# ACETAMINOPHEN SOLUTION- acetaminophen liquid Patrin Pharma, Inc.

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### **Acetaminophen Oral Solution USP UD**

**Drug Facts** 

### Active ingredient (in each 5 mL)

Acetaminophen 160 mg

### **Purpose**

Pain reliever/fever reducer

### Uses

Temporarily relieves minor aches and pains due to:

- headache
- muscular aches
- backache
- minor pain of arthritis
- the common cold
- toothache
- premenstrual and menstrual cramps

Temporarily reduces fever

## Warnings

## Liver warning

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

- an adult takes more than 6 doses in 24 hours, or greater than 4000 mg of acetaminophen, the maximum daily amount
- a child takes more than 5 doses in 24 hours
- taken with other drugs containing acetaminophen
- taken with 3 or more alcoholic drinks every day while using this product

## Allergy

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

If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor 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 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 of his product

### Ask a doctor before use if you have liver disease.

Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin.

### Stop use and ask a doctor if

- symptoms do not improve
- new symptoms occur
- pain or fever persists or gets worse
- redness or swelling is present

If pregnant or breastfeeding, ask a health professional before use.

Keep Out Of Reach Of Children.

## **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 children even if you do not notice any signs or symptoms.

### **Directions**

- Do not take more than directed (see overdose warning)
- Use the following dosage guidelines when using this product

AGE	DOSE
Adults and	20.3 mL (650 mg) every 4 to
children 12	6 hours
years of age	Not to exceed 6 doses in a
and over	24-hour period
Children 6 to	10.15 mL (325 mg) every 4
under 12	hours
years of age	Not to exceed 5 doses in a
years or age	24-hour period
Children 4 to	7.5 mL (240 mg) every 4
under 6	hours

years of age	Not to exceed 5 doses in a 24-hour period
	5 mL (160 mg) every 4 hours
under 4	Not to exceed 5 doses in a
years of age	24-hour period
Children	
under 2	Consult a doctor
years of age	

### Other Information

- Each 5 mL contains: sodium 2 mg
- Store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature]
- Keep tightly closed
- Protect from light
- Do not use if foil on cup is missing or torn

### **Inactive Ingredients**

Citric acid, FD&C Red No. 40, flavoring, glycerin, polyethylene glycol, purified water, saccharin sodium, sodium benzoate, sodium citrate, and sorbitol.

### **Questions Or Comments?**

Call (800) 936-3088. You may also report serious side effects to this phone number.

### **How Supplied**

• A red, cherry flavored solution supplied in the following oral dosage cups:

NDC 39328-031-5 mL unit dose cup 05: NDC 39328-031- Case contains 50 unit dose cups of 5 mL (39328-031-05). NDC 39328-031- Case contains 100 unit dose cups of 5 mL (39328-031-05). 99: NDC 39328-032-10.15 mL unit dose cup 10: NDC 39328-032- Case contains 50 unit dose cups of 10.15 mL 50: (39328-032-10). NDC 39328-032- Case contains 100 unit dose cups of 10.15 mL 99: (39328-032-10).

NDC 39328-034-20: 20.3 mL unit dose cup

NDC 39328-034- Case contains 50 unit dose cups of 20.3 mL

50: (39328-034-20).

NDC 39328-034- Case contains 100 unit dose cups of 20.3 mL

99: (39328-034-20).

### **Patrin Pharma**

Skokie, IL 60076 www.patrinpharma.com

Rev 02.0424

### PRINCIPAL DISPLAY PANEL - 5 mL Cup Label

Delivers 5 mL NDC 39328-031-05 Acetaminophen Oral Solution USP 160 mg/5 mL Alcohol Free For Institutional Use Only See Insert

Lot# xxxxxx Exp: yyyy/mm/dd Patrin Pharma Skokie, IL 60076 Rev 03.0324

Delivers 5 mL NDC 39328-031-05 Acetaminophen Oral Solution USP 160 mg/5 mL

Alcohol Free For Institutional Use Only



Lot# xxxxxx Exp: yyyy/mm/dd Patrin Pharma Skokie, IL 60076 Rev 03.0324

## Acetaminophen Oral Solution USP

Alcohol Free For Institutional Use Only

#### Drug Facts Active Ingredient (in each 5 mL) Purpose Acetaminophen 160 mg .... Pain reliever/fever reducer

- Temporarily relieves minor aches and pains due to:
- headache
   muscular aches
- backache
- · minor pain of arthritis · the common cold
- toothache
- premenstrual and menstrual cramps

Temporarily reduces fever

#### Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if: . an adult takes more than 6 doses in 24 hours, or greater than 4000 mg of acetaminophen, the maximum daily amount

- a child takes more than 5 doses in 24 hours

taken with other drugs containing acetaminophen
 taken with 3 or more alcoholic drinks every day while using this product

Allergy: 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: If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

- 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 of his product

Ask a doctor before use if you have liver disease

Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin.

