DESONIDE- desonide ointment
Alembic Pharmaceuticals Inc.

Desonide Ointment USP, 0.05%

For Dermatologic Use Only

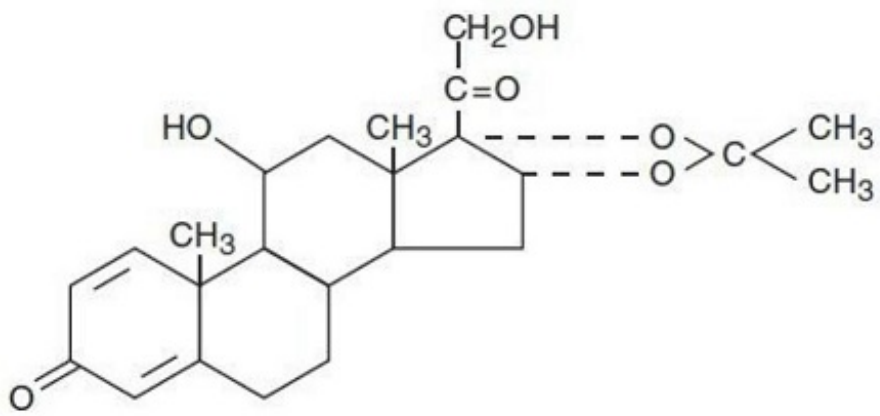
Not for Ophthalmic Use

Rx Only

DESCRIPTION

Desonide ointment USP, 0.05% contains desonide (Pregna-1,4-diene-3,20-dione,11,21-dihydroxy-16,17-[(1-methylethylidene)bis(oxy)]-,(11β,16α)) a synthetic corticosteroid for topical dermatologic use. The corticosteroids constitute a class of primary synthetic steroids used topically as anti-inflammatory and antipruritic agents.

Chemically, desonide, the active ingredient in desonide ointment USP, 0.05% is $C_{24}H_{32}O_6$. It has the following structural formula:



The molecular weight of desonide is 416.51. It is white to off-white powder. The solubility of desonide in distilled water saturated with the ether is 184 mg/L.

Each gram of desonide ointment USP, 0.05% contains 0.5 mg of desonide microdispersed in a base of white petrolatum.

CLINICAL PHARMACOLOGY

Like other topical corticosteroids, desonide has anti-inflammatory, antipruritic, and vasoconstrictive properties. The mechanism of the anti-inflammatory activity of the topical steroids, in general, is unclear. However, corticosteroids are thought to act by the induction of phospholipase A_2 inhibitory proteins, collectively called, lipocortins. It is postulated that these proteins control the biosynthesis of potent mediators of inflammation such as prostaglandins and leukotrienes by inhibiting the release of their

common precursor arachidonic acid. Arachidonic acid is released from membrane phospholipids by phospholipase A_2.

Pharmacokinetics -

The extent of percutaneous absorption of topical corticosteroids is determined by many factors, including the vehicle and the integrity of the epidermal barrier. Occlusive dressings with hydrocortisone for up to 24 hours have not been demonstrated to increase penetration; however, occlusion of hydrocortisone for 96 hours markedly enhances penetration. Topical corticosteroids can be absorbed from normal intact skin. Inflammation and/or other disease processes in the skin may increase percutaneous absorption.

Studies performed with desonide ointment USP, 0.05% indicate that it is in the low range of potency as compared with other topical corticosteroids.

INDICATIONS AND USAGE

Desonide ointment USP, 0.05% is a low potency corticosteroid indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid responsive dermatoses.

It should not be used for longer than two weeks unless directed by a physician.

CONTRAINDICATIONS

Desonide ointment USP, 0.05% is contraindicated in those patients with a history of hypersensitivity to any of the components of the preparation.

PRECAUTIONS

General -

Systemic absorption of topical corticosteroids can produce reversible hypothalamic-pituitary-adrenal (HPA) axis suppression with the potential for glucocorticosteroid insufficiency after withdrawal of treatment. Manifestations of Cushing's syndrome, hyperglycemia, and glucosuria can also be produced in some patients by systemic absorption of topical corticosteroids while on treatment.

