SAFETY DATA SHEET

METHYL PREDNISOLONE TABLETS USP

Strength : 4 MG, 8 MG, 16 MG & 32 MG **Revision No.:** 00

Pack Style : Bottle pack
unit-dose blister cartons of 100 (10 x 10) unit-dose tablets

EMERGENCY OVERVIEW

Each Methylprednisolone tablet USP intended for oral administration contains 4 mg, 8 mg, 16 mg or 32 mg of methylprednisolone and excipients generally considered to be non- toxic and non-hazardous in small quantities and under conditions of normal occupational exposure.

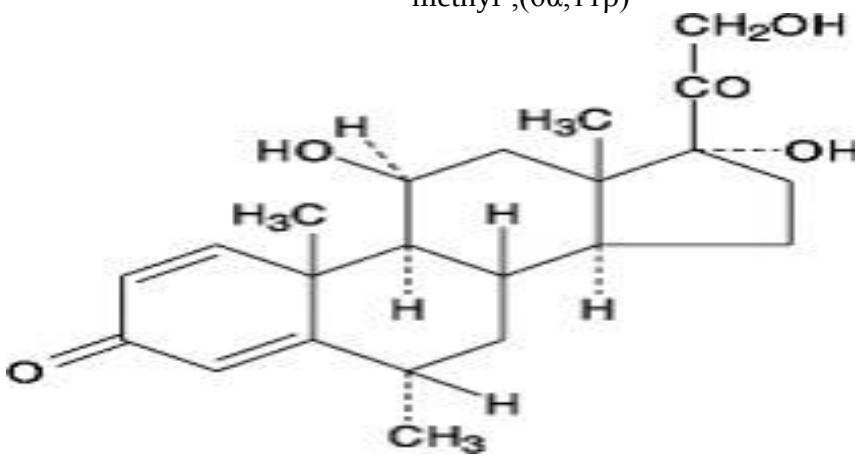
Section 1. IDENTIFICATION OF THE PRODUCT

Product Name: Methylprednisolone tablet USP, 4 MG, 8 MG, 16 MG & 32 MG

Active Pharmaceutical Ingredient : Methylprednisolone

Formula: $C_{22}H_{30}O_5$

Chemical Name: pregna-1,4-diene-3,20-dione, 11, 17, 21-trihydroxy-6-methyl-,(6α,11β)



Mechanism of Action:

Methylprednisolone tablets contain methylprednisolone which is a glucocorticoid. Glucocorticoids are adrenocortical steroids, both naturally occurring and synthetic, which are readily absorbed from the gastrointestinal tract. Naturally occurring glucocorticoids (hydrocortisone and cortisone), which also have salt-retaining properties, are used as replacement therapy in adrenocortical deficiency states. Their synthetic analogs are primarily used for their potent anti-inflammatory effects in disorders of many organ systems.Glucocorticoids cause profound and varied metabolic effects. In addition, they modify the body's immune responses to diverse stimuli.

Manufacturer / supplier identification

Company:	Cadila Healthcare Ltd. Ahmedabad, India
Address:	Sarkhej – Bavla. N.H. 8A, Moraiya. Tal. Sanand. Dist. Ahmedabad – 382210. State: Gujarat. India
Contact for information:	Tel.: +91 79 6868100 Fax: +91 79 3750319
Emergency Telephone No.	Tel.: +91 79 6868100

Therapeutic Category Glucocorticoid

Indications :

Methylprednisolone tablets are indicated in the following conditions:

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

Rheumatic Disorders

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

Rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy)

- Ankylosing spondylitis
- Acute and subacute bursitis
- Synovitis of osteoarthritis
- Acute nonspecific tenosynovitis
- Post-traumatic osteoarthritis
- Psoriatic arthritis
- Epicondylitis
- Acute gouty arthritis

Collagen Diseases

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

- Systemic lupus erythematosus
- Systemic dermatomyositis (polymyositis)
- Acute rheumatic carditis

Dermatologic Diseases

- Bullous dermatitis herpetiformis
- Severe erythema multiforme (Stevens-Johnson syndrome)

Severe seborrheic dermatitis
Exfoliative dermatitis
Mycosis fungoides
Pemphigus
Severe psoriasis

Allergic States

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

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

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
Keratitis
Optic neuritis
Allergic conjunctivitis
Chorioretinitis
Iritis and iridocyclitis

Respiratory Diseases

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

Hematologic Disorders

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

Neoplastic Diseases
For palliative management of:
Leukemias and lymphomas in adults
Acute leukemia of childhood
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.
Gastrointestinal Diseases
To tide the patient over a critical period of the disease in:
Ulcerative colitis
Regional enteritis
Nervous System
Acute exacerbations of multiple sclerosis
Miscellaneous
Tuberculous meningitis with subarachnoid block or impending block when used concurrently with appropriate antituberculous chemotherapy.
Trichinosis with neurologic or myocardial involvement.