#### Stop use and ask a doctor if:

- esymptoms do not improve new symptoms occur
- pain or fever persists or gets worse redness or swelling is present

If pregnant or breastfeeding, ask a health professional before use.

Keep Out Of Reach Of Children.

Overdose warning: Taking more than the recommended dose (overdose) may cause se 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 children even if you do not notice any signs or symptoms.

### Drug Facts (continued)

 Do not take more than directed (see overdose warning) Use the following dosage guidelines when using this product

AGE	DOSE
Adults and children	20.3 mL (650 mg) every 4 to 6 hours
12 years of age and over	Not to exceed 6 doses in a 24-hour period
Children 6 to under	10.15 mL (325 mg) every 4 hours
12 years of age	Not to exceed 5 doses in a 24-hour period
Children 4 to under	7.5 mL (240 mg) every 4 hours
6 years of age	Not to exceed 5 doses in a 24-hour period
Children 2 to under	5 mL (160 mg) every 4 hours
4 years of age	Not to exceed 5 doses in a 24-hour period
Children under 2 years of age	Consult a doctor

#### Other Information

- Each 5 mL contains: sodium 2 mg
   Store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature]
   Keep tightly closed \* Protect from light
- Keep tightly closed Protect from figure
   Do not use if foil on cup is missing or torn

#### Inactive ingredients:

Citric acid, FD&C Red No. 40, flavoring, glycerin, polyethylene glycol, purified water, saccharin sodium, sodium benzoate, sodium citrate, and sorbitol.

#### **Questions Or Comments?**

Call (800) 936-3088. You may also report serious side effects to this phone number.

#### **How Supplied**

A red, cherry flavored solution supplied in the following oral dosage cups:

NDC 39328-031-05: 5 mL unit dose cup NDC 39328-031-50: Case contains 50 unit dose cups of 5 mL (39328-031-05). NDC 39328-031-99: Case contains 100 unit dose cups of 5 mL (39328-031-05).

NDC 39328-032-10: 10.15 mL unit dose cup

NDC 39328-032-50: Case contains 50 unit dose cups of 10.15 mL (39328-032-10). NDC 39328-032-99: Case contains 100 unit dose cups of 10.15 mL (39328-032-10).

 NDC 39328-034-20:
 20.3 mL unit dose cup

 NDC 39328-034-50:
 Case contains 50 unit dose cups of 20.3 mL (39328-034-20).

 NDC 39328-034-99:
 Case contains 100 unit dose cups of 20.3 mL (39328-034-20).

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Rev 02.0424

### PRINCIPAL DISPLAY PANEL - 10.15 mL Cup Label

Delivers 10.15 mL NDC 39328-032-10 Acetaminophen Oral Solution USP 325 mg/10.15 mL

Alcohol Free For Institutional Use Only See Insert

Lot# xxxxxx Exp: yyyy/mm/dd Patrin Pharma Skokie, IL 60076 Rev 03.0324

Delivers 10.15 mL NDC 39328-032-10 Acetaminophen Oral Solution USP 325 mg/10.15 mL

Alcohol Free For Institutional Use Only See Insert

3932803210

Lot# xxxxxx Exp: yyyy/mm/dd Patrin Pharma Skokie, IL 60076 Rev 03.0324

## Acetaminophen Oral Solution USP

### Alcohol Free For Institutional Use Only **Drug Facts** Active ingredient (in each 5 mL) Purpose Acetaminophen 160 mg ... Pain reliever/fever reducer Temporarily relieves minor aches and pains due to: headache muscular aches • backache • minor pain of arthritis · toothache · premenstrual and menstrual cramps Liver warning: This product contains acetaminophen. Severe liver damage may occur if: an adult takes more than 6 doses in 24 hours, or greater than 4000 mg of acetaminophen, the maximum daily amount a child takes more than 5 doses in 24 hours taken with other drugs containing acetaminophen taken with 3 or more alcoholic drinks every day while using this product Allergy: Acetaminophen may cause severe skin reactions. Symptoms may include: eskin reddening e blisters e rash If a skin reaction occurs, stop use and seek medical help right away Sore throat: If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly. with any other drug containing acetaminophen (prescription or nonprescription). If you are not

sure whether a drug contains acetaminophen, ask a doctor or pharmacist

ofor 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 of his product

Ask a doctor before use if you have liver disease

Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin.

#### Stop use and ask a doctor if:

esymptoms do not improve •new symptoms occur

pain or fever persists or gets worse

redness or swelling is present

If pregnant or breastfeeding, ask a health professional before use.