Patients applying a topical steroid to a large surface area or to areas under occlusion should be evaluated periodically for evidence of HPA axis suppression. This may be done by using the ACTH stimulation, A.M. plasma cortisol, and urinary free cortisol tests. Patients receiving superpotent corticosteroids should not be treated for more than two weeks at a time and only small areas should be treated at any one time due to the increased risk of HPA suppressions.

No specific studies relevant to potential HPA suppression have been conducted with desonide ointment USP, 0.05%.

If HPA axis suppression is noted, an attempt should be made to withdraw the drug, to reduce the frequency of application, or to substitute a less potent corticosteroid. Recovery of HPA axis function is generally prompt upon discontinuation of topical corticosteroids. Infrequently, signs and symptoms of glucocorticosteroid insufficiency may occur requiring supplemental systemic corticosteroids. For information on systemic

supplementation, see prescribing information for those products.

Pediatric patients may be more susceptible to systemic toxicity from equivalent doses due to their larger skin surface to body mass ratios (see **PRECAUTIONS - Pediatric Use**).

If irritation develops, desonide ointment USP, 0.05% should be discontinued and appropriate therapy instituted. Allergic contact dermatitis with corticosteroids is usually diagnosed by observing a failure to heal rather than noting a clinical exacerbation as with most topical products not containing corticosteroids. Such an observation should be corroborated with appropriate diagnostic patch testing.

If concomitant skin infections are present or develop, an appropriate antifungal or antibacterial agent should be used. If a favorable response does not occur promptly, use of desonide ointment USP, 0.05% should be discontinued until the infection has been adequately controlled.

Desonide ointment USP, 0.05% should not be used in the presence of infection at the treatment site, hypersensitivity to corticosteroids, or pre-existing skin atrophy.

Desonide ointment USP, 0.05% should not be used in the eyes.

FOR EXTERNAL USE ONLY.

Information for Patients

Patients using topical corticosteroids should receive the following information and instructions:

1. This medication is to be used as directed by the physician. It is for external use only. Avoid contact with the eyes.

2. This medication should not be used for any disorder other than that for which it was prescribed.

3. The treated skin area should not be bandaged, otherwise covered or wrapped, so as to be occlusive unless directed by the physician.

4. Patients should report to their physician any signs of local adverse reactions.

Laboratory Tests –

The following tests may be helpful in evaluating patients for HPA axis suppression:

ACTH stimulation test

A.M. plasma cortisol test

Urinary free cortisol test

Carcinogenesis, Mutagenesis, Impairment of Fertility -

Long-term animal studies have not been performed to evaluate the carcinogenic, mutagenic, or fertility impairment potential of desonide ointment USP, 0.05%.

Pregnancy:

Teratogenic Effects:

Pregnancy Category C –

Corticosteroids have been shown to be teratogenic in laboratory animals when administered systemically at relatively low dosage levels. Some corticosteroids have been shown to be teratogenic after dermal application in laboratory animals. Animal reproductive studies have not been conducted with desonide ointment USP, 0.05%. It is also not known whether desonide ointment USP, 0.05% can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. There are no adequate and well-controlled studies in pregnant women. Desonide ointment USP, 0.05% should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers –

Systemically administered corticosteroids appear in human milk and could suppress growth, interfere with endogenous corticosteroid production, or cause other untoward effects. It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in human milk. Because many drugs are excreted in human milk, caution should be exercised when desonide ointment USP, 0.05% is administered to a nursing woman.

Pediatric Use –

Safety and effectiveness in pediatric patients have not been established. Because of a higher ratio of skin surface area to body mass, pediatric patients are at a greater risk than adults of HPA axis suppression and Cushing's syndrome when they are treated with topical corticosteroids. They are therefore also at greater risk of adrenal insufficiency during or after withdrawal of treatment.

