

CETIRIZINE HYDROCHLORIDE- cetirizine hydrochloride solution
BAJAJ MEDICAL, LLC

HIVES

Children's Cetirizine Hydrochloride 1 mg/mL Oral Solution, USP
6 yrs. & older

Drug Facts

Active Ingredient (in each 5 mL teaspoonful)

Cetirizine hydrochloride, USP 5 mg

Purpose

Antihistamine

Uses

reduces hives and relieves itching due to hives (urticaria). This product will not prevent hives or an allergic skin reaction from occurring.

Warnings

Severe Allergy Warning

Severe Allergy Warning: Get emergency help **immediately** if you have hives along with any of the following symptoms:

- trouble swallowing
- dizziness or loss of consciousness
- swelling of tongue
- swelling in or around mouth
- trouble speaking
- drooling
- wheezing or problems breathing

These symptoms may be signs of anaphylactic shock. This condition can be life threatening if not treated by a health professional **immediately**. Symptoms of anaphylactic shock may occur when hives first appear or up to a few hours later.

Not a Substitute for Epinephrine. If your doctor has prescribed an epinephrine injector for "anaphylaxis" or severe allergy symptoms that could occur with your hives, never use this product as a substitute for the epinephrine injector. If you have been prescribed an epinephrine injector, you should carry it with you at all times.

Do not use

Do not use

■ to **prevent** hives from any known cause such as:

- foods
- insect stings
- medicines
- latex or rubber gloves

because this product will not stop hives from occurring. Avoiding the cause of your hives is the only way to prevent them. Hives can sometimes be serious. If you do not know the cause of your hives, see your doctor for a medical exam. Your doctor may be able to help you find a cause.

■ if you have ever had an allergic reaction to this product or any of its ingredients or to an antihistamine containing hydroxyzine.

Ask a doctor before use if you have

- liver or kidney disease. Your doctor should determine if you need a different dose.
- hives that are an unusual color, look bruised or blistered
- hives that do not itch

Ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives.

When using this product

- drowsiness may occur
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery

Stop use and ask a doctor if

- an allergic reaction to this product occurs. Seek medical help right away.
- symptoms do not improve after 3 days of treatment
- the hives have lasted more than 6 weeks

If pregnant or breast-feeding:

- if breast-feeding: not recommended
- if pregnant: 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 toll-free number 1-800-222-1222.

Directions

- use with a dosing cup

adults and children 6 years and over	1 teaspoonful (5 mL) or 2 teaspoonfuls (10 mL) once daily depending upon severity of symptoms; do not take more than 2 teaspoonfuls (10 mL) in 24 hours.
adults 65	1 teaspoonful (5 mL) once daily; do not

years and over	take more than 1 teaspoonful (5 mL) in 24 hours.
children under 6 years of age	ask a doctor
consumers with liver or kidney disease	ask a doctor

Other information

Store between 20 to 25°C (68 to 77°F) or store refrigerated, 2 to 8°C (36 to 46°F)

Inactive ingredients

glacial acetic acid, glycerin, grape flavor, methylparaben, propylene glycol, propylparaben, purified water, sodium acetate, and sucrose

Questions or comments?

call toll-free **1-800-581-2528** weekdays

PRINCIPAL DISPLAY PANEL:

4 fl. oz. (120 mL) - NDC 61037-480-22

NDC 61037-480-22

***Children's* Cetirizine Hydrochloride 1 mg/mL Oral Solution, USP**

6 yrs. & older

Antihistamine

Grape Flavored

HIVES Relief

24 hour Relief of ITCHING

Due to Hives

4 fl. oz. (120 mL)

