DOLOFIN INFANTIL- acetaminophen liquid
Menper Distributors, 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.

Active Ingredient

Acetaminophen 160 mg

Purpose

Acetaminophen.....Pain reliever/fever reducer

Uses

temporarily reduces fever
temporarily relieves minor aches and pains due to:
• the common cold • flu • headache
• sore throat • toothache

Warnings

Liver warning: This product contains acetaminophen.
Severe liver damage may occur if your child takes:
• more than 5 doses in 24 hours, which is the
maximum daily amount
• with other drugs containing acetaminophen
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.

Ask a doctor before use if your child has

liver disease.

Ask a doctor or pharmacist before use if your child is

taking the blood thinning drug warfarin.

When using this product

• do not exceed recommended dose
(see overdose warning)

Stop use and ask a doctor if

• new symptoms occur
• redness or swelling is present
• pain gets worse or lasts more than 5 days

• fever gets worse or lasts more than 3 days
These could be signs of a serious condition.

Keep this and all drugs out of the reach of children.

Overdose Warning: Taking more than the recommended dose (overdose) may cause liver damage. In case of accidental overdose, seek professional assistance or contact a Poison Control Center immediately. Quick medical attention is critical even if you do not notice any signs or symptoms.

Directions

• this product does not contain directions or complete warnings for adult use.
• shake well before using
• find right dose on chart below. If possible, use weight to dose; otherwise, use age.
• use only enclosed dosing cup designed for use with this product. Do not use any other dosing device.
• if needed, repeat dose every 4 hours while symptoms last
• do not give more than 5 times in 24 hours
• do not give more than 5 days unless directed by a doctor

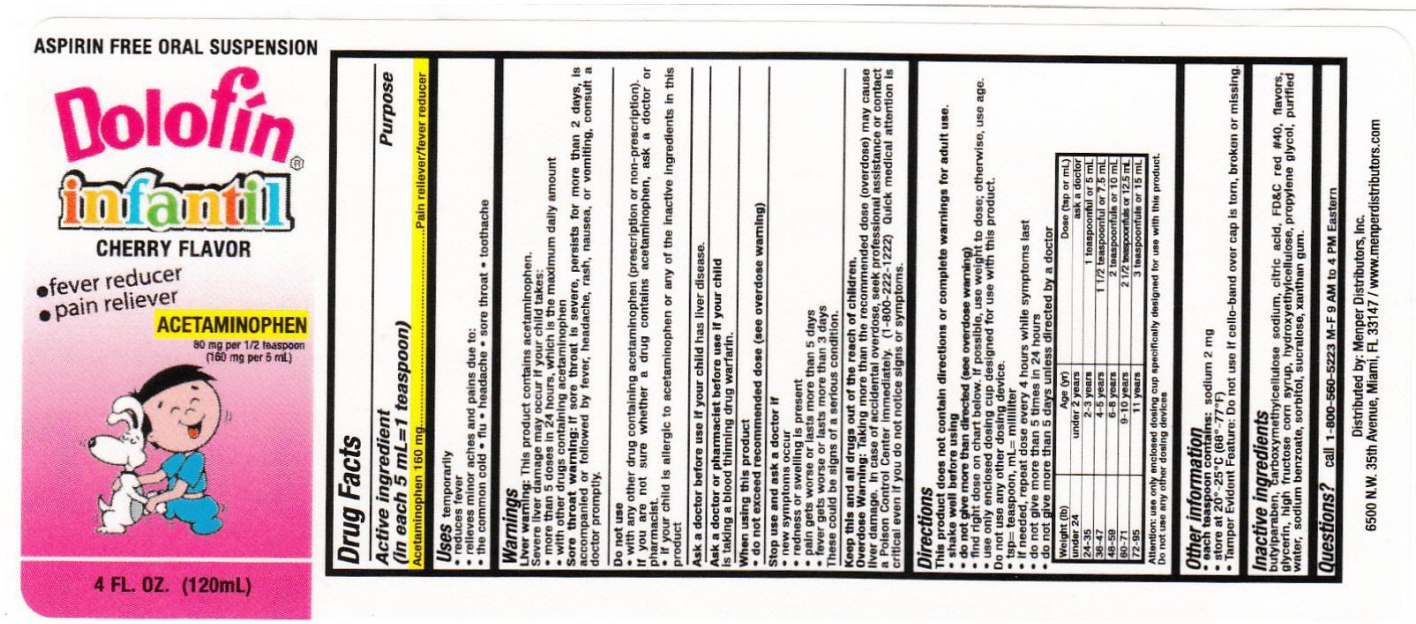
Weight (lb)	Age (yr)	Dose (tsp or mL)
under 24	under 2	ask a doctor
24-35	2-3	1 teaspoon or 5 mL
36-47	4-5	1 1/2 teaspoons or 7.5 mL
48-59	6-8	2 teaspoons or 10 mL
60-71	9-10	2 1/2 teaspoons or 12.5 mL
72-95	11	3 teaspoons or 15 mL

Other information

• store at controlled room temperature
• see bottom panel for lot number and expiration date

Inactive Ingredients

acesulfame potassium, butyl paraben, carboxymethylcellulose sodium, cellulose, citric acid, flavors, glycerin, high fructose corn syrup, propylene glycol, purified water, red 40, sodium benzoate, sorbitol, xanthan gum



DOLOFIN INFANTIL

acetaminophen liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:53145-053
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

Inactive Ingredients	
Ingredient Name	**Strength**
BUTYLPARABEN (UNII: 3QPI1U3FV8)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
CITRIC ACID ACETATE (UNII: DSO12WL7AU)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
HYDROXYETHYL CELLULOSE (100 MPA.S AT 2%) (UNII: R33S7TK2EP)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

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:53145-053-03	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 not final	part343	02/21/2012	

Labeler - Menper Distributors, Inc. (101947166)

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