Adverse effects including striae have been reported with inappropriate use of topical corticosteroids in infants and children.

HPA axis suppression, Cushing's syndrome, linear growth retardation, delayed weight gain and intracranial hypertension have been reported in children receiving topical corticosteroids. Manifestations of adrenal suppression in children include low plasma cortisol levels and absence of response to ACTH stimulation.

Manifestations of intracranial hypertension include bulging fontanelles, headaches, and bilateral papilledema.

ADVERSE REACTIONS

In controlled clinical trials, the total incidence of adverse reactions associated with the use of desonide ointment USP, 0.05% was approximately 6%. These adverse reactions were erythema, induration, pruritus, irritation, oiliness, and peripheral edema.

The following additional local adverse reactions have been reported infrequently with topical corticosteroids, and they may occur more frequently with the use of occlusive dressings and higher potency corticosteroids. These reactions are listed in approximate decreasing order of occurrence: dryness, folliculitis, acneiform eruptions, perioral dermatitis, allergic contact dermatitis, secondary infection, skin atrophy, striae, miliaria, burning and hypopigmentation.

To report SUSPECTED ADVERSE REACTIONS, contact Alembic Pharmaceuticals, Inc. at 1-866-210-9797 or FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch*.

OVERDOSAGE

Topically applied desonide ointment USP, 0.05% can be absorbed in sufficient amounts to produce systemic effects (see **PRECAUTIONS**).

DOSAGE AND ADMINISTRATION

Desonide ointment USP, 0.05% should be applied to the affected area as a thin film from two to four times daily depending on the severity of the condition.

As with other corticosteroids, therapy should be discontinued when control is achieved. If no improvement is seen within two weeks, reassessment of diagnosis may be necessary.

Desonide ointment USP, 0.05% should not be used with occlusive dressings.

HOW SUPPLIED

Desonide Ointment USP, 0.05% is available as follows:

15 g tube (NDC 62332-485-15)

60 g tube (NDC 62332-485-60)

STORAGE

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

Manufactured for:

Alembic Pharmaceuticals, Inc.

Bedminster, NJ 07921, USA

Manufactured by:

Alembic Pharmaceuticals Limited

(Derma Division),

Karakhadi, Vadodara 391450, India.