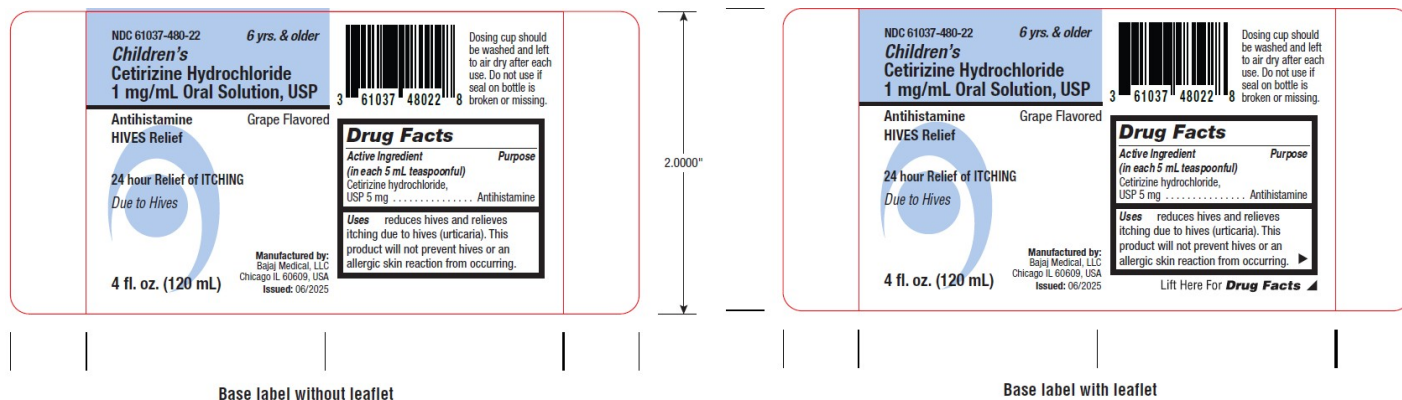
Dosing cup should be washed and left to air dry after each use. Do not use if seal on bottle is broken or missing.

Manufactured by:

Bajaj Medical, LLC

Chicago IL 60609, USA

Issued: 06/2025



Drug Facts (continued)

Warnings
Severe Allergy Warning: Get emergency help **immediately** if you have hives along with any of the following symptoms:

- trouble swallowing
- swelling of tongue
- trouble speaking
- wheezing or problems breathing
- dizziness or loss of consciousness
- swelling in or around mouth
- drooling

These symptoms may be signs of anaphylactic shock. This condition can be life threatening if not treated by a health professional **immediately**. Symptoms of anaphylactic shock may occur when hives first appear or up to a few hours later.

Not a Substitute for Epinephrine. If your doctor has prescribed an epinephrine injector for "anaphylaxis" or severe allergy symptoms that could occur with your hives, never use this product as a substitute for the epinephrine injector. If you have been prescribed an epinephrine injector, you should carry it with you at all times.

Drug Facts (continued)

Do not use

- to prevent hives from any known cause such as:
 - foods
 - insect stings
 - medicines
 - latex or rubber gloves

because this product will not stop hives from occurring. Avoiding the cause of your hives is the only way to prevent them. Hives can sometimes be serious. If you do not know the cause of your hives, see your doctor for a medical exam. Your doctor may be able to help you find a cause.

- If you have ever had an allergic reaction to this product or any of its ingredients or to an antihistamine containing hydroxyzine.

Ask a doctor before use if you have

- liver or kidney disease. Your doctor should determine if you need a different dose
- hives that are an unusual color, look bruised or blistered
- hives that do not itch

Ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives.

Drug Facts (continued)

When using this product

- drowsiness may occur
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery

Stop use and ask a doctor if

- an allergic reaction to this product occurs. Seek medical help right away.
- symptoms do not improve after 3 days of treatment
- the hives have lasted more than 6 weeks

If pregnant or breast-feeding:

- if breast-feeding: not recommended
- if pregnant: 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 toll-free number 1-800-222-1222.

Drug Facts (continued)

Directions • use with a dosing cup

adults and children 6 years and over	1 teaspoonful (5 mL) or 2 teaspoonfuls (10 mL) once daily depending upon severity of symptoms; do not take more than 2 teaspoonfuls (10 mL) in 24 hours.
adults 65 years and over	1 teaspoonful (5 mL) once daily; do not take more than 1 teaspoonful (5 mL) in 24 hours.
children under 6 years of age	ask a doctor
consumers with liver or kidney disease	ask a doctor

Other information
 Store between 20 to 25°C (68 to 77°F) or store refrigerated, 2 to 8°C (36 to 46°F)

Drug Facts (continued)

Inactive ingredients
 glacial acetic acid, glycerin, grape flavor, methylparaben, propylene glycol, propylparaben, purified water, sodium acetate, and sucrose

