

**ACETAMINOPHEN- acetaminophen solution**  
**Kesin Pharma Corporation**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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

**DRUG FACTS**

**Active Ingredients (in each 5 mL)**

**Acetaminophen** 160 mg

**PURPOSE**

Pain reliever/fever reducer

**USES**

Temporarily:

- reduces fever
- relieves minor aches and pains due to:
  - the common cold
  - flu
  - headache
  - sore throat
  - toothache

**WARNINGS**

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

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

**Sore throat warning:** severe or persistent sore throat or sore throat accompanied by high fever, headache, nausea, and vomiting may be serious. Consult physician promptly. Do not use more than 2 days or administer to children under 3 years of age unless directed by physician.

***Do not use***

***Ask a doctor before use***

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

***Ask a doctor or pharmacist before use***

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.

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

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

***Stop use and ask a doctor if***

Stop use and ask a doctor if

- symptoms do not improve
- pain gets worse or lasts more than 5 days
- fever gets worse or lasts more than 3 days
- new symptoms occur
- redness or swelling is present

These could be signs of a serious condition.

***Keep out of reach of children.***

Keep out of reach of children.

Overdose warning: 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)**
- do not take more than 5 doses in any 24-hour period
- dose as follows or as directed by doctor:
- take only with dosing cup provided
- adults and children 12 years of age and older: 20 mL (640 mg) in dosing cup every 6 hours
- children under 12 years of age: ask a doctor
- this product does not contain directions or complete warnings for use

## **OTHER INFORMATION**

each 5 mL contains: **sodium 8 mg**

store at 20 -25°C (68 -77°F)

tamper evident: DO NOT use if foil on cup is missing or torn

Alcohol Free, Dye Free, Sugar Free

## **INACTIVE INGREDIENTS**

Citric acid, grape flavor[Ma1] , edetate disodium, glycerin, maltitol, polyethylene glycol, propylene glycol, purified water, sodium benzoate, sodium metabisulfite, sorbitol, sucralose, trisodium citrate dihydrate, xanthan gum

grape flavor

## **QUESTIONS OR COMMENTS?**

Call 1-833-537-4679

## **PRINCIPAL DISPLAY PANEL**

NDC 81033-002-05

### **Acetaminophen**

Oral Solution

160mg | 5mL

Delivers 160mg | 5mL

Store at 68° - 77° F

LOT PKG By

Kesin Pharma

EXP Phoenix, Az

Alcohol, Dye, Sugar Free



NDC 81033-002-10

### **Acetaminophen**

Oral Solution

160mg | 5mL

Delivers 325mg | 10.15mL

Store at 68° - 77° F

LOT PKG By

Kesin Pharma

EXP Phoenix, Az

Alcohol, Dye, Sugar Free



NDC 81033-002-20

**Acetaminophen**

Oral Solution

160mg | 5mL

Delivers 650mg | 20.3mL

Store at 68° - 77° F

LOT PKG By  
Kesin Pharma

EXP Phoenix, Az

Alcohol, Dye, Sugar Free



NDC 81033-002-05

Acetaminophen Oral Solution

160mg/5mL

Delivers 160mg/5mL

Store at 68° - 77° F

LOT

EXP

PKG by

Kesin Pharma Phoenix, AZ

Alcohol, Dye, Sugar Free

NDC 81033-002-10

Acetaminophen Oral Solution

160mg/5mL

Delivers 325mg/10.15mL

Store at 68° - 77° F

LOT

EXP

PKG by

Kesin Pharma Phoenix, AZ

Alcohol, Dye, Sugar Free

NDC 81033-002-20

Acetaminophen Oral Solution

160mg/5mL

Delivers 650mg/20.15mL

Store at 68° - 77° F

LOT

EXP

PKG by

Kesin Pharma Phoenix, AZ

Alcohol, Dye, Sugar Free

## ACETAMINOPHEN

acetaminophen solution

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:81033-002
<b>Route of Administration</b>	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
EDETATE DISODIUM (UNII: 7FLD91C86K)	
WATER (UNII: 059QF0KO0R)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
XANTHAN GUM (UNII: TTV12P4NEE)	

### Product Characteristics

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	GRAPE	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81033-002-41	8 in 1 CASE	06/30/2021	

1	NDC:81033-002-40	40 in 1 CARTON		
1	NDC:81033-002-10	10.15 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		
2	NDC:81033-002-51	8 in 1 CASE	06/30/2021	
2	NDC:81033-002-50	50 in 1 CARTON		
2	NDC:81033-002-05	5 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		
3	NDC:81033-002-31	8 in 1 CASE	06/30/2021	
3	NDC:81033-002-30	30 in 1 CARTON		
3	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 not final	part343	06/30/2021	

**Labeler** - Kesin Pharma Corporation (117447816)

Revised: 7/2021

Kesin Pharma Corporation