Keen Out Of Reach Of Children

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 children even if you do not notice any signs or symptoms

### Drug Facts (continued)

#### Directions

Do not take more than directed (see overdose warning)
 Use the following dosage guidelines when using this product

AGE	DOSE
Adults and children	20.3 mL (650 mg) every 4 to 6 hours
12 years of age and over	Not to exceed 6 doses in a 24-hour period
Children 6 to under	10.15 mL (325 mg) every 4 hours
12 years of age	Not to exceed 5 doses in a 24-hour period
Children 4 to under	7.5 mL (240 mg) every 4 hours
6 years of age	Not to exceed 5 doses in a 24-hour period
Children 2 to under	5 mL (160 mg) every 4 hours
4 years of age	Not to exceed 5 doses in a 24-hour period
Children under 2 years of age	Consult a doctor

#### Other Information

Each 5 mL contains: sodium 2 mg Store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature]

Keep tightly closed • Protect from light Do not use if foil on cup is missing or torn

### Inactive Ingredients:

Citric acid, FD&C Red No. 40, flavoring, glycerin, polyethylene glycol, purified water, saccharin sodium, sodium benzoate, sodium citrate, and sorbitol.

#### **Questions Or Comments?**

Call (800) 936-3088. You may also report serious side effects to this phone number.

### **How Supplied**

. A red, cherry flavored solution supplied in the following oral dosage cups:

 NDC 39328-031-05:
 5 mL unit dose cup

 NDC 39328-031-50:
 Case contains 50 unit dose cups of 5 mL (39328-031-05).

 NDC 39328-031-99:
 Case contains 100 unit dose cups of 5 mL (39328-031-05).

NDC 39328-032-10: 10.15 mL unit dose cup NDC 39328-032-50: Case contains 50 unit do

Case contains 50 unit dose cups of 10.15 mL (39328-032-10). NDC 39328-032-99: Case contains 100 unit dose cups of 10.15 mL (39328-032-10).

NDC 39328-034-20: 20.3 mL unit dose cup

NDC 39328-034-50: Case contains 50 unit dose cups of 20.3 mL (39328-034-20). NDC 39328-034-99: Case contains 100 unit dose cups of 20.3 mL (39328-034-20).

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Rev 02 0424

## PRINCIPAL DISPLAY PANEL - 20.3 mL Cup Label

Delivers 20.3 mL NDC 39328-034-20 Acetaminophen Oral Solution USP

650 mg/20.3 mL Alcohol Free For Institutional Use Only See Insert

Lot# xxxxxx Exp: yyyy/mm/dd Patrin Pharma Skokie, IL 60076 Rev 03.0324

Delivers 20.3 mL NDC 39328-034-20 Acetaminophen Oral Solution USP 650 mg/20.3 mL

Alcohol Free For Institutional Use Only

See Insert 3932803420

Lot# xxxxxx Exp: yyyy/mm/dd Patrin Pharma

Skokie, IL 60076 Rev 03.0324

### Acetaminophen Oral Solution USP

Alcohol Free For Institutional Use Only

#### **Drug Facts**

Active ingredient (in each 5 mL) Acetaminophen 160 mg. . Pain reliever/fever reducer

#### Uses

emporarily relieves minor aches and pains due to:

- headache
- muscular aches
- backache
- minor pain of arthritis
   the common cold
- toothache
- premenstrual and menstrual cramps

Temporarily reduces fever

Liver warning: This product contains acetaminophen. Severe liver damage may occur if:
• an adult takes more than 6 doses in 24 hours, or greater than 4000 mg of acetaminophen, the

- maximum daily amount
   a child takes more than 5 doses in 24 hours
- taken with other drugs containing acetaminophen
   taken with 3 or more alcoholic drinks every day while using this product

Allergy: 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: If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor 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 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 of his product

Ask a doctor before use if you have liver disease.

Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin.

#### Stop use and ask a doctor if:

- esymptoms do not improve
- w symptoms occur
- pain or fever persists or gets worse
- redness or swelling is prese
- If pregnant or breastfeeding, ask a health professional before use.

Keep Out Of Reach Of Children

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 children even if you do not notice any signs or symptoms.

### Drug Facts (continued)

#### Directions

- Do not take more than directed (see overdose warning)
- · Use the following dosage guidelines when using this product

AGE	DOSE
Adults and children	20.3 mL (650 mg) every 4 to 6 hours
12 years of age and over	Not to exceed 6 doses in a 24-hour period
Children 6 to under	10.15 mL (325 mg) every 4 hours
12 years of age	Not to exceed 5 doses in a 24-hour period
Children 4 to under	7.5 mL (240 mg) every 4 hours
6 years of age	Not to exceed 5 doses in a 24-hour period
Children 2 to under	5 mL (160 mg) every 4 hours
4 years of age	Not to exceed 5 doses in a 24-hour period
Children under 2 years of age	Consult a doctor

#### Other Information

- Each 5 mL contains: sodium 2 mg Store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature]
- Keep tightly closed Protect from light
  Do not use if foil on cup is missing or torn

Inactive Ingredients:
Citric acid, FD&C Red No. 40, flavoring, glycerin, polyethylene glycol, purified water, saccharin sodium, sodium benzoate, sodium citrate, and sorbitol.

