BACITRACIN- bacitracin ointment
Paddock Laboratories, LLC

Bacitracin Ophthalmic Ointment USP

STERILE Rx Only

DESCRIPTION:

Each gram of ointment contains 500 units of Bacitracin in a low melting special base containing White Petrolatum and Mineral Oil.

CLINICAL PHARMACOLOGY:

The antibiotic, Bacitracin, exerts a profound action against many gram-positive pathogens, including the common Streptococci and Staphlococci. It is also destructive for certain gram-negative organisms. It is ineffective against fungi.

INDICATIONS AND USAGE:

For the treatment of superficial ocular infections involving the conjunctiva and/or cornea caused by Bacitracin susceptible organisms.

CONTRAINDICATIONS:

This product should not be used in patients with a history of hypersensitivity to Bacitracin.

PRECAUTIONS:

Bacitracin ophthalmic ointment should not be used in deep-seated ocular infections or in those that are likely to become systemic. The prolonged use of antibiotic containing preparations may result in overgrowth of nonsusceptible organisms particularly fungi. If new infections develop during treatment appropriate antibiotic or chemotherapy should be instituted.

ADVERSE REACTIONS:

Bacitracin has such a low incidence of allergenicity that for all practical purposes side reactions are practically non-existent. However, if such reaction should occur, therapy should be discontinued.

To report SUSPECTED ADVERSE REACTIONS, contact Perrigo at 1-866-634-9120 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DOSAGE AND ADMINISTRATION:

The ointment should be applied directly into the conjunctival sac 1 to 3 times daily. In blepharitis all scales and crusts should be carefully removed and the ointment then spread uniformly over the lid margins. Patients should be instructed to take appropriate measures to avoid gross contamination of the ointment when applying the ointment directly to the infected eye.

HOW SUPPLIED:

NDC 0574-**4022**-13 3 – 1 g sterile tamper evident tubes with ophthalmic tip.

NDC 0574-**4022**-35 3.5 g (1/8 oz.) sterile tamper evident tubes with ophthalmic tip.

Store at 20°-25°C (68°-77°F) [see USP Controlled Room Temperature].

Manufactured For

Perrigo®

Minneapolis, MN 55427

0S400 RC J1

Rev 08-13 A

R0813

Ini0813

PACKAGE/LABEL PRINCIPAL DISPLAY PANEL – 1 g Carton (Sample Only)

