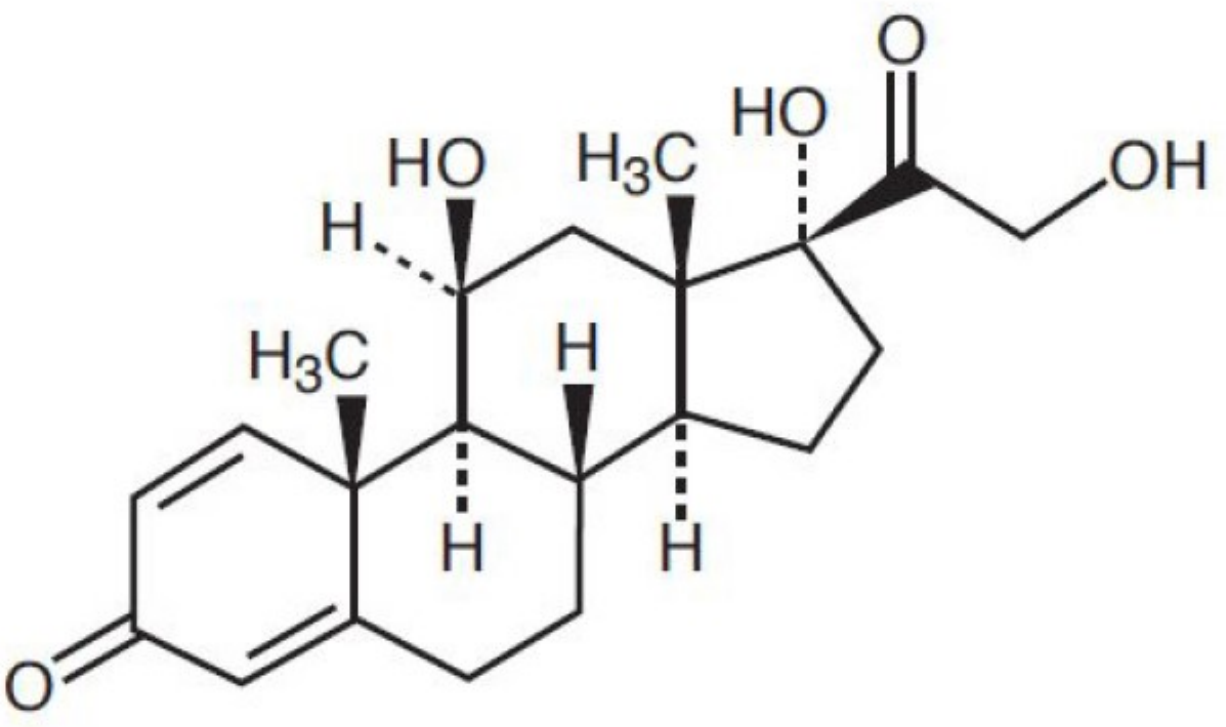
PREDNISOLONE- prednisolone oral solution solution
Heritage Pharma Labs Inc. d/b/a Avet Pharmaceuticals Labs Inc.

PREDNISOLONE ORAL SOLUTION, USP 15 mg per 5 mL

Rx only

DESCRIPTION

Prednisolone oral solution contains prednisolone which is a glucocorticoid. Glucocorticoids are adrenocortical steroids, both naturally occurring and synthetic, which are readily absorbed from the gastrointestinal tract. Prednisolone is a white to practically white, odorless, crystalline powder. It is very slightly soluble in water, soluble in methanol and in dioxane; sparingly soluble in acetone and in alcohol, slightly soluble in chloroform.
The chemical name for Prednisolone is Pregna-1,4 -diene -3, 20 - dione, 11, 17, 21-trihydroxy-,(11β). Its molecular weight is 360.45. The molecular formula is $C_{21}H_{28}O_5$ and the structural formula is:



Prednisolone oral solution contains 15 mg of prednisolone in each 5 mL. Benzoic acid, 0.1% is added as a preservative. It also contains ethyl alcohol 5% (v/v), citric acid, edetate disodium, glycerin, propylene glycol, purified water, saccharin sodium, sucrose, natural and artificial wild cherry flavor, FD&C red #40.

