PANADOL- acetaminophen suspension
GlaxoSmithKline Consumer Healthcare LP

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 ingredient (in each 5mL)

Acetaminophen 160 mg

Purposes

Pain reliever/fever reducer

Uses

- temporarily relieves minor aches and pains due to:
  - colds
  - flu
  - headache
  - toothache
- temporarily reduces fever

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

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.

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 allergic to acetaminophen or any of the inactive ingredients in this product

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

Stop use and ask a doctor if

- pain gets worse or lasts more than 5 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- any new symptoms appear

These could be signs of a serious condition.

Keep out of reach of children.

Overdose warning:

Taking more than the recommended dose can cause serious health problems. In case of oversdose, get medical help or contact a Poison Control Center right away. 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

- **do not take more than directed** (see overdose warning)
- find right dose in chart. If possible use weight to dose; otherwise, use age
- if needed, repeat dose every 4 hours while symptoms persist or as directed by a doctor
- do not take more than 5 doses in 24 hours, unless directed by a doctor
- use only with enclosed pre-marked measuring cup for accuracy. Do not use any other dosing device.

Age	**Weight**	**Dosage**
under 2 yrs	under 24 lbs	ask a doctor
2 - 3 yrs	24 – 35 lbs	5 mL*
4 – 5 yrs	36 – 47 lbs	7.5 mL
6 – 8 yrs	48 – 59 lbs	10 mL
9 – 10 yrs	60 – 71 lbs	12.5 mL
11 yrs	72 – 95 lbs	15 mL

Other information

- store below 30°C (86°F)

Inactive ingredients

benzoic acid, FD&C red no. 40, flavor, glycerin, hydrochloric acid*, polyethylene glycol, potassium sorbate, propylene glycol, purified water, sodium hydroxide*, sodium saccharin, sorbitol solution

***contains one or more of these ingredients**

Questions or comments?

1-800-455-7139 (English/Spanish) weekdays

Principal Display Panel

NDC 0135-0537-03

Panadol®

Children's

ACETAMINOPHEN

160 mg per 5 mL

LIQUID

SPain Reliever

Fever Reducer

EE NEW WARNINGS INFORMATION

Ages 2-11 years

Fast relief of fever and pain

Gentle on your stomach

- Ibuprofen free
- No sugar added
- Aspirin free

artificial

raspberry flavor

4 fl oz (118 mL)

Tamper Evident Feature: Do not use if printed overwrap is missing or broken.

READ AND KEEP CARTON FOR COMPLETE INFORMATION

GlaxoSmithKline Consumer Healthcare, L.P.

Moon Township, PA 15108

Made in Canada

Keep Carton

102003XB

PANADOL

acetaminophen suspension

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0135-0537
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**
BENZOIC ACID (UNII: 8SKN0B0MIM)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics			
Color	RED (light red)	**Score**	
Shape		**Size**	
Flavor	RASPBERRY	**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0135-0537-01	1 in 1 CARTON	10/15/2012	
1		15 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:0135-0537-02	1 in 1 CARTON	10/15/2012	
2		54.7 mL in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:0135-0537-03	1 in 1 CARTON	10/15/2012	
3		118 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	10/15/2012	

Labeler - GlaxoSmithKline Consumer Healthcare LP (828924212)

Revised: 1/2016 GlaxoSmithKline Consumer Healthcare LP