Questions or comments?
 call toll-free 1-800-581-2528 weekdays

Manufactured by:
 Bajaj Medical, LLC
 Chicago IL 60609, USA
 Issued: 06/2025

NDC 61037-480-22 6 yrs. & older
Children's Cetirizine Hydrochloride 1 mg/mL Oral Solution, USP

Antihistamine HIVES Relief Grape Flavored

24 hour Relief of ITCHING Due to Hives

4 fl. oz. (120 mL)

Manufactured by:
 Bajaj Medical, LLC
 Chicago IL 60609, USA
 Issued: 06/2025

Drug Facts

Active ingredient (in each 5 mL teaspoonful)
 Cetirizine hydrochloride, USP 5 mg

Purpose
 Antihistamine

Uses reduces hives and relieves itching due to hives (urticaria). This product will not prevent hives or an allergic skin reaction from occurring.

Lift Here For **Drug Facts**

PRINCIPAL DISPLAY PANEL:

16 fl. oz. (480 mL) - NDC 61037-480-23

NDC 61037-480-23

Children's Cetirizine Hydrochloride 1 mg/mL Oral Solution, USP

6 yrs. & older

Antihistamine

Grape Flavored

HIVES Relief

24 hour Relief of ITCHING

Due to Hives

16 fl. oz. (480 mL)

Dosing cup should be washed and left to air dry after each use. Do not use if seal on bottle is broken or missing.

Manufactured by:

Bajaj Medical, LLC

Chicago IL 60609, USA

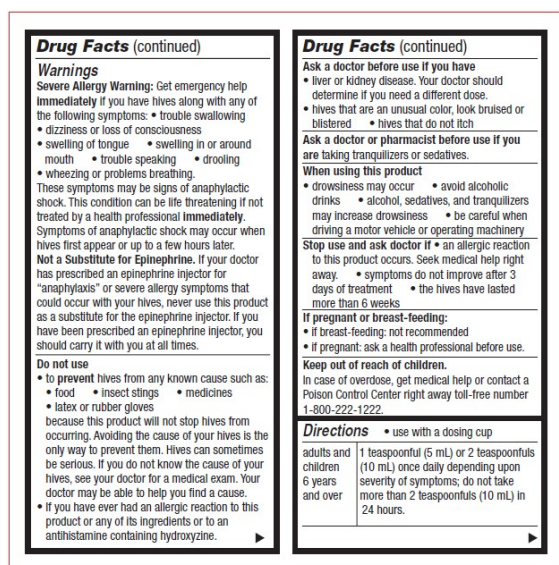
Issued: 06/2025



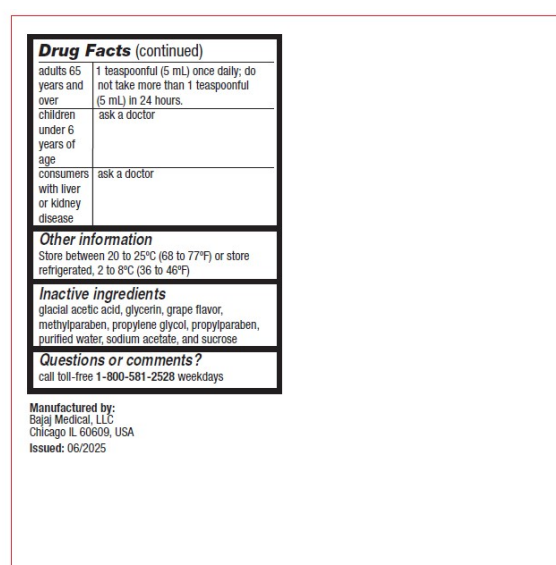
Base label without leaflet



Base label with leaflet



Leaflet Panel #1



Leaflet Panel #2

PRINCIPAL DISPLAY PANEL:

8 fl. oz. (240 mL) - NDC 61037-480-24

NDC 61037-480-24

Children's Cetirizine Hydrochloride 1 mg/mL Oral Solution, USP

6 yrs. & older

Antihistamine

Grape Flavored

HIVES Relief

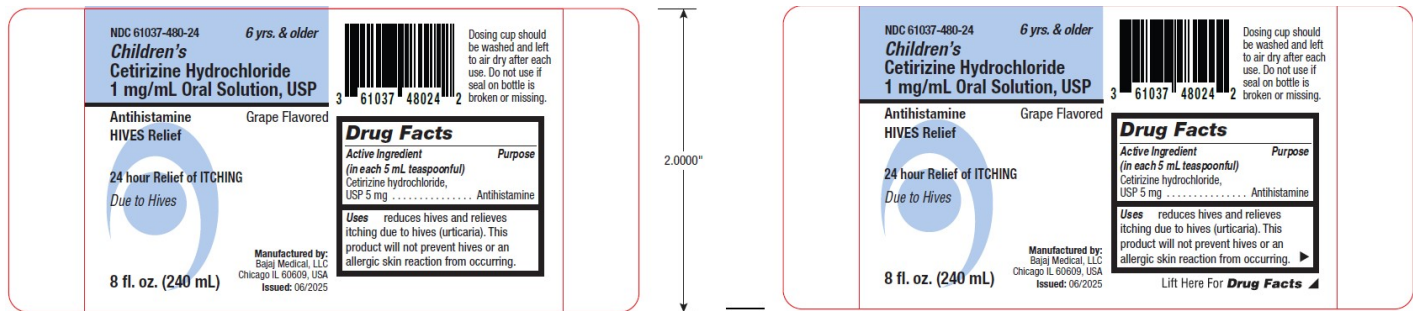
24 hour Relief of ITCHING

Due to Hives

8 fl. oz. (240 mL)

Dosing cup should be washed and left to air dry after each use. Do not use if seal on bottle is broken or missing.

Manufactured by:
Bajaj Medical, LLC
Chicago IL 60609, USA
Issued: 06/2025



Base label without leaflet

Base label with leaflet

Drug Facts (continued)

Warnings
Severe Allergy Warnings: Get emergency help immediately if you have hives along with any of the following symptoms:

- trouble swallowing
- swelling of tongue
- trouble speaking
- wheezing or problems breathing
- dizziness or loss of consciousness
- swelling in or around mouth
- drooling

These symptoms may be signs of anaphylactic shock. This condition can be life threatening if not treated by a health professional immediately. Symptoms of anaphylactic shock may occur when hives first appear or up to a few hours later.

Not a Substitute for Epinephrine. If your doctor has prescribed an epinephrine injector for "anaphylaxis" or severe allergy symptoms that could occur with your hives, never use this product as a substitute for the epinephrine injector. If you have been prescribed an epinephrine injector, you should carry it with you at all times.

Drug Facts (continued)

Do not use

- to prevent hives from any known cause such as:
 - foods
 - insect stings
 - medicines
 - latex or rubber gloves

because this product will not stop hives from occurring. Avoiding the cause of your hives is the only way to prevent them. Hives can sometimes be serious. If you do not know the cause of your hives, see your doctor for a medical exam. Your doctor may be able to help you find a cause.

- If you have ever had an allergic reaction to this product or any of its ingredients or to an antihistamine containing hydroxyzine.

Ask a doctor before use if you have

- liver or kidney disease. Your doctor should determine if you need a different dose
- hives that are an unusual color, look bruised or blistered
- hives that do not itch

Ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives.

Drug Facts (continued)

When using this product

- drowsiness may occur
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery

Stop use and ask a doctor if

- an allergic reaction to this product occurs. Seek medical help right away.
- symptoms do not improve after 3 days of treatment
- the hives have lasted more than 6 weeks

If pregnant or breast-feeding:

- if breast-feeding: not recommended
- if pregnant: 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 toll-free number 1-800-222-1222.