Mfg. License No.: G/25/2216

Revised: 7/2025

PRINCIPAL DISPLAY PANEL

Rx Only

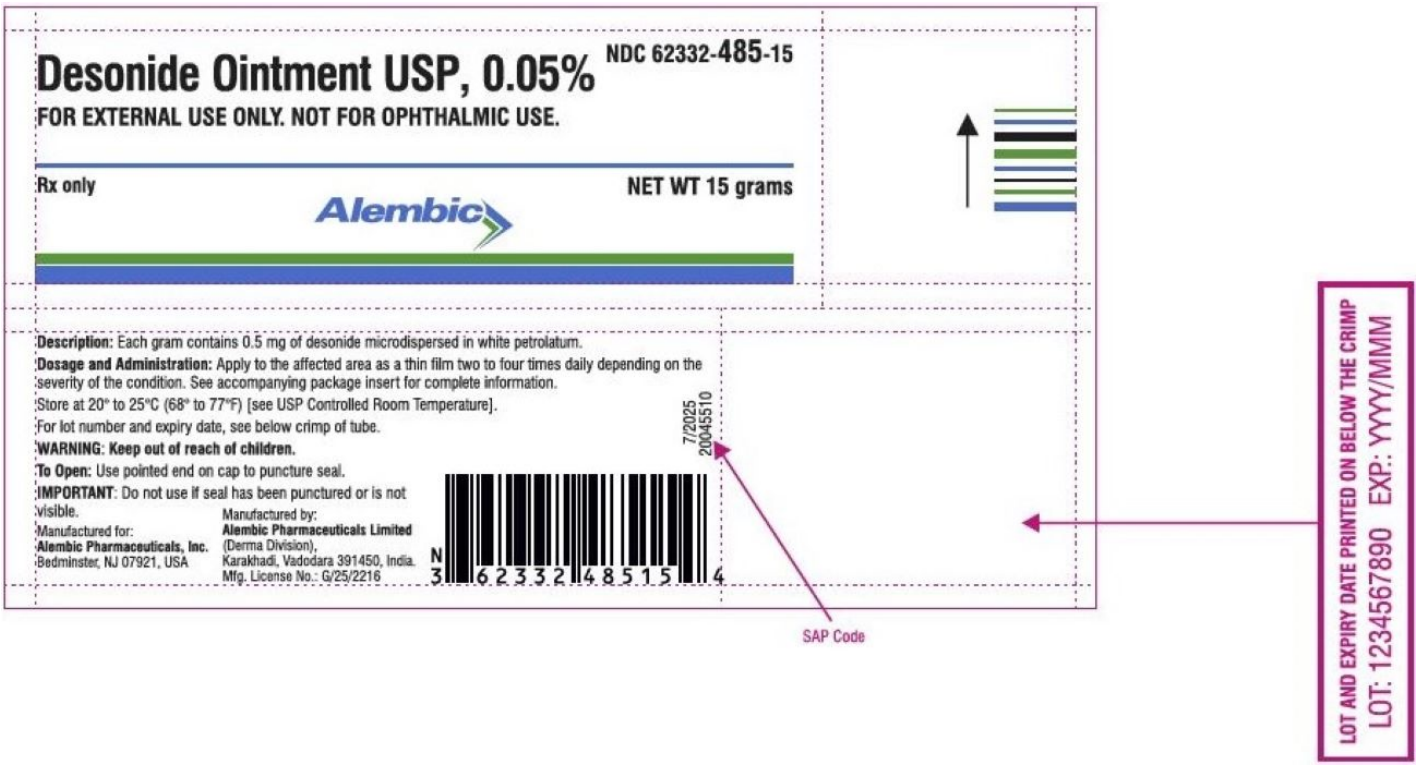
NDC 62332-485-15

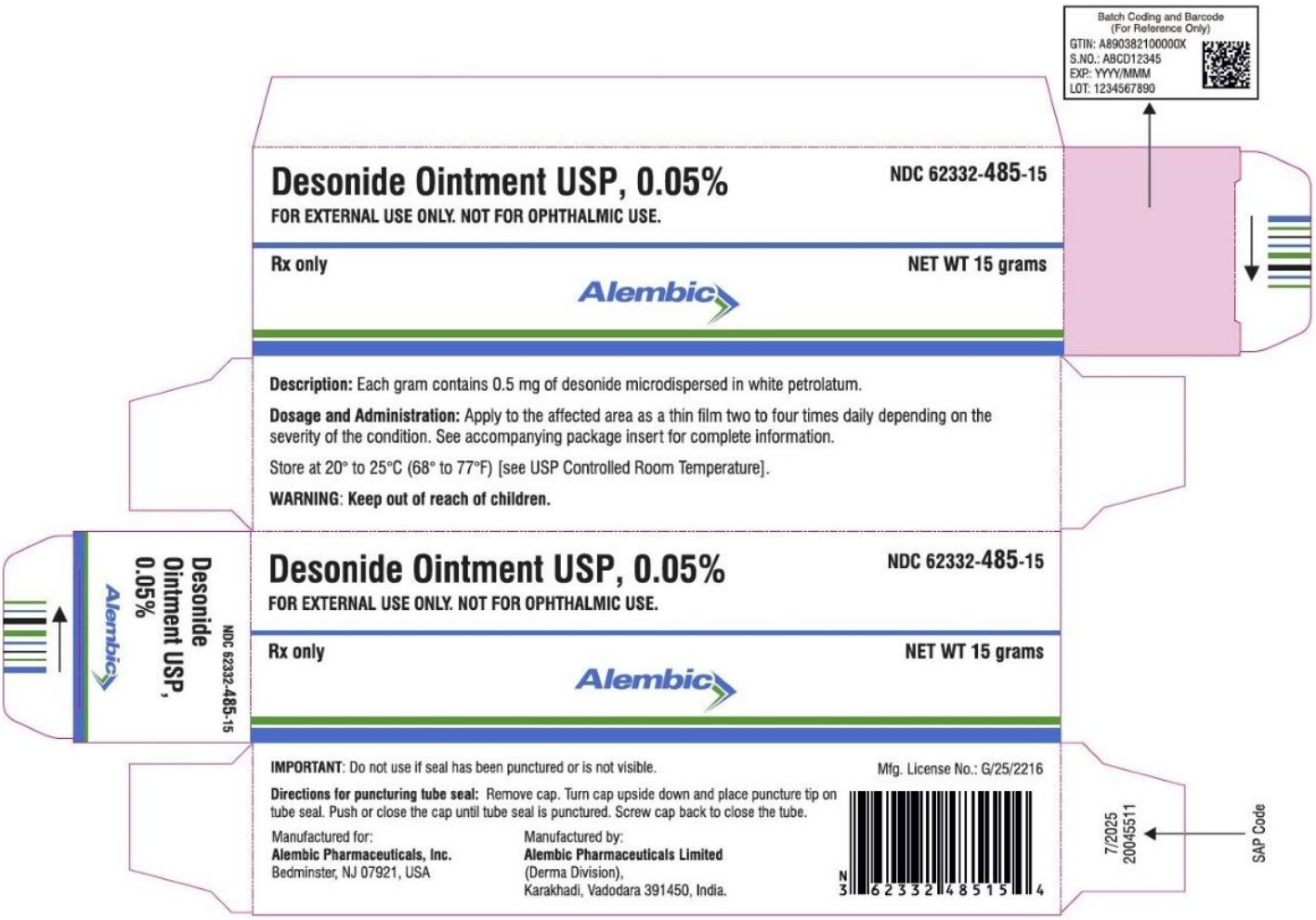
Desonide Ointment USP, 0.05%

FOR EXTERNAL USE ONLY

NOT FOR OPHTHALMIC USE

NET WT 15 grams





PRINCIPAL DISPLAY PANEL

Rx Only

NDC 62332-485-60

Desonide Ointment USP, 0.05%

FOR EXTERNAL USE ONLY

NOT FOR OPHTHALMIC USE

NET WT 60 grams

NDC 62332-485-60

Desonide Ointment USP, 0.05%

FOR EXTERNAL USE ONLY. NOT FOR OPHTHALMIC USE.

Rx only **NET WT 60 grams**

Alembic

Description: Each gram contains 0.5 mg of desonide microdispersed in white petrolatum.

Dosage and Administration: Apply to the affected area as a thin film two to four times daily depending on the severity of the condition. See accompanying package insert for complete information.

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

For lot number and expiry date, see below crimp of tube.

WARNING: Keep out of reach of children.

To Open: Use pointed end on cap to puncture seal.

IMPORTANT: Do not use if seal has been punctured or is not visible.

Manufactured for:
Alembic Pharmaceuticals, Inc.
Bedminster, NJ 07921, USA

Manufactured by:
Alembic Pharmaceuticals Limited
(Derma Division),
Karakhadi, Vadodara 391450, India.
Mfg. License No.: G/25/2216

