FEBRIX KIDS PLUS- acetaminophen, chlorpheniramine maleate, dextromethorphan hydrobromide, phenylephrine hydrochloride suspension
Plus Distributors 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.

Drug Facts

Active ingredients (in each 5 mL)

Acetaminophen 160 mg

Chlorpheniramine maleate 1 mg

Dextromethorphan HBr 5 mg

Phenylephrine HCl 2.5 mg

Purposes

Pain reliever/fever reducer

Antihistamine

Cough suppressant

Nasal decongestant

Uses

- temporarily relieves the following cold/flu symptoms:
  - minor aches and pains
  - sore throat
  - cough
  - sneezing and runny nose
  - headache
  - nasal congestion
  - stuffy nose
- temporarily reduces fever

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if your child takes:

- more than 5 doses (10 mL) in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen

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

- to make a child sleepy
- in a child who is 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 child's prescription drug contains an MAOI, ask a doctor or pharmacist before giving this product.
- with any other drug containing acetaminophen (prescription or non-prescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- if your child is allergic to acetaminophen or any of the inactive ingredients in this product

Ask a doctor before use if the child has

- liver disease
- glaucoma
- thyroid disease
- diabetes
- heart disease
- high blood pressure
- a breathing problem such as chronic bronchitis
- cough that occurs with too much phlegm (mucus)
- persistent or chronic cough such as occurs with asthma

Ask a doctor or pharmacist before use if your child is taking

- sedatives or tranquilizers
- the blood thinning drug warfarin

When using this product

- **do not exceed recommended dose (see overdose warning)**
- excitability may occur, especially in children
- marked drowsiness may occur
- sedatives and tranquilizers may increase drowsiness

Stop use and ask a doctor if

- new symptoms occur
- redness or swelling is present
- pain, nasal congestion or cough gets worse or lasts more than 5 days
- fever gets worse or last more than 3 days
- nervousness, dizziness or sleeplessness occurs
- cough comes back or occurs with rash or headache that lasts

These could be signs of a serious condition.

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 adult as well as children even if you do not notice any signs or symptoms.

Directions

- **this product does not contain directions or complete warnings for adult use**

- mL=milliliter
- shake well before using
- do not give more than 5 doses in any 24-hours peroid
- measure only with dosing cup provided. Do not use any other dosing device
- keep dosing cup with product
- if needed, repeat dose every 4 hours while symptoms last
- find the right dose on chart below. If possible, use weight to dose, otherwise, use age.

Weight (lb)	Age (yr)	Dose (mL)
48-95	6-11	10 mL
36-47	4-5	do not use unless directed by a doctor
under 36	under 4	do not use

Other Information

- store between 20-25ºC (68-77ºF).Do not refrigerate

Inactive ingredients

anhydrous citric acid, carboxymethylcellulose sodium, D&C red #33, FD&C blue #1, FD&C red #40, flavor, glycerin, microcrystalline cellulose, purified water, sodium benzoate, sorbitol, sucrose, xanthan gum

