BENZOYL PEROXIDE- benzoyl peroxide liquid
Burel Pharmaceuticals, LLC

BENZOYL PEROXIDE TOPICAL WASH

DRUG FACTS

Active Ingredient

benzoyl peroxide USP, 5% or 10%

Purpose

Acne medication

Use

- For the treatment of acne

Warnings:

For external use only.

- Avoid contact with eyes, eyelids, lips and mucous membranes.

Do not use if you

- have very sensitive skin
- are sensitive to benzoyl peroxide

When using this product

- **Avoid unnecessary sun exposure and use a sunscreen.**
- Avoid contact with eyes, lips, and mouth.
- Avoid contact with hair or dyed fabrics, which may be bleached by this product.
- Skin irritation may occur, characterized by redness, burning, itching, peeling, or possibly swelling.
- Irritation may be reduced by using the product less frequently or in a lower concentration.
- Skin irritation and dryness is more likely to occur if you use another topical acne medication at the same time. If irritation occurs, only use one topical acne medication at a time.
- **Stop use and ask a doctor if irritation becomes severe.**

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

SHAKE WELL.

- Clean the skin thoroughly before applying this product.
- ***Sensitivity Test for a New User.*** Apply product sparingly to one or two small affected areas during the first 3 days. If no discomfort occurs,follow the directions stated below.
- One to three times daily, wet skin and cover the entire affected area with a thin layer, liberally applying to areas to be cleansed. Massage gently into skin for 10-20 seconds working into a full lather, rinse thoroughly and pat dry.
- Because excessive drying of the skin may occur, start with one application daily, then gradually increase to two or three times daily if needed or as directed by a doctor.
- If bothersome dryness or peeling occurs, reduce application to once a day or every other day.
- **If going outside, apply sunscreen after using this product.**
- Follow directions in the sunscreen labeling.
- If irritation or sensitivity develops stop use of both products and ask a doctor.

Other information

Store at controlled room temperature, 15° - 30°C (59° - 86°F)

Inactive Ingredients

Carbomer interpolymer type A NF, cetyl alcohol NF, edetate disodium USP, glycerin USP, glyceryl stearate/PEG-100 stearate, laureth-12, magnesium aluminum silicate NF, propylene glycol USP, purified water USP, sodium coco-sulfate, sodium lauroamphoacetate, and xanthan gum NF.

