

ACETAMINOPHEN - acetaminophen suppository
Physicians Total Care, Inc.

Pediatric Acephen™, Acetaminophen Suppositories, 120 mg

ACTIVE INGREDIENT (in each rectal suppository)

Acetaminophen 120 mg

PURPOSE

pain reliever/fever reducer

USES

temporarily

- reduces fever
- relieves minor aches, pains, and headache

WARNINGS

For rectal use only

Liver Warning: This product contains acetaminophen. Severe liver damage may occur if your child inserts:

- more than 5 suppositories in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen

Do not use

- if your child is allergic to acetaminophen
- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

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

- fever lasts more than 3 days (72 hours), or recurs
 - you need to use this product for pain for more than 5 days continuously
- Severe or recurrent pain, or high or continued fever may indicate a serious illness.

KEEP OUT OF REACH OF CHILDREN

If swallowed or in case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical in case of overdose for children even if you do not notice any signs or symptoms.

DOSAGE & ADMINISTRATION

Directions

This product does not contain directions or complete warnings for adult use.

- **do not use more than directed**
- remove foil wrapper
- insert suppository well up into rectum
- children 3-6 years:
 - 1 suppository every 4 to 6 hours while symptoms persist
 - do not exceed 5 suppositories in any 24-hour period
- children under 3 years: ask a doctor

Other Information

- for your safety, suppositories are packaged in tamper-evident sealed foil. Do not use if foil is torn or open.
- store at 8°-25°C (46°-77°F)

INACTIVE INGREDIENT

butylated hydroxyanisole, butylated hydroxytoluene, glyceryl stearate, hydrogenated vegetable oil, polyethylene glycol 100 stearate, polysorbate 80

QUESTIONS

call **1-800-922-1038**
Monday-Friday 9am-4pm EST

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

SEE NEW WARNINGS INFORMATION
READ AND KEEP CARTON FOR NEW LIVER WARNING
NDC 54868-5624-0
12 rectal suppositories
Acetaminophen Suppositories USP 120 mg
ASPIRIN FREE
Pain Reliever • Fever Reducer
50 Rectal Suppositories



ACETAMINOPHEN			
acetaminophen suppository			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54868-5624(NDC:0713-0118)

Route of Administration RECTAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Acetaminophen (UNII: 362O9ITL9D) (Acetaminophen - UNII:362O9ITL9D)	Acetaminophen	120 mg

Inactive Ingredients

Ingredient Name	Strength
Butylated Hydroxyanisole (UNII: REK4960K2U)	
Butylated Hydroxytoluene (UNII: 1P9D0Z171K)	
Glyceryl Monostearate (UNII: 230OU9XXE4)	
Hydrogenated Coconut Oil (UNII: JY81OXM1OM)	
Peg-100 Stearate (UNII: YD01N1999R)	
Polysorbate 80 (UNII: 6OZP39ZG8H)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54868-5624-0	12 in 1 BOX		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA018060	06/29/2006	

Labeler - Physicians Total Care, Inc. (194123980)

Establishment

Name	Address	ID/FEI	Business Operations
Physicians Total Care, Inc.		194123980	relabel

Revised: 6/2012

Physicians Total Care, Inc.