

**ACETAMINOPHEN PAIN RELIEVER/FEVER REDUCER- acetaminophen suppository**  
**Physicians Total Care, Inc.**

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**Active ingredient (in each rectal suppository)**

Acetaminophen 650 mg

**Purpose**

Pain reliever/fever reducer

**Uses**

temporarily

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

**Warnings**

Liver warning:

This product contains acetaminophen. Severe liver damage may occur if

- an adult or child 12 years and older takes more than 6 doses in 24 hours, which is the maximum daily amount
- taken with other drugs containing acetaminophen
- an adult takes 3 or more alcoholic drinks every day while using this product

For rectal use only

**Do not use**

- in children under 12 years
- if you are 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**

- you have liver disease
- you are taking the blood thinning drug warfarin

**Stop use and ask a doctor if**

- fever lasts more than 3 days (72 hours), or recurs.
- pain gets worse or lasts more than 10 days.
- new symptoms occur.
- redness or swelling is present in the painful area.

These may be signs of a serious condition.

**If pregnant or breast-feeding,**

ask a health professional before use.

**Keep out of reach of children.**

If swallowed or in case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222) Quick medical attention is critical in case of overdose for adults and for children even if you do not notice any signs or symptoms.

### Directions

- do not use more than directed
- remove wrapper
- carefully insert suppository well up into the rectum
- adults and children 12 years and older:
  - 1 suppository every 4 to 6 hours while symptoms last
  - do not exceed 6 suppositories in any 24 hour period
- children under 12 years: ask a doctor

### Other information

- tamper-evident: suppositories are individually wrapped. Do not use if printed wrapper is opened or damaged.
- store at 20°-25°C (68°-77°F) or in a cool place

### Inactive ingredients

hydrogenated vegetable oil

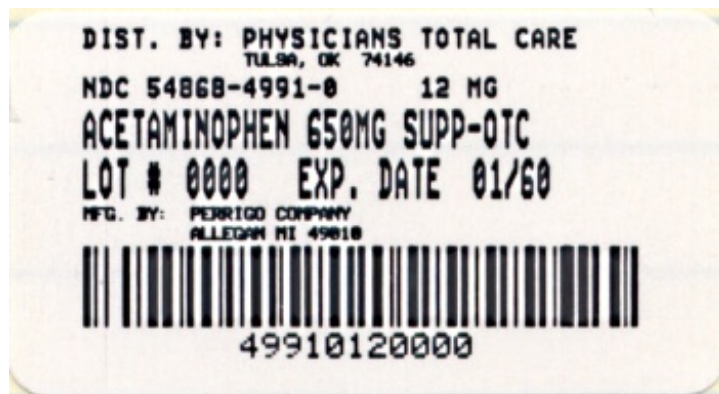
### Questions or comments?

1-800-719-9260

### PRINCIPAL DISPLAY PANEL

Acetaminophen Suppositories USP, 650 mg

NDC 54868-4991-0



Pain Reliever/Fever Reducer

See New Warnings Information

Read and Keep Carton for New Liver Warning

650 mg Each

**ACETAMINOPHEN PAIN RELIEVER/FEVER REDUCER**

acetaminophen suppository

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:54868-4991(NDC:45802-730)
<b>Route of Administration</b>	RECTAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
HYDROGENATED PALM KERNEL OIL (UNII: FM8D1RE2VP)	

**Packaging**

#	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:54868-4991-0	2 in 1 CARTON		
1		6 in 1 BLISTER PACK		

**Marketing Information**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ANDA	ANDA070608	02/03/2004	

**Labeler** - Physicians Total Care, Inc. (194123980)**Establishment**

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

Revised: 4/2011

Physicians Total Care, Inc.