Drug Facts (continued)

Directions • use with a dosing cup

adults and children 6 years and over	1 teaspoonful (5 mL) or 2 teaspoonfuls (10 mL) once daily depending upon severity of symptoms; do not take more than 2 teaspoonfuls (10 mL) in 24 hours.
adults 65 years and over	1 teaspoonful (5 mL) once daily; do not take more than 1 teaspoonful (5 mL) in 24 hours.
children under 6 years of age	ask a doctor
consumers with liver or kidney disease	ask a doctor

Other information
Store between 20 to 25°C (68 to 77°F) or store refrigerated, 2 to 8°C (36 to 46°F)

Drug Facts (continued)

Inactive ingredients
glacial acetic acid, glycerin, grape flavor, methylparaben, propylene glycol, propylparaben, purified water, sodium acetate, and sucrose

Questions or comments?
call toll-free 1-800-581-2528 weekdays

Manufactured by:
Bajaj Medical, LLC
Chicago IL 60609, USA
Issued: 06/2025

NDC 61037-480-24 6 yrs. & older
Children's Cetirizine Hydrochloride 1 mg/mL Oral Solution, USP

Antihistamine HIVES Relief

Grape Flavored

24 hour Relief of ITCHING Due to Hives

8 fl. oz. (240 mL)

Manufactured by: Bajaj Medical, LLC, Chicago IL 60609, USA, Issued: 06/2025

Drug Facts

Active Ingredient (in each 5 mL teaspoonful) Cetirizine hydrochloride, USP 5 mg Purpose Antihistamine

Uses reduces hives and relieves itching due to hives (urticaria). This product will not prevent hives or an allergic skin reaction from occurring.

Lift Here For Drug Facts

PRINCIPAL DISPLAY PANEL:
5 mL - NDC 61037-480-32

NDC 61037-480-32

Children's Cetirizine Hydrochloride 1 mg/mL Oral Solution, USP

6 yrs. & older

Antihistamine

Grape Flavored

HIVES Relief

24 hour Relief of ITCHING

Due to Hives

100 Unit Dose Cups

(Each Cup Delivers 5 mL)

Do not use if seal on cup is broken or missing.

Manufactured by:
Bajaj Medical, LLC
Chicago IL 60609, USA
Issued: 06/2025

NDC 61037-480-32

6 yrs. & older

Children's

Cetirizine Hydrochloride

1 mg/mL Oral Solution, USP

Antihistamine

HIVES RELIEF

24 hour Relief of ITCHING

Due to Hives

Do not use if seal on cup is broken or missing.

100 Unit Dose Cups

(Each Cup Delivers 5 mL)

Grape Flavored

Manufactured by:

Bajaj Medical, LLC

Chicago IL 60609, USA

Issued: 06/2025

Drug Facts

Active Ingredient (in each 5 mL teaspoonful) Purpose

Cetirizine hydrochloride, USP 5 mg Antihistamine

Uses reduces hives and relieves itching due to hives (urticaria). This product will not prevent hives or an allergic skin reaction from occurring.

3

61037 48032

7

3.800"

Base label without leaflet

NDC 61037-480-32

6 yrs. & older

Children's

Cetirizine Hydrochloride

1 mg/mL Oral Solution, USP

Antihistamine

HIVES RELIEF

24 hour Relief of ITCHING

Due to Hives

Do not use if seal on cup is broken or missing.

100 Unit Dose Cups

(Each Cup Delivers 5 mL)

Grape Flavored

Manufactured by:

Bajaj Medical, LLC

Chicago IL 60609, USA

Issued: 06/2025

Drug Facts

Active Ingredient (in each 5 mL teaspoonful) Purpose

Cetirizine hydrochloride, USP 5 mg Antihistamine

Uses reduces hives and relieves itching due to hives (urticaria). This product will not prevent hives or an allergic skin reaction from occurring.

3

61037 48032

7

Lift Here For Drug Facts

Base label with leaflet

Drug Facts (continued)

Warnings

Severe Allergy Warning: Get emergency help immediately if you have hives along with any of the following symptoms: • trouble swallowing • dizziness or loss of consciousness • swelling of tongue • swelling in or around mouth • trouble speaking • drooling • wheezing or problems breathing. These symptoms may be signs of anaphylactic shock. This condition can be life threatening if not treated by a health professional immediately. Symptoms of anaphylactic shock may occur when hives first appear or up to a few hours later. Not a Substitute for Epinephrine. If your doctor has prescribed an epinephrine injector for "anaphylaxis" or severe allergy symptoms that could occur with your hives, never use this product as a substitute for the epinephrine injector. If you have been prescribed an epinephrine injector, you should carry it with you at all times.