#### **Questions Or Comments?**

Call (800) 936-3088. You may also report serious side effects to this phone number.

### **How Supplied**

· A red, cherry flavored solution supplied in the following oral dosage cups:

NDC 39328-031-05:

NDC 39328-031-50: Case contains 50 unit dose cups of 5 mL (39328-031-05). NDC 39328-031-99: Case contains 100 unit dose cups of 5 mL (39328-031-05).

NDC 39328-032-10: 10.15 mL unit dose cup

Case contains 50 unit dose cups of 10.15 mL (39328-032-10). NDC 39328-032-50: Case contains 100 unit dose cups of 10.15 mL (39328-032-10). NDC 39328-032-99:

NDC 39328-034-20: 20.3 mL unit dose cup

Case contains 50 unit dose cups of 20.3 mL (39328-034-20). NDC 39328-034-50: NDC 39328-034-99: Case contains 100 unit dose cups of 20.3 mL (39328-034-20).

#### Patrin Pharma

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Rev 02.0424

### ACETAMINOPHEN SOLUTION

acetaminophen liquid

### **Product Information**

**Product Type** 

HUMAN OTC DRUG

Item Code (Source)

NDC:39328-031

<b>Active</b>	Ingredient/Active	Moiety
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Ingredient Name	<b>Basis of Strength</b>	Strength
Acetaminophen (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	Acetaminophen	160 mg in 5 mL

Inactive Ingredients			
Ingredient Name	Strength		
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)			
FD&C RED NO. 40 (UNII: WZB9127XOA)			
Glycerin (UNII: PDC6A3C0OX)			
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)			
WATER (UNII: 059QF0KO0R)			
Saccharin sodium (UNII: SB8ZUX40TY)			
Sodium benzoate (UNII: OJ245FE5EU)			
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)			
Sorbitol (UNII: 506T60A25R)			

Product Characteristics			
Color	RED	Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:39328- 031-50	5 in 1 CASE	09/27/2023	
1		10 in 1 TRAY		
1	NDC:39328- 031-05	5 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		
2	NDC:39328- 031-99	10 in 1 CASE	05/13/2024	
2		10 in 1 TRAY		
2	NDC:39328- 031-05	5 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	09/27/2023	

# **ACETAMINOPHEN SOLUTION**

acetaminophen liquid

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:39328-032	
Route of Administration	ORAL			

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
Acetaminophen (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII: 36209ITL9D)	Acetaminophen	325 mg in 10.15 mL

Inactive Ingredients	
Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
Glycerin (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
WATER (UNII: 059QF0KO0R)	
Saccharin sodium (UNII: SB8ZUX40TY)	
Sodium benzoate (UNII: OJ245FE5EU)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
Sorbitol (UNII: 506T60A25R)	

<b>Product Characteristics</b>			
Color RED Score			
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

P	ackaging				
#	# Item Code Package Description Marketing Start Date Date				
1	NDC:39328- 032-50	5 in 1 CASE	09/27/2023		
1		10 in 1 TRAY			
1	NDC:39328- 032-10	10.15 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product			
2	NDC:39328- 032-99	10 in 1 CASE	05/13/2024		
2		10 in 1 TRAY			
2	NDC:39328- 032-10	10.15 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	09/27/2023	

# **ACETAMINOPHEN SOLUTION**

acetaminophen liquid

<b>Product Information</b>			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:39328-034
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	<b>Basis of Strength</b>	Strength
Acetaminophen (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	Acetaminophen	650 mg in 20.3 mL

Inactive Ingredients	
Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
Glycerin (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
WATER (UNII: 059QF0KO0R)	
Saccharin sodium (UNII: SB8ZUX40TY)	
Sodium benzoate (UNII: OJ245FE5EU)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
Sorbitol (UNII: 506T60A25R)	

Product Characteristics			
Color	RED	Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:39328- 034-50	5 in 1 CASE	10/16/2023	
1		10 in 1 TRAY		
1	NDC:39328- 034-20	20.3 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		

NDC:3932 034-99	8- 10 in 1 CASE	05/13/2024
2	10 in 1 TRAY	
NDC:3932	8- 20.3 mL in 1 CUP, UNIT-DOSE Combination Product	; Type 0: Not a

Marketing End Date

# Labeler - Patrin Pharma, Inc. (806841677)

Revised: 5/2024 Patrin Pharma, Inc.