

ACEPHEN - acetaminophen suppository
Central Texas Community Health Centers

Acephen™ Acetaminophen Suppositories USP
325 mg

ACTIVE INGREDIENT (in each rectal suppository)

Acetaminophen 325 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

- a child 6 to 12 years takes more than 5 doses in 24 hours
- 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

Allergy alert: acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away.

Do not use

- in children under 6 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
- new symptoms occur
- pain gets worse or lasts more than 10 days
- 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. 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 foil wrapper
- insert suppository well up into rectum

children under 6 years	do not use
children 6-12 years	1 suppository every 4 to 6 hours (maximum of 5 doses in 24 hours)
adults and children 12 years and older	2 suppositories every 4 to 6 hours (maximum of 6 doses)

Other Information

- store at room temperature 15°-30°C (59°-86°F)

INACTIVE INGREDIENTS

glyceryl stearate, hydrogenated vegetable oil, polyethylene glycol 100 stearate, sorbitan monooleate

QUESTIONS?

call **1-800-922-1038**

PRINCIPAL DISPLAY PANEL - 325 mg Suppository Box Label

CommUnityCare Federally Qualified Health Centers

Acetaminophen
325mg Supp.

Date:

Name:
Dr.

Hancock item only

123456

1/1/01

Acetaminophen 325mg Suppositories NDC 76413-302-12

Batch: 123456

Lot: 123456

Exp: 1/1/01

G&W LABS

Federal law prohibits the transfer of this drug to any other person than the patient for whom prescribed.

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acetaminophen suppository

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76413-302(NDC:0713-0164)
Route of Administration	RECTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Acetaminophen (UNII: 362O9ITL9D) (Acetaminophen - UNII:362O9ITL9D)	Acetaminophen	325 mg

Inactive Ingredients

Ingredient Name	Strength
Glyceryl Monostearate (UNII: 230OU9XXE4)	
Hydrogenated Coconut Oil (UNII: JY81OXM1OM)	
Peg-100 Stearate (UNII: YD01N1999R)	
Sorbitan Monooleate (UNII: 06XEA2VD56)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76413-302-12	12 in 1 BOX; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA072344	03/27/1992	

Labeler - Central Texas Community Health Centers (079674019)

Establishment

Name	Address	ID/FEI	Business Operations
Central Texas Community Health Centers		079674019	REPACK(76413-302) , RELABEL(76413-302)

Revised: 3/2016

Central Texas Community Health Centers