CLINICAL PHARMACOLOGY

Naturally occurring glucocorticoids (hydrocortisone and cortisone), which also have saltretaining properties, are used as replacement therapy in adrenocortical deficiency

states. Their synthetic analogs such as prednisolone are primarily used for their potent anti-inflammatory effects in disorders of many organ systems.
Glucocorticoids such as prednisolone cause profound and varied metabolic effects. In addition, they modify the body's immune responses to diverse stimuli.

INDICATIONS AND USAGE

Prednisolone Oral Solution, USP is indicated in the following conditions:

1. Endocrine Disorders

Primary or secondary adrenocortical insufficiency (hydrocortisone or cortisone is the first choice: synthetic analogs may be used in conjunction with mineralocorticoids where applicable; in infancy mineralocorticoid supplementation is of particular importance).

Congenital adrenal hyperplasia
Nonsuppurative thyroiditis
Hypercalcemia associated with cancer

2. Rheumatic Disorders

As adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in:

Psoriatic arthritis
Rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy)
Ankylosing spondylitis
Acute and subacute bursitis
Acute nonspecific tenosynovitis
Acute gouty arthritis
Post-traumatic osteoarthritis
Synovitis of osteoarthritis
Epicondylitis

3. Collagen Diseases

During an exacerbation or as maintenance therapy in selected cases of:

Systemic lupus erythematosus
Acute rheumatic carditis

4. Dermatologic Diseases

Pemphigus
Bullous dermatitis herpetiformis
Severe erythema multiforme (Stevens-Johnson syndrome)
Exfoliative dermatitis
Mycosis fungoides
Severe psoriasis
Severe seborrheic dermatitis

5. Allergic States

Control of severe or incapacitating allergic conditions intractable to adequate trials of conventional treatment:

Seasonal or perennial allergic rhinitis
Bronchial asthma
Contact dermatitis
Atopic dermatitis
Serum sickness
Drug hypersensitivity reactions

6. Ophthalmic Diseases

Severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa such as:

Allergic corneal marginal ulcers
Herpes zoster ophthalmicus
Anterior segment inflammation
Diffuse posterior uveitis and choroiditis
Sympathetic ophthalmia
Allergic conjunctivitis
Keratitis
Chorioretinitis
Optic neuritis
Iritis and iridocyclitis

7. Respiratory Diseases

Symptomatic sarcoidosis Loeffler’s syndrome not manageable by other means
Berylliosis
Fulminating or disseminated pulmonary tuberculosis when used concurrently with appropriate chemotherapy
Aspiration pneumonitis

8. Hematologic Disorders

Idiopathic thrombocytopenic purpura in adults
Secondary thrombocytopenia in adults
Acquired (autoimmune) hemolytic anemia
Erythroblastopenia (RBC anemia)
Congenital (erythroid) hypoplastic anemia

9. Neoplastic Diseases

For palliative management of:

Acute leukemia of childhood
Leukemias and lymphomas in adults

10. Edematous States

To induce a diuresis or remission of proteinuria in the nephrotic syndrome, without

uremia, of the idiopathic type or that due to lupus erythematosus.

11. Gastrointestinal Diseases

To tide the patient over a critical period of the disease in:

Ulcerative colitis
Regional enteritis

12. Miscellaneous

Tuberculous meningitis with subarachnoid block or impending block used concurrently with appropriate antituberculous chemotherapy. Trichinosis with neurologic or myocardial involvement.
In addition to the above indications prednisolone oral solution is indicated for systemic dermatomyositis (polymyositis).

CONTRAINDICATIONS

Systemic fungal infections.

WARNINGS

In patients on corticosteroid therapy subjected to unusual stress, increased dosage of rapidly acting corticosteroids before, during, and after the stressful situation is indicated.