Questions? Call 1-866-525-0688

Manufactured for:
Burel Pharmaceuticals, LLC
Mason, OH 45040 USA

Rev. 04/24

PRINCIPAL DISPLAY PANEL - 5% 5oz (148 g) Bottle Label

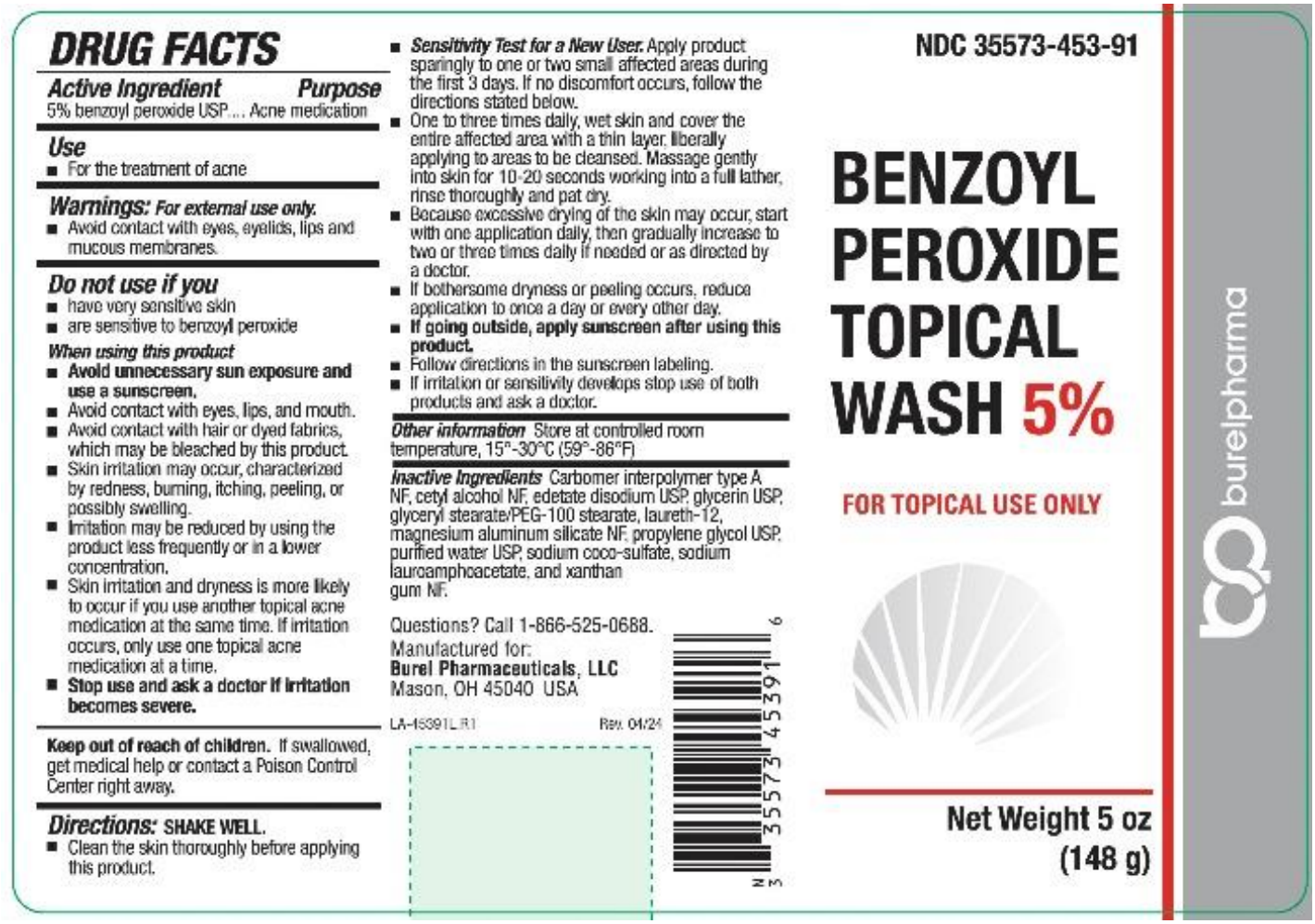
NDC 35573-453-91

**BENZOYL
PEROXIDE
TOPICAL
WASH 5%**

FOR TOPICAL USE ONLY

**Net Weight 5 oz
(148 g)**

burelpharma



PRINCIPAL DISPLAY PANEL - 5% 8oz (237 g) Bottle Label

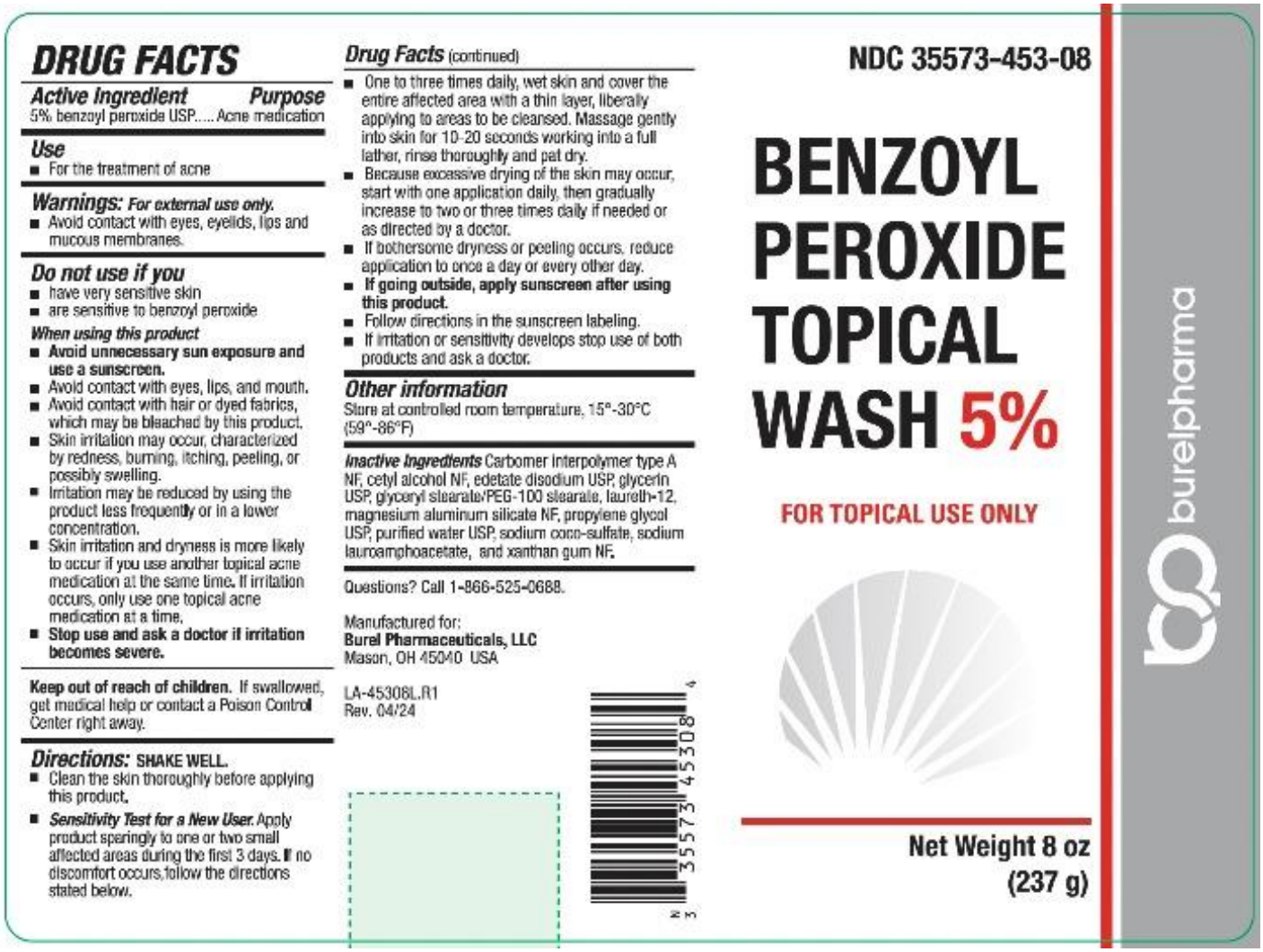
NDC 35573-453-08

**BENZOYL
PEROXIDE
TOPICAL
WASH 5%**

FOR TOPICAL USE ONLY

**Net Weight 8 oz
(237 g)**

burelpharma



PRINCIPAL DISPLAY PANEL - 10% 5oz (148 g) Bottle Label

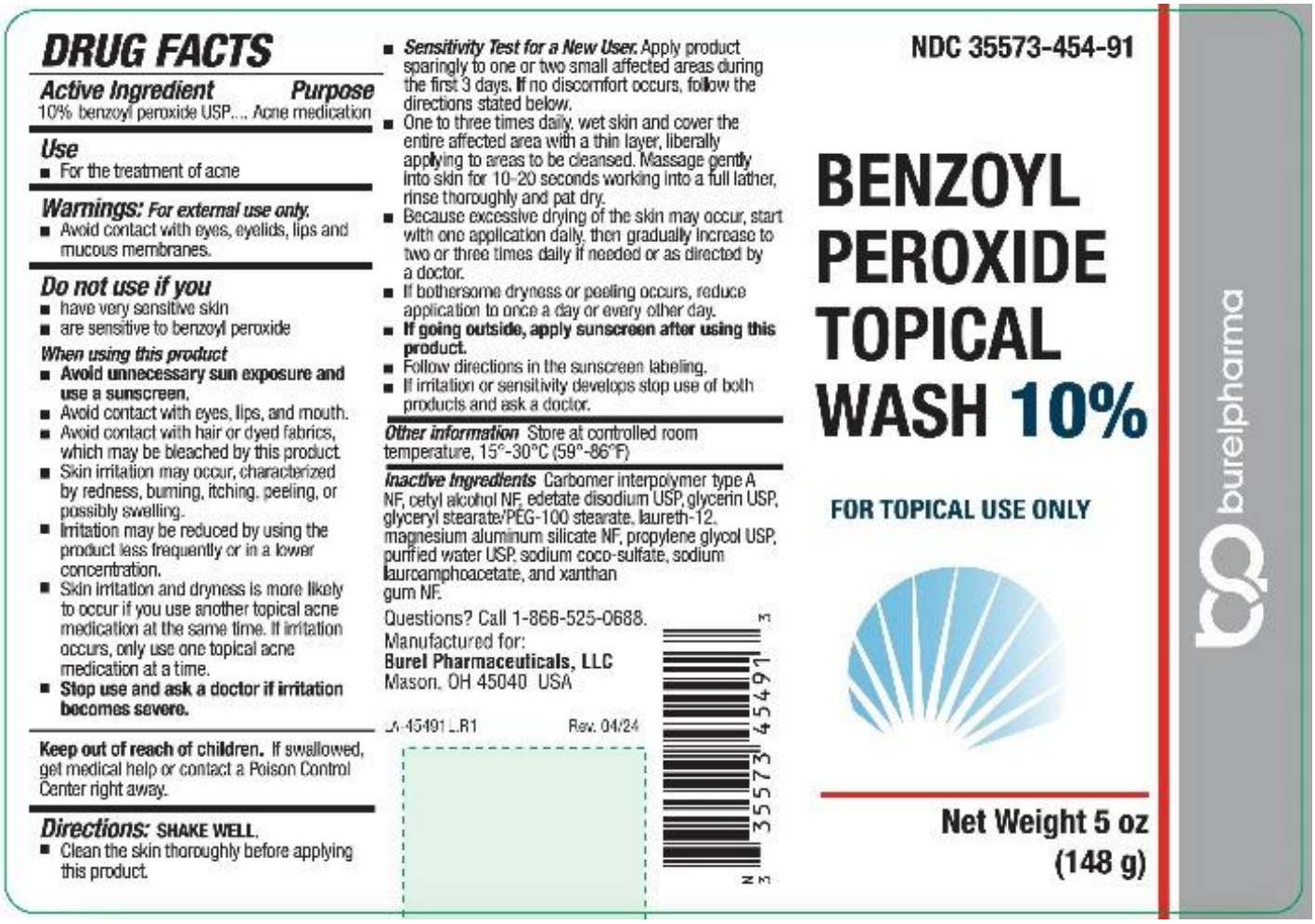
NDC 35573-454-91