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SAP Code

LOT AND EXPIRY DATE PRINTED ON BELOW THE CRIMP
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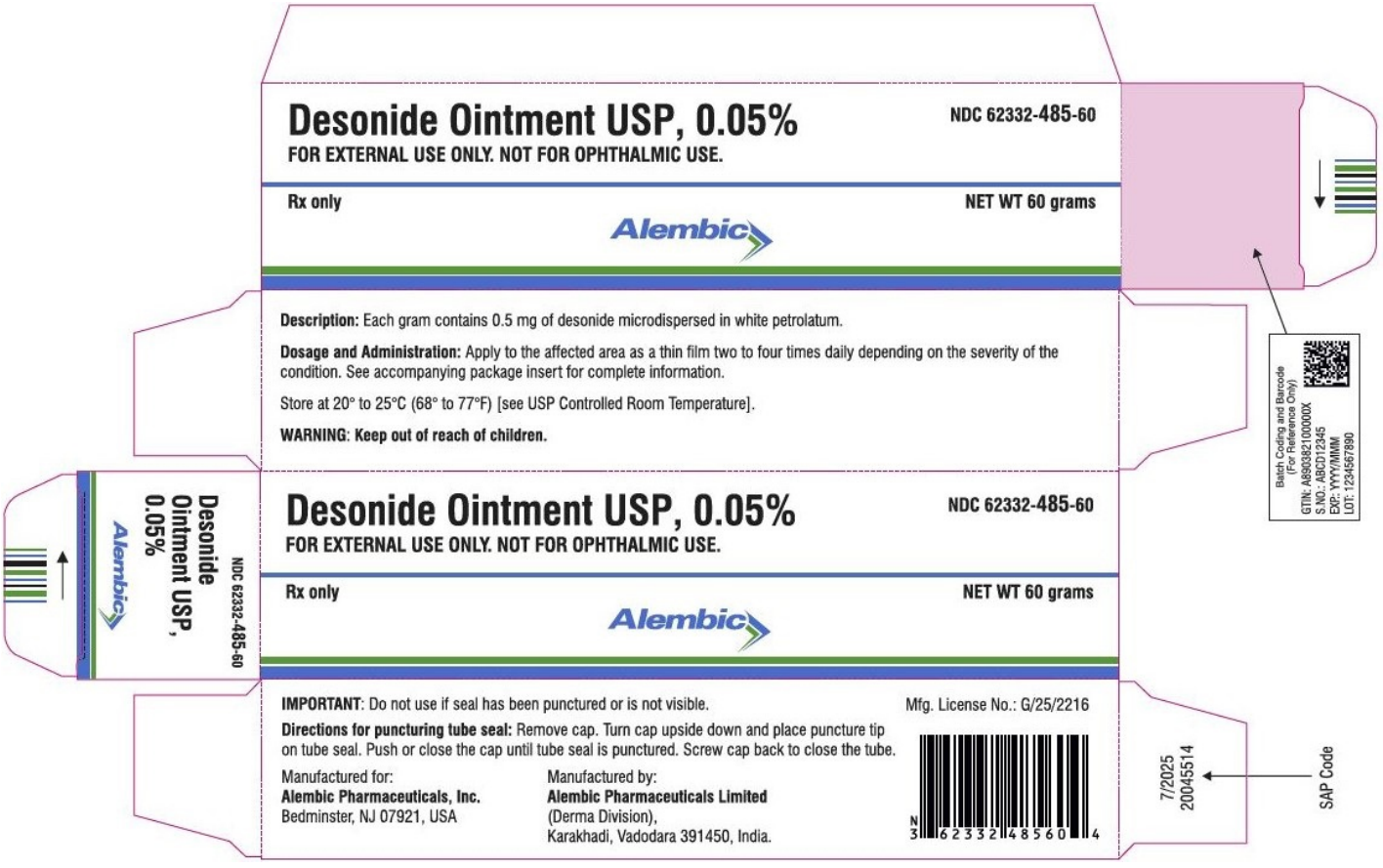

DESONIDE

desonide ointment

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:62332-485
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DESONIDE (UNII: J280872D1O) (DESONIDE - UNII:J280872D1O)	DESONIDE	0.5 mg in 1 g

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62332-485-15	1 in 1 CARTON	10/24/2019	
1		15 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:62332-485-60	1 in 1 CARTON	10/24/2019	
2		60 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA212473	10/24/2019	

Labeler - Alembic Pharmaceuticals Inc. (079288842)

Registrant - Alembic Pharmaceuticals Limited (650574663)

Establishment

Name	Address	ID/FEI	Business Operations
Alembic Pharmaceuticals Limited		871411532	MANUFACTURE(62332-485) , ANALYSIS(62332-485)