Immunosuppression and Increased Risk of Infection

Corticosteroids, including prednisolone oral solution, suppress the immune system and increase the risk of infection with any pathogen, including viral, bacterial, fungal, protozoan, or helminthic pathogens. Corticosteroids can:

- Reduce resistance
- Exacerbate existing infections
- Increase the risk if disseminated infections
- Increase the risk of reactivation or exacerbation of latent infections
- Mask some signs of infection

Corticosteroid-associated infections can be mild but can be severe and at times fatal. The rate of infectious complications increases with increasing corticosteroid dosages.

Monitor for the development of infection and consider prednisolone oral solution withdrawal or dosage reduction as needed.

Do not administer prednisolone oral solution by an intraarticular, intrabursal, intratendinous, or intralesional route in the presence of acute local infection.

Tuberculosis
If prednisolone oral solution is used to treat a condition in patients with latent tuberculosis or tuberculin reactivity, reactivation of tuberculosis may occur. Closely monitor such patients for reactivation. During prolonged prednisolone oral solution therapy, patients with latent tuberculosis or tuberculin reactivity should receive chemoprophylaxis.

Varicella Zoster and Measles Viral Infections

Varicella and measles can have a serious or even fatal course in non-immune patients taking corticosteroids, including prednisolone oral solution. In corticosteroids-treated patients who have not had these diseases or are non-immune, particular care should be taken to avoid exposure to varicella and measles:

- If a prednisolone oral solution-treated patient is exposed to varicella, prophylaxis with varicella zoster immune globulin may be indicated. If varicella develops, treatment with antiviral agents may be considered.
- If a prednisolone oral solution-treated patient is exposed to measles, prophylaxis with immunoglobulin may be indicated.

Hepatitis B Virus Reactivation
Hepatitis B virus reactivation can occur in patients who are hepatitis B carriers treated with immunosuppressive dosages of corticosteroids, including prednisolone oral solution. Reactivation can also occur infrequently in corticosteroids-treated patients who appear to have resolved hepatitis B infection.

Screen patients for hepatitis B infection before initiating immunosuppressive (e.g. prolonged) treatment with prednisolone oral solution. For patients who show evidence of hepatitis B infection, recommend consultation with physician with expertise in managing hepatitis B regarding monitoring and consideration for hepatitis B antiviral therapy.

Fungal Infections
Corticosteroids, including prednisolone oral solution, may exacerbate systemic fungal infections; therefore, avoid prednisolone oral solution use in the presence of such infections unless prednisolone oral solution is needed to control drug reactions. For patients on chronic prednisolone oral solution therapy who develop systemic fungal infections, prednisolone oral solution withdrawal or dosage reduction is recommended.

Amebiasis
Corticosteroids, including prednisolone oral solution, may activate latent amebiasis. Therefore, it is recommended that latent amebiasis or active amebiasis be ruled out before initiating prednisolone oral solution in patients who spent time in the tropics or patients with unexplained diarrhea.

Strongyloides Infestation
Corticosteroids, including prednisolone oral solution, should be used with great care in patients with known or suspected Stronyloides (threadworm) infestation. In such patients, corticosteroid-induced immunosuppression may lead to Strongyloides hyperinfection and dissemination with widespread larval migration, often accompanied by severe enterocolitis and potentially fatal gram-negative septicemia.

Cerebral Malaria
Avoid corticosteroids, including prednisolone oral solution, in patients with cerebral malaria.

Kaposi's Sarcoma
Kaposi's sarcoma has been reported to occur in patients receiving corticosteroids therapy, most often for chronic conditions. Discontinuation of corticosteroids may result in clinical improvement of Kaposi's sarcoma.

Prolonged use of corticosteroids may produce posterior subcapsular cataracts, glaucoma with possible damage to the optic nerves, and may enhance the establishment

of secondary ocular infections due to fungi or viruses.

Average and large doses of hydrocortisone or cortisone can cause elevation of blood pressure, salt and water retention, and increased excretion of potassium. These effects are less likely to occur with the synthetic derivatives except when used in large doses. Dietary salt restriction and potassium supplementation may be necessary. All corticosteroids increase calcium excretion.

While on corticosteroid therapy, patients should not be vaccinated against smallpox. Other immunization procedures should not be undertaken in patients who are on corticosteroids, especially on high dose, because of possible hazards of neurological complications and a lack of antibody response.

