ACETAMINOPHEN- acetaminophen solution
Kesin Pharma Corporation

5mL, 10.15mL, 20.3mL, ACETAMINOPHEN oral solution 160mg per 5mL, 10.15mL

ACETAMINOPHEN Oral Solution 160mg per 5mL

ACETAMINOPHEN Oral Solution
160mg per 5mL

Active Ingredients (in each 5 mL)

Acetaminophen 160 mg

PURPOSE

Pain reliever/fever reducer

USES

Temporarily relieves minor aches and pains due to:

- headaches
- backaches
- toothaches
- muscular aches
- minor pain of arthritis
- the common cold
- premenstrual and menstrual cramps
- sore throat
- flu

Temporarily reduces fever

WARNINGS

Liver warning: This product contains acetaminophen. Severe liver damage may occur if:

- adult takes more than more than 6 doses in in 24 hours, which is the maximum daily amount
- child takes more than 5 doses in 24 hours
- taken with other drugs containing acetaminophen
- adult has 3 or more alcoholic drinks everyday while using this product

Ask a doctor before use if the user has liver disease.

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.

Sore throat warning: If sore throat is severe, persistent for more than 2 days, or is accompanied or followed by a fever,
headache, nausea, rash, or vomiting, consult a physician promptly.

Do not use
- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- for more than 3 days for fever unless directed by a doctor
- for more that 10 days for pain unless directed by a doctor
- if you are allergic to acetaminophen or any of the inactive ingredients in this product

Ask a doctor or pharmacist before use if the user is taking the blood thinning drug warfarin.

Stop use and ask a doctor if

Stop use and ask a doctor if
- symptoms do not improve
- new symptoms occur
- pain gets worse or lasts more than 5 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present

These could be signs of a serious condition.

If Pregnant or breast-feedinging

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children.

KEEP OUT OF REACH OF CHILDREN.

Overdose warning:

Overdose warning: Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get
medical help or contact a Poison Control Center right away (1-800-222-1222). Quick medical attention is critical for adults as
well as for children even if you do not notice any signs or symptoms.

DIRECTIONS

- **do not take more than directed (see overdose warning)**

Age	Dose
adults and children 12 years of age and over	20.3 mL (650 mg) every 4 to 6 hours not to excdeed 6 doses in a 24-hour period
children 6 to Under 12 years of age	10.15 mL (325 mg) every 4 hours not to exceed 5 doses in a 24-hour period
children 4 to under 6 years of age	7.5 mL (240 mg) every 4 hours not to exceed 5 doses in a 24-hour period
children under 2 years of age	consult a doctor

OTHER INFORMATION

- store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature].
- keep tightly closed
- protect from light
- tamper evident: DO NOT use if foil on cup is missing or torn
- a clear, grape flavored solution supplied in the following oral dosage forms:

NDC 81033-002-05: 5 mL (160mg) unit dose cup
NDC 81033-002-55: Case contains 100 unit dose cups of 5 mL (81033-002-05); packaged in a carton of 50 unit dose cups each.
NDC 81033-002-10: 10.15mL (325mg) unit dose cup
NDC 81033-002-54: Case contains 100 unit dose cups of 10.15 mL (81033-002-10); packaged in a carton of 50 unit dose cups
each.
NDC 81033-002-20: 20.3 mL (650mg) unit dose cup
NDC 81033-002-53: Case contains 100 unit dose cups of 20.3 mL (81033-002-20); packaged in a carton of 50 unit dose cups
each.

INACTIVE INGREDIENTS

Citric acid, grape flavor, methylparaben, monoammonium glycyrrhizinate, potassium citrate, propylene glycol, propylparaben, purified water, sorbitol, sucralose

QUESTIONS OR COMMENTS?

Call Kesin Pharma at 1-833-537-4679. You may also report serious side effects to this phone number.

Packaged by:
Kesin Pharma
Oldsmar, FL 34677
Effective: 08/2024

Revision 01

PRINCIPAL DISPLAY PANEL

NDC 81033-002-05

Acetaminophen Oral Solution

160mg/5mL

Delivers160mg/5mL

Store at 68° - 77° F

LOT

EXP

PKG by Kesin Pharma

Oldsmar, FL

Alcohol, Dye, Sugar Free

For Institutional Use

NDC 81033-002-10

Acetaminophen Oral Solution

160mg/5mL

Delivers 325mg/10.15mL

Store at 68° - 77° F

LOT

EXP

PKG by Kesin Pharma

Oldsmar, FL

Alcohol, Dye, Sugar Free

For Institutional Use

NDC 81033-002-20

Acetaminophen Oral Solution

160mg/5mL

Delivers 650mg/20.15mL

Store at 68° - 77° F

LOT

EXP

PKG by Kesin Pharma

Oldsmar, FL

Alcohol, Dye, Sugar Free

For Institutional Use

ACETAMINOPHEN

acetaminophen solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:81033-002(NDC:84447-104)
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
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBITOL (UNII: 506T60A25R)	
AMMONIUM GLYCYRRHIZATE (UNII: 3VRD35U26C)	
POTASSIUM CITRATE (UNII: EE90ONI6FF)	
WATER (UNII: 059QF0KO0R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics

Color		**Score**	
Shape		**Size**	
Flavor	GRAPE	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81033-002-40	40 in 1 CARTON	06/30/2021	
1	NDC:81033-002-10	10.15 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		
2	NDC:81033-002-50	50 in 1 CARTON	06/30/2021	
2	NDC:81033-002-05	5 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		
3	NDC:81033-002-30	30 in 1 CARTON	06/30/2021	
3	NDC:81033-002-20	20.3 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		
4	NDC:81033-002-55	100 in 1 CASE	06/30/2021	
4	NDC:81033-002-05	5 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		
5	NDC:81033-002-54	100 in 1 CASE	06/30/2021	
5	NDC:81033-002-10	10.15 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		
6	NDC:81033-002-53	100 in 1 CARTON	06/30/2021	
6	NDC:81033-002-20	20.3 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	06/30/2021	

Labeler - Kesin Pharma Corporation (117447816)

Establishment

Name	Address	ID/FEI	Business Operations
Kesin Pharma Corporation		117447816	repack(81033-002)

Establishment

Name	Address	ID/FEI	Business Operations
Kesin Pharma Corporation		119132647	repack(81033-002)

Revised: 12/2024 Kesin Pharma Corporation