

PEDIACARE SINGLE DOSE FEVER REDUCER- acetaminophen liquid
Medtech Products 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.

PediaCare Single Dose Fever Reducer

CHILDREN

Ages 6-8 NEW!

or 48-59 lbs

Drug Facts

Active ingredient

(in each 5 mL)

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
 - 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 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 dosage (see overdose warning)

Stop use and ask a doctor if:

- pain gets worse or lasts for more than 5 days.
- fever gets worse or lasts for 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 accidental 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.**
- Each packet provides 1 dose for a child who is 48 to 59 pounds or 6 to 8 years of age. If possible, use weight to determine dose; otherwise use age.

To use:

- Fold back at the dotted line to reveal the tear strip.
- Tear across (not up & down) at the exposed tear slit
- Remove and discard strip
- Squeeze medicine into child's mouth.
- If needed, repeat dose every 4 hours while symptoms last.
- Do not give more than 5 times in 24 hours (see overdose warning).
- Do not give more than 5 days unless directed by a doctor.

Other information

- Store at room temperature
- See bottom panel for lot number and expiration date
- Keep this box for future reference

Inactive ingredients

citric acid, FD&C red no.40, flavors, glycerin, high fructose corn syrup, microcrystalline cellulose/carboxymethylcellulose sodium, potassium sorbate, purified water, sorbitol, sucralose, xanthan gum

Questions or comments?

PRINCIPAL DISPLAY PANEL

Children Ages 6-8
 or 48-59 lbs
 PediaCare Squeezable Packet
 Fever Reducer
 Pain Reliever
 Acetaminophen
 160mg/5mL
 Oral Suspension
 6 Single Dose Packets
 0.34 FL OZ (10 mL) EACH



CHILDREN
Ages 4-5 NEW!
or 36-47 lbs

Drug Facts

Active ingredient

(in each 5 mL)

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
 - 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 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 dosage (see overdose warning)

Stop use and ask a doctor if:

- pain gets worse or lasts for more than 5 days.

- fever gets worse or lasts for 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 accidental 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.**
- Each packet provides 1 dose for a child who is 36 to 47 pounds or 4 to 5 years of age. If possible, use weight to determine dose; otherwise use age.

To use:

- Fold back at the dotted line to reveal the tear strip.
- Tear across (not up & down) at the exposed tear slit
- Remove and discard strip
- Squeeze medicine into child's mouth.
- If needed, repeat dose every 4 hours while symptoms last.
- Do not give more than 5 times in 24 hours (see overdose warning).
- Do not give more than 5 days unless directed by a doctor.

Other information

- Store at room temperature
- See bottom panel for lot number and expiration date
- Keep this box for future reference

Inactive ingredients

citric acid, FD&C red no.40, flavors, glycerin, high fructose corn syrup, microcrystalline cellulose/carboxymethylcellulose sodium, potassium sorbate, purified water, sorbitol, sucralose, xanthan gum

Questions or comments?

1-888-474-3099 Mon.-Fri. 8 am to 8 pm EST **PediaCare.com**

PRINCIPAL DISPLAY PANEL

Children Ages 4-5
or 36-47 lbs
PediaCare Squeezable Packet
Fever Reducer
Pain Reliever

Acetaminophen
160mg/5mL
Oral Suspension
7 Single Dose Packets
0.25 FL OZ (7.5 mL) EACH



PEDIACARE SINGLE DOSE FEVER REDUCER

acetaminophen liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63029-075
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
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
XANTHAN GUM (UNII: TTV12P4NEE)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

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:63029-075-07	7 in 1 BOX, UNIT-DOSE		
1		7.5 mL in 1 DOSE PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part343	05/15/2013	

PEDIACARE SINGLE DOSE FEVER REDUCER

acetaminophen liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63029-010
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
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
WATER (UNII: 059QF0K00R)	
SORBITOL (UNII: 506T60A25R)	
XANTHAN GUM (UNII: TTV12P4NEE)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

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:63029-010-10	6 in 1 BOX, UNIT-DOSE		
1		10 mL in 1 DOSE PACK		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part343	05/15/2013	

Labeler - Medtech Products Inc. (122715688)

Revised: 7/2013

Medtech Products Inc.