Use in pregnancy: Since adequate human reproduction studies have not been done with corticosteroids, the use of these drugs in pregnancy, nursing mothers or women of childbearing potential requires that the possible benefits of the drug be weighed against the potential hazards to the mother and embryo or fetus. Infants born of mothers who have received substantial doses of corticosteroids during pregnancy should be carefully observed for signs of hypoadrenalism.

PRECAUTIONS

General

Drug-induced secondary adrenocortical insufficiency may be minimized by gradual reduction of dosage. This type of relative insufficiency may persist for months after discontinuation of therapy; therefore, in any situation of stress occurring during that period, hormone therapy should be reinstituted. Since mineralocorticoid secretion may be impaired, salt and/or a mineralocorticoid should be administered concurrently.

There is an enhanced effect of corticosteroids on patients with hypothyroidism and in those with cirrhosis.

Corticosteroids should be used cautiously in patients with ocular herpes simplex because of possible corneal perforation.

The lowest possible dose of corticosteroid should be used to control the condition under treatment, and when reduction in dosage is possible, the reduction should be gradual.

Psychic derangements may appear when corticosteroids are used, ranging from euphoria, insomnia, mood swings, personality changes, and severe depression, to frank psychotic manifestations. Also, existing emotional instability or psychotic tendencies may be aggravated by corticosteroids.

Aspirin should be used cautiously in conjunction with corticosteroids in hypoprothrombinemia.

Steroids should be used with caution in nonspecific ulcerative colitis, if there is a probability of impending perforation, abscess or other pyogenic infections; diverticulitis; fresh intestinal anastomoses; active or latent peptic ulcer; renal insufficiency; hypertension; osteoporosis; and myasthenia gravis.

Growth and development of infants and children on prolonged corticosteroid therapy

should be carefully observed.

Information for Patients
Patients who are on immunosuppressant doses of corticosteroids should be warned to avoid exposure to chickenpox or measles. Patients should also be advised that if they are exposed, medical advice should be sought without delay.

ADVERSE REACTIONS

Fluid and Electrolyte Disturbances
- Sodium retention
- Fluid retention
- Congestive heart failure in susceptible patients
- Potassium loss
- Hypokalemic alkalosis
- Hypertension

Musculoskeletal
- Muscle weakness
- Steroid myopathy
- Loss of muscle mass
- Osteoporosis
- Vertebral compression fractures
- Aseptic necrosis of femoral and humeral heads
- Pathologic fracture of long bones

Gastrointestinal
- Peptic ulcer with possible perforation and hemorrhage
- Pancreatitis
- Abdominal distention
- Ulcerative esophagitis

Dermatologic
- Impaired wound healing
- Thin fragile skin
- Petechiae and ecchymoses
- Facial erythema
- Increased sweating
- May suppress reactions to skin tests

Neurological

- Convulsions
- Increased intracranial pressure with papilledema (pseudo-tumor cerebri) usually after treatment
- Vertigo
- Headache

Endocrine
- Menstrual irregularities
- Development of Cushingoid state
- Suppression of growth in children

Secondary adrenocortical and pituitary unresponsiveness, particularly in times of stress, as in trauma, surgery or illness
Decreased carbohydrate tolerance
Manifestations of latent diabetes mellitus
Increased requirements for insulin or oral hypoglycemic agents in diabetics

Ophthalmic
Posterior subcapsular cataracts
Increased intraocular pressure
Glaucoma
Exophthalmos

Metabolic
Negative nitrogen balance due to protein catabolism

To report SUSPECTED ADVERSE REACTIONS, contact Avet Pharmaceuticals Inc. at 1-866-901-DRUG (3784) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DOSAGE AND ADMINISTRATION

Dosage of Prednisolone Oral Solution, USP should be individualized according to the severity of the disease and the response of the patient. For infants and children, the recommended dosage should be governed by the same considerations rather than strict adherence to the ratio indicated by age or body weight.

Hormone therapy is an adjunct to and not a replacement for conventional therapy.

Dosage should be decreased or discontinued gradually when the drug has been administered for more than a few days.