Do not use

• to prevent hives from any known cause such as: • food • insect stings • medicines • latex or rubber gloves because this product will not stop hives from occurring. Avoiding the cause of your hives is the only way to prevent them. Hives can sometimes be serious. If you do not know the cause of your hives, see your doctor for a medical exam. Your doctor may be able to help you find a cause. • If you have ever had an allergic reaction to this product or any of its ingredients or to an antihistamine containing hydroxyzine.

Drug Facts (continued)

Ask a doctor before use if you have

• liver or kidney disease. Your doctor should determine if you need a different dose. • hives that are an unusual color, look bruised or blistered • hives that do not itch

Ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives.

When using this product

• drowsiness may occur • avoid alcoholic drinks • alcohol, sedatives, and tranquilizers may increase drowsiness • be careful when driving a motor vehicle or operating machinery

Stop use and ask doctor if • an allergic reaction to this product occurs. Seek medical help right away. • symptoms do not improve after 3 days of treatment • the hives have lasted more than 6 weeks

if pregnant or breast-feeding:

• if breast-feeding: not recommended • if pregnant: 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 toll-free number 1-800-222-1222.

Directions

• use with a dosing cup

adults and children 6 years and over

1 teaspoonful (5 mL) or 2 teaspoonfuls (10 mL) once daily depending upon severity of symptoms; do not take more than 2 teaspoonfuls (10 mL) in 24 hours.

Leaflet Panel #1

Drug Facts (continued)

adults 65 years and over

1 teaspoonful (5 mL) once daily; do not take more than 1 teaspoonful (5 mL) in 24 hours.

children under 6 years of age

ask a doctor

consumers with liver or kidney disease

ask a doctor

Other information

Store between 20 to 25°C (68 to 77°F) or store refrigerated, 2 to 8°C (36 to 46°F)

Inactive ingredients

glacial acetic acid, glycerin, grape flavor, methylparaben, propylene glycol, propylparaben, purified water, sodium acetate, and sucrose

Questions or comments?

call toll-free 1-800-581-2528 weekdays

Manufactured by:

Bajaj Medical, LLC

Chicago IL 60609, USA

Issued: 06/2025

Leaflet Panel #2

CETIRIZINE HYDROCHLORIDE

cetirizine hydrochloride solution

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61037-480
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
CETIRIZINE HYDROCHLORIDE (UNII: 64O047KTOA) (CETIRIZINE -		CETIRIZINE	1 mg

UNII:YO7261ME24)		HYDROCHLORIDE		in 1 mL	
Inactive Ingredients					
Ingredient Name				Strength	
SUCROSE (UNII: C151H8M554)					
SODIUM ACETATE (UNII: 4550K0SC9B)					
WATER (UNII: 059QF0KO0R)					
GLYCERIN (UNII: PDC6A3C0OX)					
ACETIC ACID (UNII: Q40Q9N063P)					
METHYLPARABEN (UNII: A2I8C7HI9T)					
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)					
PROPYLPARABEN (UNII: Z8IX2SC1OH)					
Product Characteristics					
Color			Score		
Shape			Size		
Flavor		GRAPE	Imprint Code		
Contains					
Packaging					
#	Item Code	Package Description		Marketing Start Date	Marketing End Date
1	NDC:61037-480-22	120 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		05/08/2025	
2	NDC:61037-480-23	480 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		05/08/2025	
3	NDC:61037-480-24	240 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		05/08/2025	
4	NDC:61037-480-26	5 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		05/08/2025	
5	NDC:61037-480-32	5 mL in 1 BOX, UNIT-DOSE; Type 0: Not a Combination Product		05/08/2025	
Marketing Information					
Marketing Category		Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
ANDA		ANDA091327		05/08/2025	

Labeler - BAJAJ MEDICAL, LLC (078774921)

Registrant - BAJAJ MEDICAL, LLC (078774921)

Establishment

Name	Address	ID/FEI	Business Operations
------	---------	--------	---------------------

BAJAJ MEDICAL, LLC		078774921	analysis(61037-480) , label(61037-480) , manufacture(61037-480) , pack(61037-480)
-----------------------	--	-----------	--

Revised: 6/2025

BAJAJ MEDICAL, LLC