**BENZOYL
PEROXIDE
TOPICAL
WASH 10%**

FOR TOPICAL USE ONLY

**Net Weight 5 oz
(148 g)**

burelpharma



PRINICIPAL DISPLAY PANEL - 10% 8oz (237 g) Bottle Label

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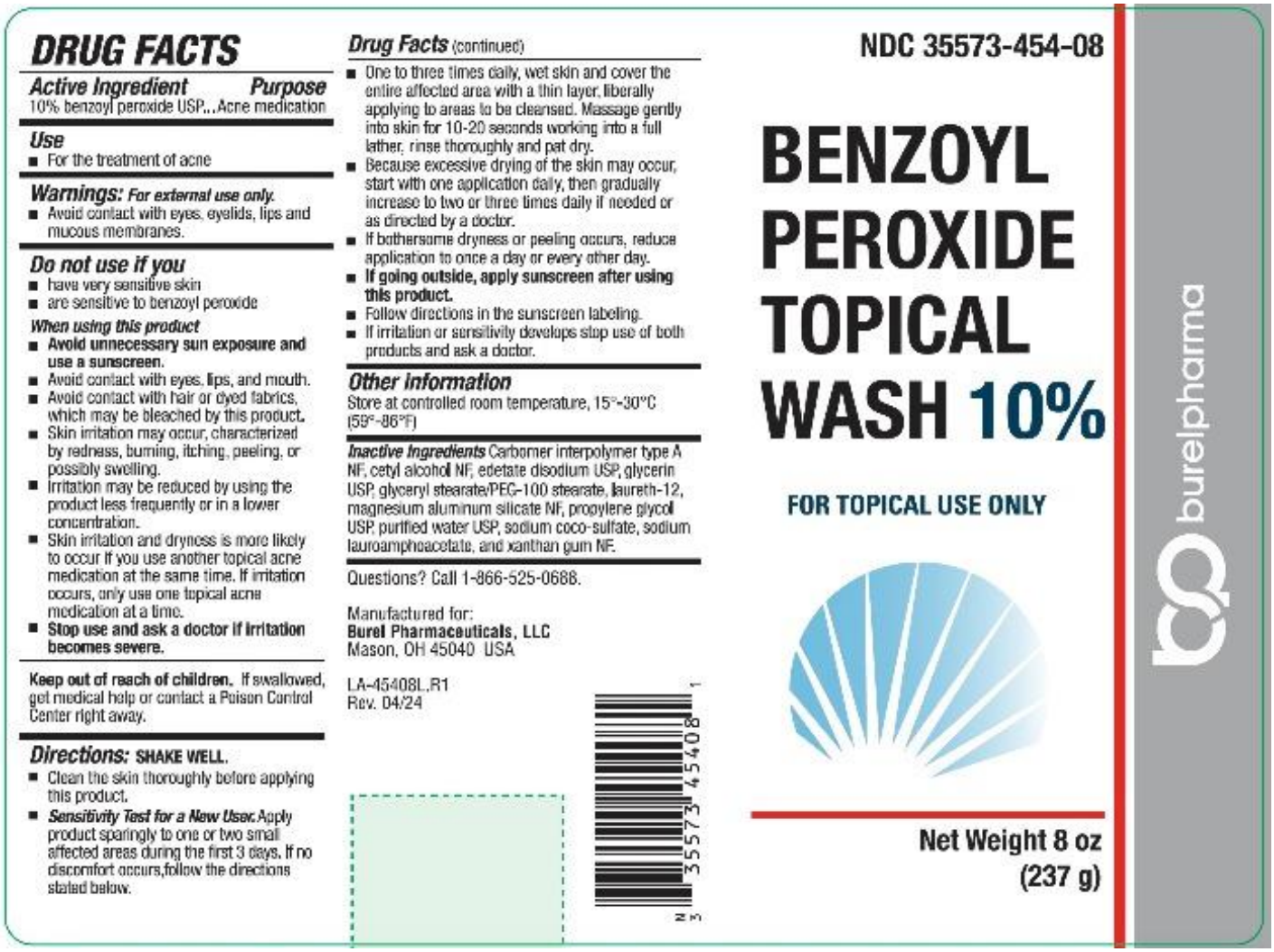

BENZOYL PEROXIDE

benzoyl peroxide liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:35573-453
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Benzoyl Peroxide (UNII: W9WZN9A0GM) (Benzoyl Peroxide - UNII:W9WZN9A0GM)	Benzoyl Peroxide	50 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
cetyl alcohol (UNII: 936JST6JCN)	
edetate disodium (UNII: 7FLD91C86K)	

glycerin (UNII: PDC6A3C0OX)	
