PAIN RELIEVER CHILDRENS- acetaminophen suspension
P & L Development, 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 ingredient (in each 5 mL)

Acetaminophen 160 mg

Purpose

Pain reliever/fever reducer

Uses

- temporarily reduces fever
- 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

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 accompanyed or followed by fever, headache, rash, nausea, or vomiting, consult a doctor prompty.

Do not use

- 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 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 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 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**)
- **shake well before using**
- mL = milliliter
- use only the enclosed dosing cup designed for use with 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
- find the right dose on chart below. If possible,use weight to dose; otherwise;use age.

Weight (lb)	Age (year)	Dose (mL)*
under 24	under 2	ask a doctor
24-35	2-3	5 mL
36-47	4-5	7.5 mL
48-59	6-8	10 mL

60-71	9-10	12.5 mL
72-95	11	15 mL

*or as directed by a doctor

Other information

- **each 5 mL contains**: sodium 2 mg
- store between 20-25ºC (68-77ºF)
- do not refrigerate
- see bottom panel for lot number and expiration date

Inactive ingredients

butylparaben, carboxymethylcellulose sodium, citric acid, D&C red #33, FD&C red #40, flavors, glycerin, high fructose corn syrup, microcrystalline cellulose, propylene glycol, purified water, sodium benzoate, sorbitol, sucralose, xanthan gum

Questions or comments?

Call **1-877-753-3935 Monday-Friday 9AM-5PM EST**

Principal Display Panel

Compare to the active ingredient in Children's Tylenol® Oral Suspension**

Children's

Pain Reliever

Acetaminophen 160 mg per 5 mL

Oral Suspension

Pain Reliever / Fever Reducer

For Ages 2-11 years

Alcohol free

Aspirin free

Ibuprofen free

FL OZ (mL)

BUBBLE GUM FLAVOR

**This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Children's Tylenol® Oral Suspension.

TAMPER EVIDENT: DO NOT USE IF CARTON IS OPENED OR IF PRINTED SAFETY SEAL AROUND BOTTLE OR UNDER CAP IS BROKEN OR MISSING.

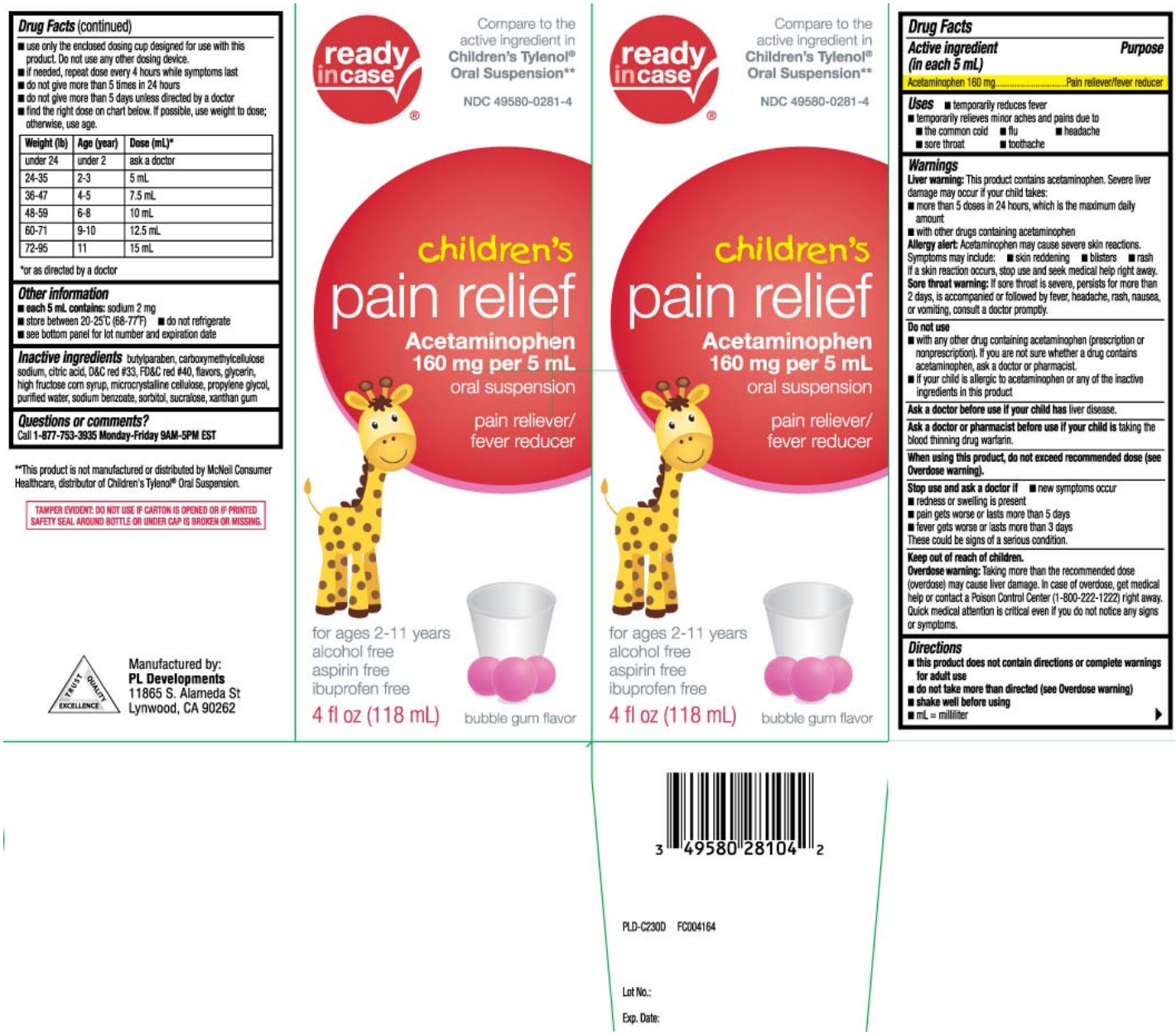
Manufactured by:

PL Developments

11865 S. Alameda St

Lynwood, CA 90262

Package Label



READYinCASE Children's Pain Relief

PAIN RELIEVER CHILDRENS

acetaminophen suspension

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:49580-0281

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)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color		**Score**	
Shape		**Size**	
Flavor	BUBBLE GUM	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49580-0281-4	1 in 1 BOX	04/30/2016	04/30/2025
1		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	04/30/2016	04/30/2025

Labeler - P & L Development, LLC (101896231)

Revised: 2/2023

P & L Development, LLC