

GOOD SENSE PAIN RELIEF CHILDRENS CHILDRENS- acetaminophen suspension
Aidarex Pharmaceuticals 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.

Perrigo Children's Pain Relief Drug Facts

Active ingredient (in each 5 mL = 1 teaspoon)

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

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

- 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 your child has ever had an allergic reaction to this product or any of its ingredients

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

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

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 right away. (1-800-222-1222) 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 give more than directed (see overdose warning)
- shake well before using
- mL = milliliter; tsp = teaspoonful
- find right dose on chart. If possible, use weight to dose; otherwise, use age.
- remove the children protective cap and squeeze your child's dose into the dosing cup
- repeat dose every 4 hours while symptoms last
- do not give more than 5 times in 24 hours

Weight (lb)	Age (yr)	Dose (mL or tsp)*
under 24	under 2 years	ask a doctor
24-35	2-3 years	5 mL (1 tsp)
36-47	4-5 years	7.5 mL (1 ½ tsp)
48-59	6-8 years	10 mL (2 tsp)
60-71	9-10 years	12.5 mL (2 ½ tsp)
72-95	11 years	15 mL (3 tsp)

*or as directed by a doctor

Attention: use only enclosed dosing cup specifically designed for use with this product. Do not use any other dosing device.

Other information

- each 5 mL (1 tsp) contains: sodium 3 mg
- store at 20-25°C (68-77°F)
- do not use if printed neckband is broken or missing

Inactive ingredients

anhydrous citric acid, butylparaben, calcium sulfate, carrageenan, D&C red #33, FD&C blue #1, flavor,

glycerin, high fructose corn syrup, hydroxyethyl cellulose, microcrystalline cellulose and carboxymethylcellulose sodium, propylene glycol, purified water, sodium benzoate, sorbitol solution, tribasic sodium phosphate

Questions or comments?

1-800-719-9260

Principal Display Panel

For Ages 2 – 11

Children's

Pain Relief

Acetaminophen Oral Suspension

Fever Reducer/Pain Reliever

Suspension Liquid

Alcohol Free

Aspirin Free

Ibuprofen Free

Grape Flavor

Compare to active ingredient of Children's Tylenol® Oral Suspension

160 mg per 5 mL

CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION. SEE PACKAGE INSERT. KEEP OUT OF REACH OF CHILDREN. STORE AT CONTROLLED ROOM TEMP 15-30C (59-86F)



PACKAGED AND DISTRIBUTED BY: **AIDAREX PHARMACEUTICALS LLC.**

ACETAMINOPHEN ORAL SUSP.

160mg/5ml

120ml

GENERIC FOR: CHILDREN'S TYLENOL
NDC: 33261-0770-01

TAKE ____ TBSP ____ TIMES DAILY
TOME ____ TBSP ____ VECES AL DIA

MFG: FOR: PERRIGO ALLEGAN, MI 49010

EACH 5 ML CONTAINS THE FOLLOWING ACTIVE INGREDIENTS:
ACETAMINOPHEN.....160mg
GRAPE FLAVOR
ALCOHOL FREE

RX 1001024529

ACETAMINOPHEN ORAL SUSP.
160mg/5ml
NDC: 33261-0770-01
RX 1001024529 120ml

ACETAMINOPHEN ORAL SUSP.
160mg/5ml
NDC: 33261-0770-01
RX 1001024529 120ml

ACETAMINOPHEN ORAL SUSP.
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RX 1001024529 120ml

ACETAMINOPHEN ORAL SUSP.
160mg/5ml
NDC: 33261-0770-01
RX 1001024529 120ml

PEEL HERE
UNTIL
PATIENT
DOES
CHART
TILL
PEEL HERE

Repackaged By :
Aidarex Pharmaceuticals LLC,
Corona, CA 92880

GOOD SENSE PAIN RELIEFCHILDRENS CHILDRENS

acetaminophen suspension

Product Information				
Product Type		HUMAN OTC DRUG	Item Code (Source)	NDC:33261-770(NDC:0113-0130)
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
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)				
BUTYL PARABEN (UNII: 3QPIIU3FV8)				
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)				
CARRAGEENAN (UNII: 5C69YCD2YJ)				
D&C RED NO. 33 (UNII: 9DBA0SBB0L)				
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)				
GLYCERIN (UNII: PDC6A3C0OX)				
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)				
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
WATER (UNII: 059QF0KO0R)				
SODIUM BENZOATE (UNII: OJ245FE5EU)				
SORBITOL (UNII: 506T60A25R)				
CALCIUM SULFATE (UNII: WAT0DDB505)				
SODIUM PHOSPHATE, TRIBASIC (UNII: A752Q30A6X)				
Product Characteristics				
Color	PURPLE (viscous)		Score	
Shape			Size	
Flavor	GRAPE		Imprint Code	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:33261-770-01	1 in 1 CARTON		
1		118 mL in 1 BOTTLE, PLASTIC		
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL		part343	02/25/1993	

