ACEPHEN - acetaminophen suppository
Cosette Pharmaceuticals, Inc.

Acephen™ Acetaminophen Suppositories USP
650 mg

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

For rectal use only

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
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 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. 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
- carefully insert suppository well up into rectum
- adults and children 12 years and older
  - 1 suppository every 4 to 6 hours while symptoms persist
  - do not exceed 6 doses in any 24-hour period
- **children under 12 years: do not use**

OTHER INFORMATION

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

INACTIVE INGREDIENTS

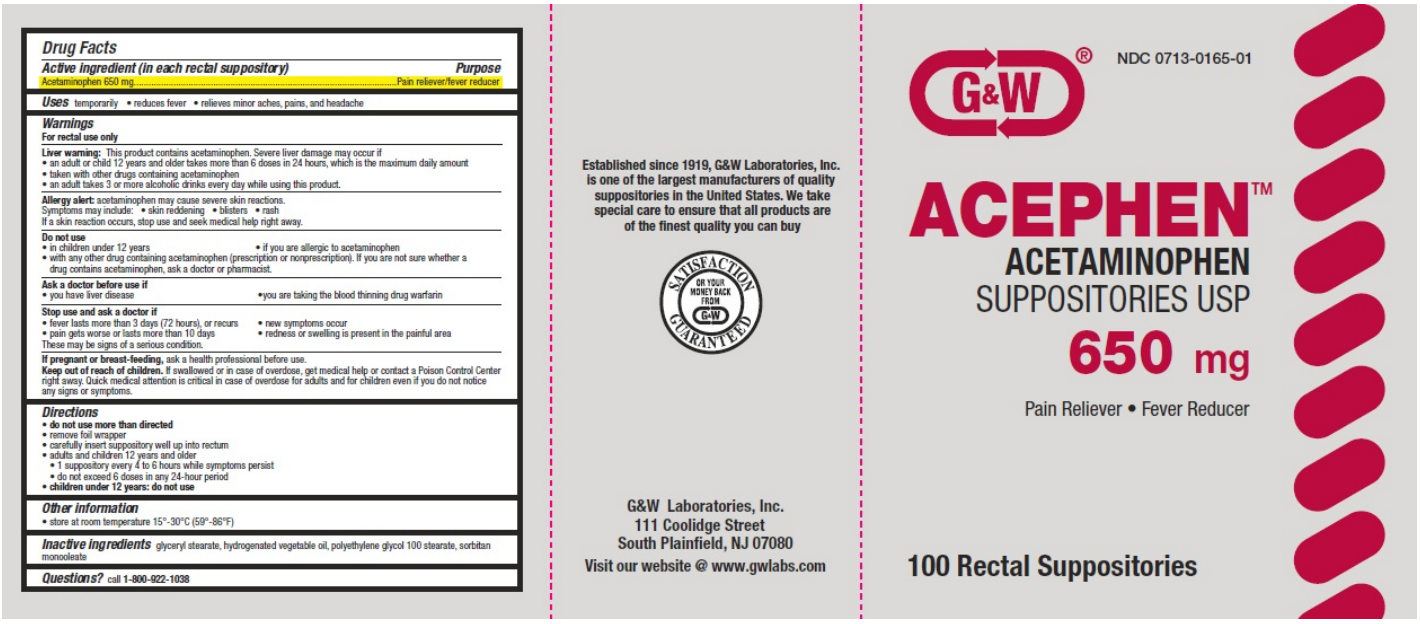
glyceryl stearate, hydrogenated vegetable oil, polyethylene glycol 100 stearate, sorbitan monooleate

QUESTIONS?

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

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 0713-0165-01
G&W ACEPHEN^{TM} Acetaminophen Suppositories USP 650 mg
Pain Reliever • Fever Reducer
100 Rectal Suppositories



ACEPHEN

acetaminophen suppository

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0713-0165
Route of Administration	RECTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 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:0713-0165-12	12 in 1 BOX; Type 0: Not a Combination Product	03/27/1992	
2	NDC:0713-0165-01	100 in 1 BOX; Type 0: Not a Combination Product	03/27/1992	
3	NDC:0713-0165-50	50 in 1 BOX; Type 0: Not a Combination Product	03/27/1992	
4	NDC:0713-0165-10	1000 in 1 BOX; Type 0: Not a Combination Product	03/27/1992	
5	NDC:0713-0165-05	500 in 1 BOX; Type 0: Not a Combination Product	03/27/1992	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA072237	03/27/1992	

Labeler - Cosette Pharmaceuticals, Inc. (116918230)

Registrant - Cosette Pharmaceuticals, Inc. (116918230)

Establishment

Name	Address	ID/FEI	Business Operations
Cosette Pharmaceuticals, Inc.		116918230	analysis(0713-0165) , manufacture(0713-0165) , label(0713-0165) , pack(0713-0165)

Revised: 8/2019 Cosette Pharmaceuticals, Inc.