Rx Only

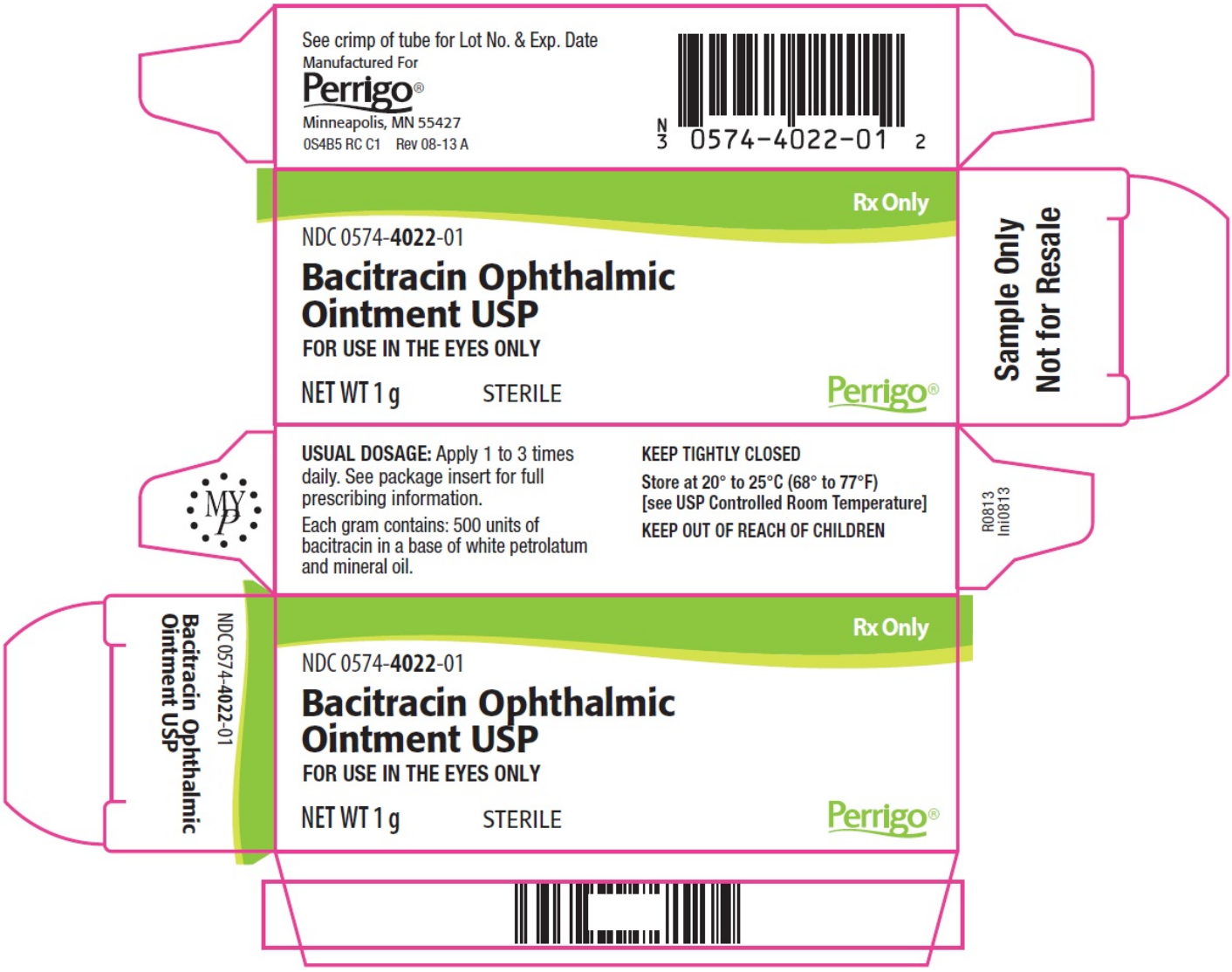
NDC 0574-4022-01

Bacitracin Ophthalmic Ointment USP

FOR USE IN THE EYES ONLY

NET WT 1 g

STERILE



PACKAGE/LABEL PRINCIPAL DISPLAY PANEL – 1 g Label

Rx Only

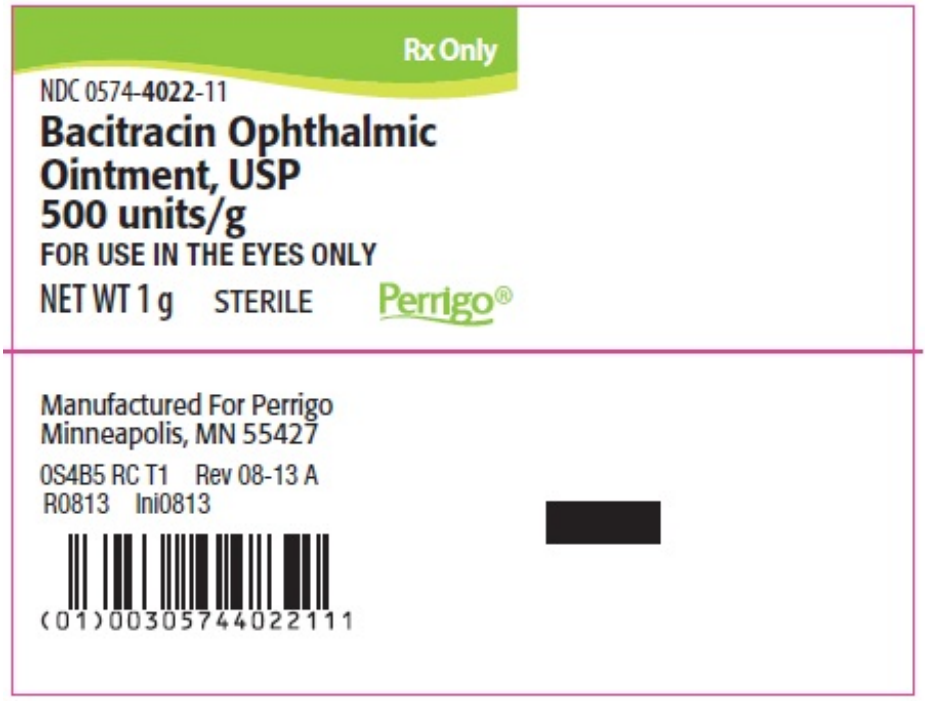
NDC 0574-4022-11