Principal Display Panel

Children's Pain Relief Plus Multi-symptom Cold

Acetaminophen 160 mg

Pain reliever/fever reducer

Chlorpheniramine maleate 1 mg

Antihistamine

Dextromethorphan HBr 5 mg

Cough suppressant

Phenylephrine HCl 2.5 mh

Nasal decongestant

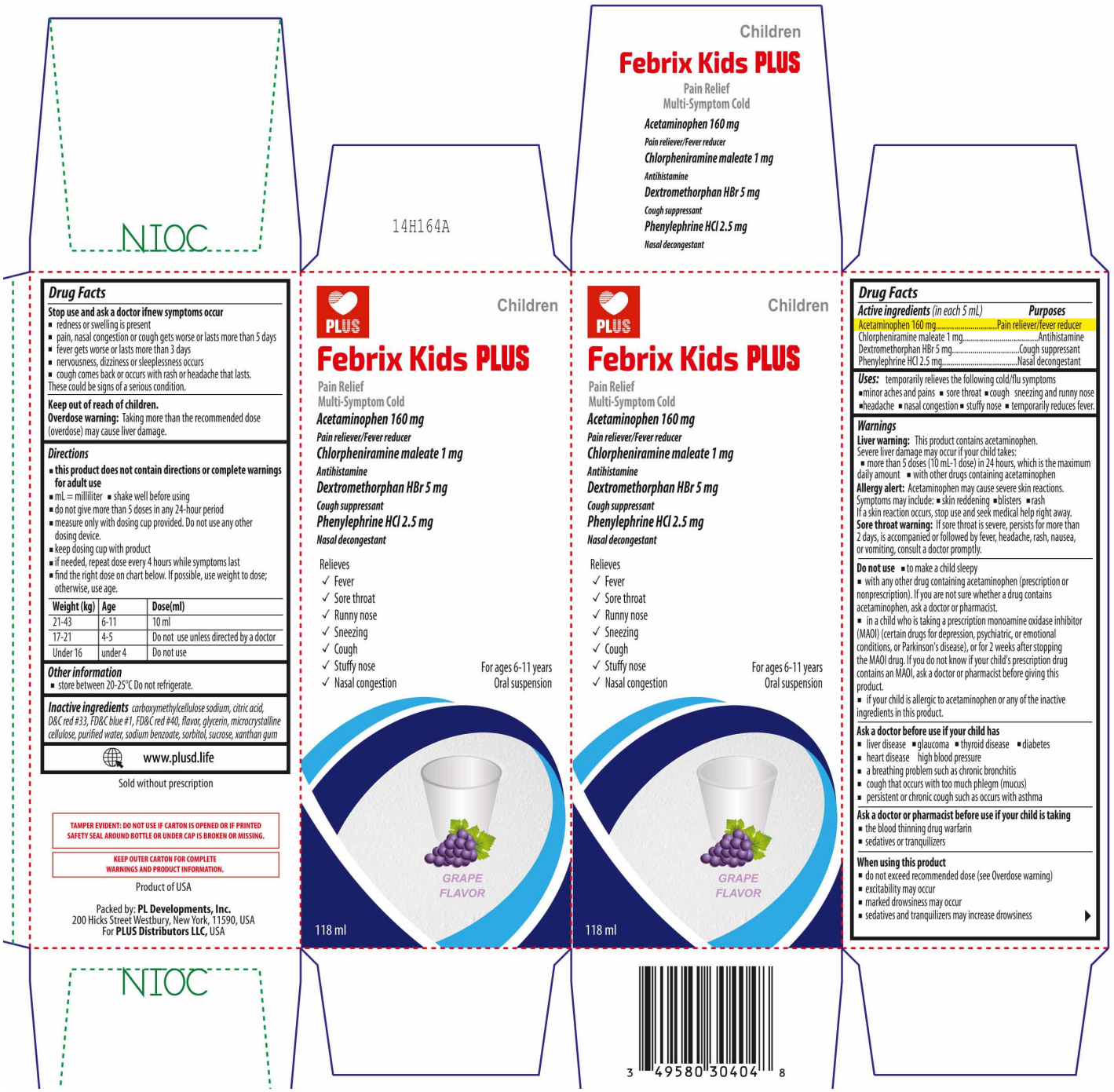
Relieves

- fever
- sore throat
- runny nose
- sneezing
- cough
- stuffy nose
- nasal congestion

for ages 6-11 years

oral suspension

Package Label



Febrix Kids PLUS

FEBRIX KIDS PLUS

acetaminophen, chlorpheniramine maleate, dextromethorphan hydrobromide, phenylephrine hydrochloride suspension

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:72828-304
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	160 mg in 5 mL
CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	1 mg in 5 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	5 mg in 5 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	2.5 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL (UNII: 506T60A25R)	
SUCROSE (UNII: C151H8M554)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color		**Score**	
Shape		**Size**	
Flavor	GRAPE	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72828-304-04	1 in 1 BOX	02/01/2019	
1		118 mL in 1 BOTTLE, PLASTIC; 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	02/01/2019	

Labeler - Plus Distributors LLC (116922831)