXTROSE - UNII:IY9XDZ 35W2)	DEXTROSE	1.87 g in 5 mL	
PHOSPHORIC ACID (UNII: E4GA8884NN) (PHOSPHORIC ACID - UNII: E4GA8884NN)	PHOSPHORIC ACID	21.5 mg in 5 mL	
FRUCTOSE (UNII: 6YSS42VSEV) (FRUCTOSE - UNII:6YSS42VSEV)	FRUCTOSE	1.87 g in 5 mL	
TROCTOSE (OMI. 013342V3EV) (FROCTOSE - OMI.013342V3EV)	TROCTOSE	1.07 g 111 3 1111	

Inactive Ingredients		
Ingredient Name	Strength	
FD&C RED NO. 40 (UNII: WZB9127XOA)		
GLYCERIN (UNII: PDC6A3C0OX)		
METHYLPARABEN (UNII: A2I8C7HI9T)		
WATER (UNII: 059QF0KO0R)		

Product Characteristics		
Color	red	Score
Shape		Size
Flavor	BERRY (Mixed Berry)	Imprint Code
Contains		

	Packaging			
-	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:65197-202-	1 in 1 CARTON	06/01/2023	
:	L	118 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing I	Marketing Information		
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		06/01/2023	
other		00,01,2023	

Labeler - WellSpring Pharmaceutical Corporation (110999054)

Revised: 5/2023 WellSpring Pharmaceutical Corporation