

M-PAP- acetaminophen liquid
Method Pharmaceuticals, LLC

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.

M-PAP

M-PAP

Acetaminophen Liquid

160 mg/5 mL

Pain Reliever / Fever Reducer

Sugar Free / Alcohol Free

Aspirin Free

CHERRY FLAVOR

Drug Facts

Active ingredient

(in each 5 mL teaspoonful)

Acetaminophen, USP 160 mg

Purpose

Pain reliever/fever reducer

Uses

temporarily relieves minor aches and pains due to:

- Headache
- muscular aches
- backache
- arthritis
- the common cold
- toothache
- menstrual cramps
- reduces fever

Warnings

Liver Warning: This product contains acetaminophen. Severe liver damage may occur if you take:

- more than 8 teaspoonfuls (40 mL) in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen
- 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.

Ask a doctor before use

if you have health issues especially liver disease.

Ask a doctor or pharmacist before use

if you are taking other drugs, including the blood thinner warfarin.

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 10 days for pain unless directed by a doctor
- for more than 3 days for fever unless directed by a doctor
- if you are allergic to acetaminophen or any of the inactive ingredients in this product.

Stop use and ask a doctor if

- new symptoms occur such as rash, hives, itching or hoarseness
- redness or swelling is present
- pain gets worse or lasts for more than 10 days
- fever gets worse or lasts for more than 3 days
- symptoms do not improve

These could be signs of a serious condition.

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical even if you do not notice any signs or symptoms.

Directions

Do not exceed recommended dosage.

Overdose Warnings: Taking more than the recommended dose (overdose) can cause serious health problems, including liver damage.

- adults and children 12 years of age and older: take 2 teaspoonfuls (10 mL) every 6 hours; do not exceed

8 teaspoonfuls (40 mL) in 24 hours

- children under 12 years of age: Under the direct guidance of a licensed professional, doctor, or pharmacist.

Other Information

If dispensed, dispense in a tight, light resistant container with a child-resistant cap.

Store at 20°C to 25°C (68°F to 77°F), excursions permitted between 15°C and 30°C (between 59°F and

86°F)

Inactive Ingredients

Bitter Mask, Cherry Flavor, Citric Acid, FD&C Red No. 40, Glycerin, Polyethylene Glycol, Purified Water, Sodium Benzoate, Sodium Citrate Dihydrate, Sodium Saccharin, Sorbitol.

Questions?

1-877-250-3427 M-F (8 a.m. to 5 p.m. CST), or directly to Medwatch at 1-800-332-1088.

Serious side effects associated with use of this product may be reported to this number.

See New Warnings Information

Tamper evident by foil seal under cap.

Do not use if foil seal is broken or missing.

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.

Distributed by:

Method Pharmaceuticals

Fort Worth, Texas 76118

Rev. 06/19

PRINCIPAL DISPLAY PANEL

NDC 58657-525-04

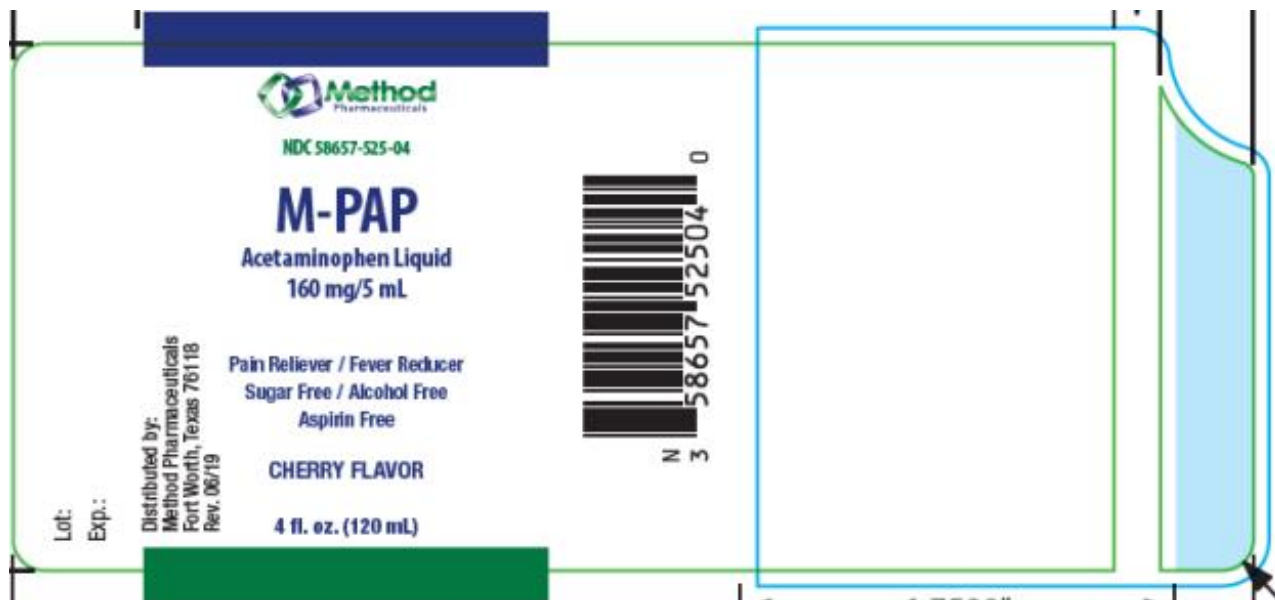
M-PAP

Acetaminophen Liquid

160 mg/5 mL

Cherry Flavor

4 fl. oz. (120 mL)



PRINCIPAL DISPLAY PANEL

NDC 58657-525-16

M-PAP

Acetaminophen Liquid

160 mg/5 mL

Cherry Flavor

16 fl. oz. (473 mL)


See New Warnings Information

Tamper evident by foil seal under cap.
Do not use if foil seal is broken or missing.


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.

Distributed by:
Method Pharmaceuticals
Fort Worth, Texas 76118

Rev. 06/19



Lot:
Exp.:



NDC 58657-525-16

M-PAP

Acetaminophen Liquid
160 mg/5 mL

Pain Reliever / Fever Reducer
Sugar Free / Alcohol Free
Aspirin Free

CHERRY FLAVOR

16 fl. oz. (473 mL)

M-PAP

acetaminophen liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58657-525
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
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	

POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
WATER (UNII: 059QF0K00R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58657-525-04	120 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/01/2019	
2	NDC:58657-525-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/01/2019	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part343	08/01/2019	

Labeler - Method Pharmaceuticals, LLC (060216698)