The severity, prognosis, expected duration of the disease, and the reaction of the patient to medication are primary factors in determining dosage.

If a period of spontaneous remission occurs in a chronic condition, treatment should be discontinued.

Blood pressure, body weight, routine laboratory studies, including two-hour postprandial blood glucose and serum potassium, and a chest X-ray should be obtained at regular intervals during prolonged therapy. Upper GI X-rays are desirable in patients with known or suspected peptic
ulcer disease.

The initial dosage of Prednisolone Oral Solution, USP may vary from 5 mg to 60 mg per day depending on the specific disease entity being treated. In situations of less severity lower doses will generally suffice while in selected patients higher initial doses may be required. The initial dosage should be maintained or adjusted until a satisfactory response is noted. If after a reasonable period of time there is a lack of satisfactory clinical response, Prednisolone Oral Solution, USP should be discontinued and the patient transferred to other appropriate therapy. IT SHOULD BE EMPHASIZED THAT DOSAGE REQUIREMENTS ARE VARIABLE AND MUST BE INDIVIDUALIZED ON THE BASIS OF THE DISEASE UNDER TREATMENT AND THE RESPONSE OF THE PATIENT.

After a favorable response is noted, the proper maintenance dosage should be determined by decreasing the initial drug dosage in small decrements at appropriate time

intervals until the lowest dosage which will maintain an adequate clinical response is reached. It should be kept in mind that constant monitoring is needed in regard to drug dosage. Included in the situations which may make dosage adjustments necessary are changes in clinical status secondary to remissions or exacerbations in the disease process, the patient's individual drug responsiveness, and the effect of patient exposure to stressful situations not directly related to the disease entity under treatment. In this latter situation it may be necessary to increase the dosage of Prednisolone Oral Solution, USP for a period of time consistent with the patient's condition. If after long-term therapy the drug is to be stopped, it is recommended that it be withdrawn gradually rather than abruptly.

HOW SUPPLIED

Prednisolone Oral Solution, USP containing 15 mg of Prednisolone in each 5 mL (teaspoonful) is a clear pinkish-red wild cherry flavored liquid and is supplied in 240 mL bottles (NDC 23155-927-51), 480 mL (NDC 23155-927-52) bottles.

Pharmacist: Dispense 15 mg/5 mL Prednisolone Oral Solution, USP with suitable calibrated measuring device to assure proper measuring of dose.

DOSE/VOLUME CHART

15 mg prednisolone	=	1 teaspoon
10 mg prednisolone	=	2/3 teaspoon
7.5 mg prednisolone	=	1/2 teaspoon
5 mg prednisolone	=	1/3 teaspoon

Dispense in tight, light-resistant and child-resistant container as defined in USP/NF.

Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature]. DO NOT REFRIGERATE.

Distributed by:
Avet Pharmaceuticals Inc.
East Brunswick, NJ 08816
1.866.901.DRUG (3784)