Bacitracin Ophthalmic Ointment, USP 500 units/g

FOR USE IN THE EYES ONLY

NET WT 1 g

STERILE



PACKAGE/LABEL PRINCIPAL DISPLAY PANEL – 3 – 1 g Tube Carton

Rx Only

NDC 0574-4022-13

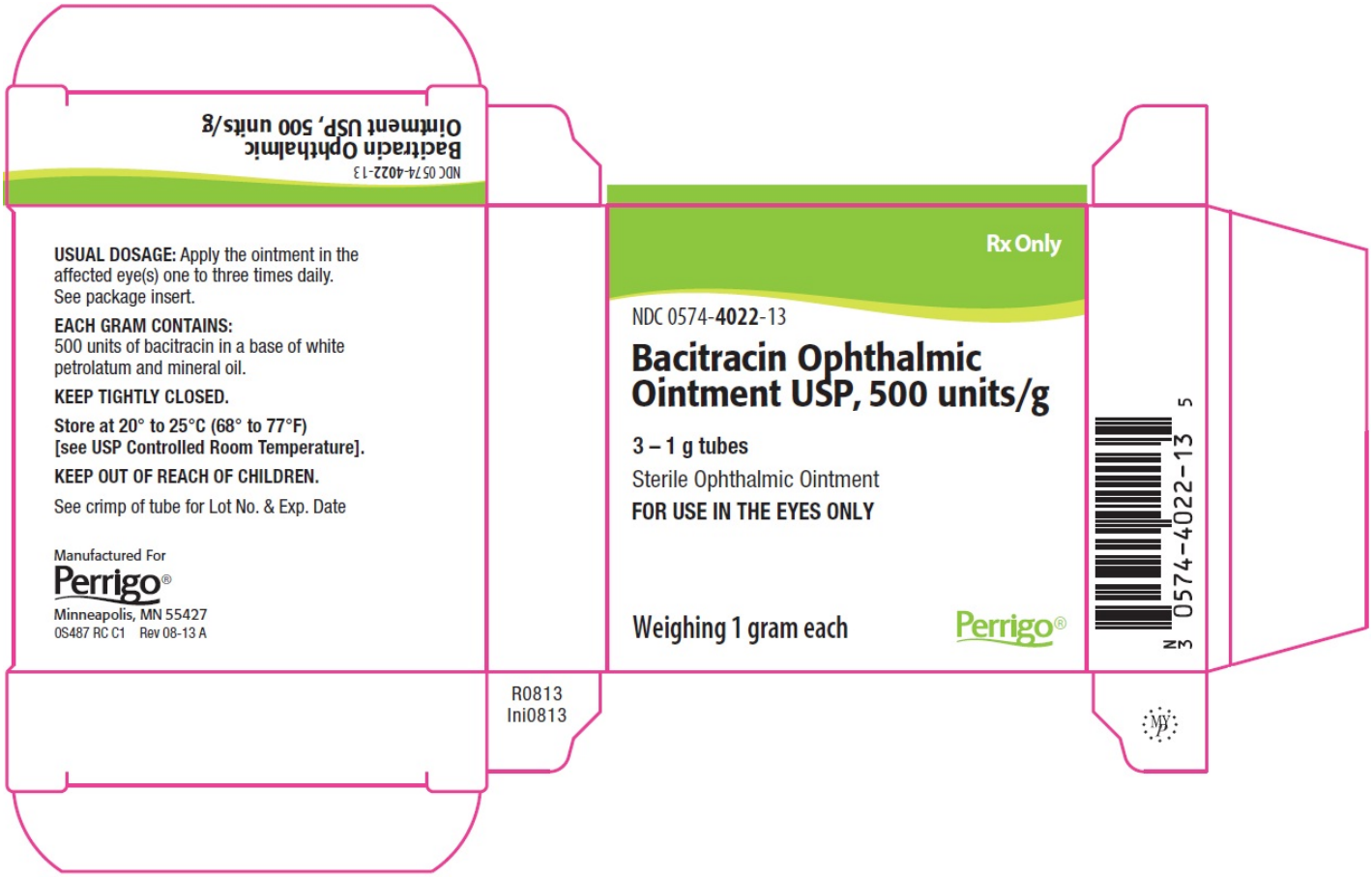
Bacitracin Ophthalmic Ointment USP, 500 units/g