GLYCERYL STEARATE/PEG-100 STEARATE (UNII: RD25J5V947)	
laureth-12 (UNII: OAH19558U1)	
magnesium aluminum silicate (UNII: 6M3P64V0NC)	
propylene glycol (UNII: 6DC9Q167V3)	
water (UNII: 059QF0KO0R)	
sodium coco-sulfate (UNII: 3599J29ANH)	
sodium lauroamphoacetate (UNII: SLK428451L)	
xanthan gum (UNII: TTV12P4NEE)	

Product Characteristics

Color	white (viscous)	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:35573-453-91	148 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/15/2022	
2	NDC:35573-453-08	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/15/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M006	04/15/2022	

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Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Benzoyl Peroxide (UNII: W9WZN9A0GM) (Benzoyl Peroxide - UNII:W9WZN9A0GM)	Benzoyl Peroxide	100 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
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edetate disodium (UNII: 7FLD91C86K)	
glycerin (UNII: PDC6A3C0OX)	
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Labeler - Burel Pharmaceuticals, LLC (609436204)

Establishment

Name	Address	ID/FEI	Business Operations
Groupe PARIMA Inc.		252437850	label(35573-453, 35573-454) , manufacture(35573-453, 35573-454) , pack(35573-453, 35573-454)

Revised: 4/2024 Burel Pharmaceuticals, LLC