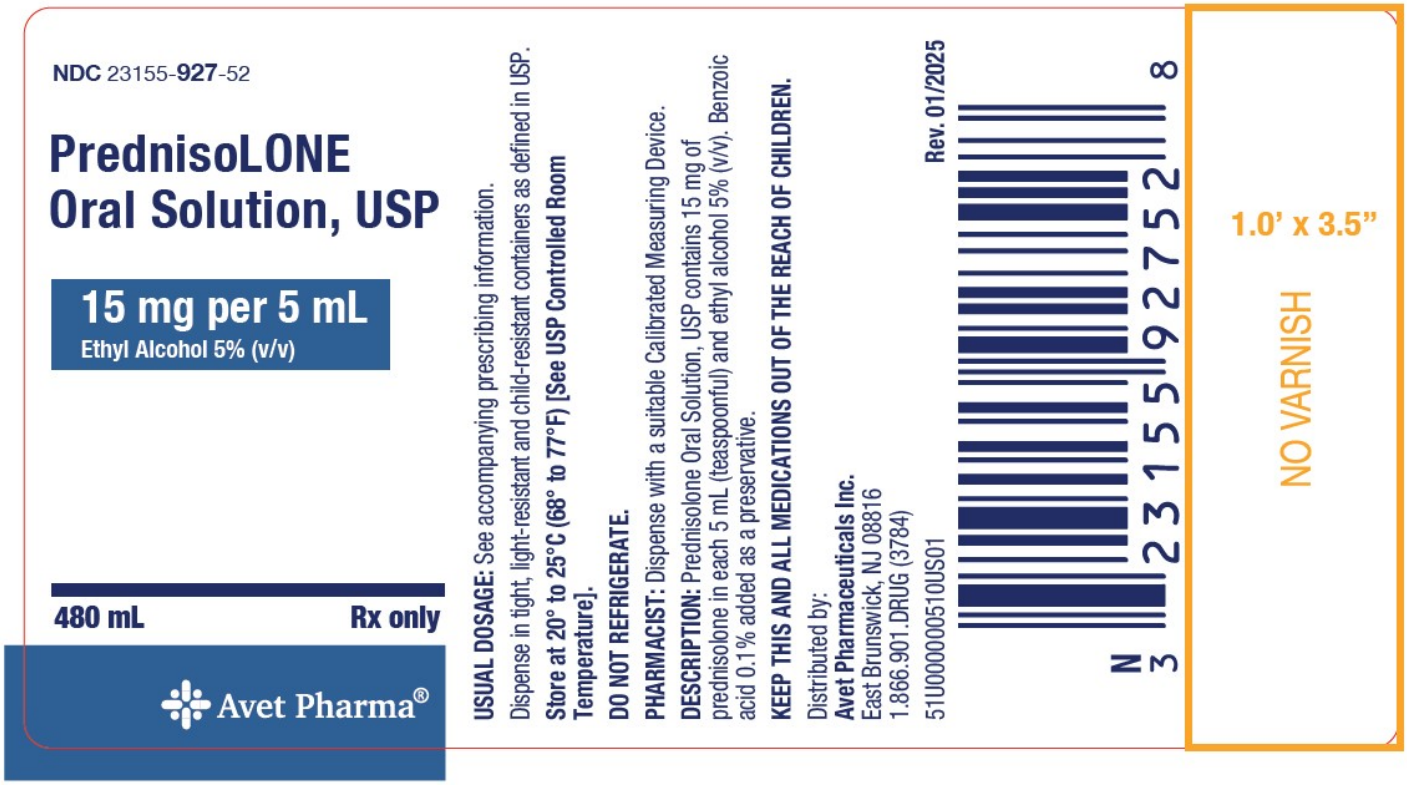
Avet Pharma®

Revised: 01/2025

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

PrednisoLONE Oral Solution, USP 15 mg per 5 mL - NDC 23155-927-51- 240 mL Bottle Label

PrednisoLONE Oral Solution, USP 15 mg per 5 mL - NDC 23155-927-52- 480 mL Bottle Label



PREDNISOLONE

prednisolone oral solution solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:23155-927
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PREDNISOLONE (UNII: 9PHQ9Y1OLM) (PREDNISOLONE - UNII:9PHQ9Y1OLM)	PREDNISOLONE	15 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
CHERRY (UNII: BUC5I9595W)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
ALCOHOL (UNII: 3K9958V90M)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SUCROSE (UNII: C151H8M554)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	

Product Characteristics

Color	pink (clear pinkish-red)	**Score**	
Shape		**Size**	
Flavor	CHERRY (wild cherry)	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:23155-927-51	240 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/01/2025	
2	NDC:23155-927-52	480 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/01/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA040323	03/01/2025	

Labeler - Heritage Pharma Labs Inc. d/b/a Avet Pharmaceuticals Labs Inc. (780779901)

Registrant - Chartwell RX, LLC (079394054)

Establishment

Name	Address	ID/FEI	Business Operations
Chartwell Pharmaceuticals Carmel, LLC		118673485	analysis(23155-927) , manufacture(23155-927) , pack(23155-927)

Establishment

Name	Address	ID/FEI	Business Operations
Heritage Pharma Labs Inc. d/b/a Avet Pharmaceuticals Labs Inc.		189630168	label(23155-927)