3 – 1 g tubes

Sterile Ophthalmic Ointment

FOR USE IN THE EYES ONLY

Weighing 1 gram each



PACKAGE/LABEL PRINCIPAL DISPLAY PANEL – 1 g Label

Rx Only

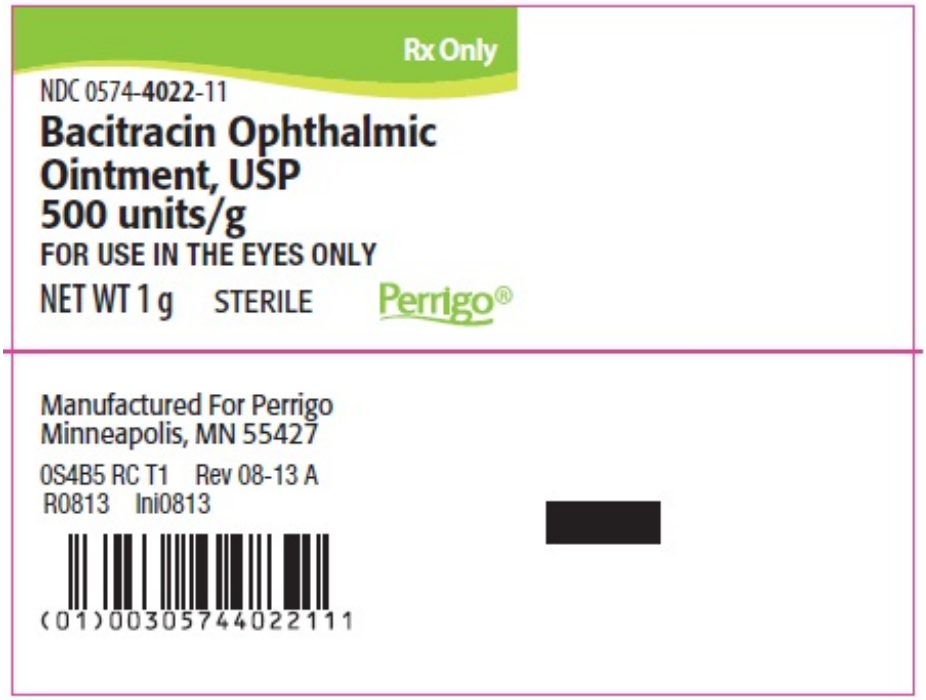
NDC 0574-4022-11

Bacitracin Ophthalmic Ointment, USP 500 units/g

FOR USE IN THE EYES ONLY

NET WT 1 g

STERILE



PACKAGE/LABEL PRINCIPAL DISPLAY PANEL – 3.5 g Carton

Rx Only

NDC 0574-4022-35

Bacitracin Ophthalmic Ointment USP

NET WT 3.5 g (1/8 oz)

STERILE

PACKAGE/LABEL PRINCIPAL DISPLAY PANEL – 3.5 g Label

Rx Only

NDC 0574-4022-35

Bacitracin Ophthalmic Ointment USP

NET WT 3.5 g (1/8 oz)

STERILE

BACITRACIN

bacitracin ointment

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0574-4022
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BACITRACIN (UNII: 58H6RWO52I) (BACITRACIN - UNII:58H6RWO52I)	BACITRACIN	500 [USP'U] in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
PETROLATUM (UNII: 4T6H12BN9U)	
MINERAL OIL (UNII: T5L8T28FGP)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0574-4022-01	1 in 1 CARTON		
1	NDC:0574-4022-11	1 g in 1 TUBE		
2	NDC:0574-4022-13	3 in 1 CARTON		
2	NDC:0574-4022-11	1 g in 1 TUBE		
3	NDC:0574-4022-35	1 in 1 CARTON		
3		3.5 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA061212	03/10/2014	

Labeler - Paddock Laboratories, LLC (967694121)

Revised: 12/2013 Paddock Laboratories, LLC