INFANTS PAIN RELIEVER- acetaminophen suspension Rij Pharmaceutical Corporation

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 1.6 mL = 2 droppers ful)

Acetaminophen 160 mg

Purpose

Fever reducer/ pain reliever

Uses

temporarily:

- reduces fever
- relieves minor aches and pains due to:
 - the common cold
 - flu
 - headache
 - sore throat
 - immunizations
 - 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 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; taking more than the recommended dose (overdose) may not provide more relief and could cause serious health problems

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 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.
- shake well before using
- find right dose on chart below. If possible, use weight to dose; otherwise, use age.
- fill to dose level. Do not use any other dosing device.
- dispense liquid slowly into child's mouth, toward inner cheek.
- if needed, repeat dose every 4 hours while symptoms last.
- do not give use than 5 times in 24 hours
- replace original bottle cap to maintain child resistance
- use only with enclosed dropper
- rinse dropper after each use

Dosing Chart

Weight (lbs.)	Age (yrs.)	Dose (mL)
under 24	under 2	ask a doctor
24-35	2-3	2 droppersful (0.8 + 0.8 mL)

Attention: Specifically designed for use with enclosed dropper. Use only enclosed dropper to dose this product. Do not use any other dosing devices.

Other information

- TAMPER EVIDENT: DO NOT USE THIS PRODUCT IF PRINTED INNER CAP SEAL IS BROKEN OR MISSING
- shake well before use.
- Store at room Temperature 15° 30°C (59° 86°F)
- protect from freezing.

Inactive ingredients

butyl paraben, cellulose, citric acid, FD&C Blue # 1 FD&C Red # 33, glycerin, high fructose corn syrup, propylene glycol, sodium benzoate, sorbitol, water, xanthan gum

PRINCIPAL DISPLAY PANEL



COATING

Drug Facts Active ingredient

(in each 1.6 mL =2 droppersful)

Uses temporarily: ■ reduces fever
■ relieves minor aches and pains due to: ■ the common cold ■ flu
■ headaches ■ sore throat ■ immunizations ■ toothaches

Warnings

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■ more than 5 doses in 24 hours, which is the maximum daily amount

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loctor 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.
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Directions
■ This product does not contain directions or complete warnings for adult use. ▶

Drug Facts (continued)

Directions (continued)

Purpose

- shake well before using
 shake well before using
 find the right dose on chart
 below. If possible, use weight to
 dose; otherwise, use age.
 fill to dose level. Do not use any
 other dosing device.

- mouth, toward inner cheek.

 if needed, repeat dose every 4
 hours while symptoms last.

 do not use more than 5 times in

- 24 hours
 replace original bottle cap to
 maintain child resistance
 use only with enclosed dropper
 rinse dropper after each use
 Dosing Chart

ı	Weight(lbs.)	Age(yrs.)	Dose	mL)	
ı	under 24	under 2	ask a (loctor	
ı	24-35	2-3	2 drop (0.8 + 0	persful .8 mL)	
ı	Attention: Specifically designed				

Attention: Specifically designed for use with enclosed dropper. Use only enclosed dropper to dose this product. Do not use any other dosing devices.

Other information:

TAMPER EVIDENT: DO NOT USE
THIS PRODUCT IF PRINTED INNE
CAP SEAL IS BROKEN OR MISSING
shake well before use.
Store at room l'empatry
15°C - 30°C (5°S - 68°F)
protect from freezing

Inactive ingredients: butyl paraben, cellulose, citric aci FD & C Blue #1 FD & C Red #33, glycerin, high fructose com syrup, propylene glycol, sodium benzoate sorbitol, water, xanthan gum NDC -53807-220-05



Infants' Pain Reliever

> SUSPENSION DROPS **FEVER REDUCER PAIN RELIEVER**

Acetaminophen

Effective Relief of Infants' Fever and Pain

Ibuprofen Free • Aspirin Free **Alcohol Free**

For dropper dosage only

Grape Flavor 80 mg per 0.8 mL

 $^{1}/_{2}$ fl.oz (15mL)

Compare to the active ingredients in infants' Tylenol®*

INFANT Pain Reliever contains no aspirin and is unlikely to cause the serious side effects that may occur with aspirin in infants and young children dehydrated by fever, INFANT Pain Reliever is also unlikely to cause the stomach upset that may occur with aspirin or to cause a reaction in those allergic to aspirin.

† This product is not manufac-tured or distributed by McNeil Consumer Healthcare owner of the registered trademark Tylenol Drops®.

All Preferred Plus Pharmacy products are satisfaction guaranteed or your money back from retailer where purchased.

Manufactured By: RIJ PHARMACEUTICAL CORP. 40 Commercial Avenue, Middletown, NY. 10941

Distributed By: Kinray Inc. Whitestone, NY 11357

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INFANTS PAIN RELIEVER

acetaminophen suspension

Product Information

HUMAN OTC DRUG NDC:53807-220 Product Type Item Code (Source)

Route of Administration ORAL

Active Ingredient/Active Moiety

receive ingredient receive relative		
Ingredient Name	Basis of Strength	Strength
Acetaminophen (UNII: 362O9ITL9D) (acetaminophen - UNII:362O9ITL9D)	Acetaminophen	160 mg in 1.6 mL

Inactive Ingredients	
Ingredient Name	Strength
BUTYLPARABEN (UNII: 3QPI1U3FV8)	
PO WDERED CELLULO SE (UNII: SMD1X3XO9 M)	
CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GLYCERIN (UNII: PDC6 A3C0 OX)	
HIGH FRUCTO SE CORN SYRUP (UNII: XY6 UN3QB6S)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SO DIUM CITRATE (UNII: 1Q73Q2JULR)	
XANTHAN GUM (UNII: TTV12P4NEE)	
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics				
Color	PURPLE	Score		
Shape		Size		
Flavor	GRAPE	Imprint Code		
Contains				

]	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:53807-220- 05	1 in 1 CARTON	03/16/1999		
1		15 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 NOT FINAL	part343	03/16/1999	

Labeler - Rij Pharmaceutical Corporation (144679156)

Establishment				
Name	Address	ID/FEI	Business Operations	
Rij Pharmaceutical Corporation		144679156	manufacture(53807-220)	