Restriction on Use / Contraindications: Systemic fungal infections and known hypersensitivity to components.

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SECTION 2. HAZARD(S) IDENTIFICATION

Dosage and Administration

The initial dosage of methylprednisolone tablets may vary from 4 mg to 48 mg of methylprednisolone 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, methylprednisolone 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 methylprednisolone 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.

Multiple Sclerosis

In treatment of acute exacerbations of multiple sclerosis daily doses of 200 mg of prednisolone for a week followed by 80 mg every other day for 1 month have been shown to be effective (4 mg of methylprednisolone is equivalent to 5 mg of prednisolone).

ADT® (Alternate Day Therapy)

Alternate day therapy is a corticosteroid dosing regimen in which twice the usual daily dose of corticoid is administered every other morning. The purpose of this mode of therapy is to provide the patient requiring long-term pharmacologic dose treatment with the beneficial effects of corticoids while minimizing certain undesirable effects, including pituitary-adrenal suppression, the Cushingoid state, corticoid withdrawal symptoms, and growth suppression in children.

The rationale for this treatment schedule is based on two major premises: (a) the anti-inflammatory or therapeutic effect of corticoids persists longer than their physical presence and metabolic effects and (b) administration of the corticosteroid every other morning allows for reestablishment of more nearly normal hypothalamic-pituitary-adrenal (HPA) activity on the off-steroid day.

A brief review of the HPA physiology may be helpful in understanding this rationale. Acting primarily through the hypothalamus a fall in free cortisol stimulates the pituitary gland to produce increasing amounts of corticotropin (ACTH) while a rise in free cortisol inhibits ACTH secretion. Normally the HPA system is characterized by diurnal (circadian) rhythm. Serum levels of ACTH rise from a low point about 10 pm to a peak level about 6 am. Increasing levels of ACTH stimulate

adrenal cortical activity resulting in a rise in plasma cortisol with maximal levels occurring between 2 am and 8 am. This rise in cortisol dampens ACTH production and in turn adrenal cortical activity. There is a gradual fall in plasma corticoids during the day with lowest levels occurring about midnight.

The diurnal rhythm of the HPA axis is lost in Cushing's disease, a syndrome of adrenal cortical hyperfunction characterized by obesity with centripetal fat distribution, thinning of the skin with easy bruisability, muscle wasting with weakness, hypertension, latent diabetes, osteoporosis, electrolyte imbalance, etc. The same clinical findings of hyperadrenocorticism may be noted during long-term pharmacologic dose corticoid therapy administered in conventional daily divided doses. It would appear, then, that a disturbance in the diurnal cycle with maintenance of elevated corticoid values during the night may play a significant role in the development of undesirable corticoid effects. Escape from these constantly elevated plasma levels for even short periods of time may be instrumental in protecting against undesirable pharmacologic effects.

During conventional pharmacologic dose corticosteroid therapy, ACTH production is inhibited with subsequent suppression of cortisol production by the adrenal cortex. Recovery time for normal HPA activity is variable depending upon the dose and duration of treatment. During this time the patient is vulnerable to any stressful situation. Although it has been shown that there is considerably less adrenal suppression following a single morning dose of prednisolone (10 mg) as opposed to a quarter of that dose administered every six hours, there is evidence that some suppressive effect on adrenal activity may be carried over into the following day when pharmacologic doses are used. Further, it has been shown that a single dose of certain corticosteroids will produce adrenal cortical suppression for two or more days. Other corticoids, including methylprednisolone, hydrocortisone, prednisone, and prednisolone, are considered to be short acting (producing adrenal cortical suppression for 1¼ to 1½ days following a single dose) and thus are recommended for alternate day therapy.

The following should be kept in mind when considering alternate day therapy:

1. Basic principles and indications for corticosteroid therapy should apply. The benefits of ADT should not encourage

the indiscriminate use of steroids.

2. ADT is a therapeutic technique primarily designed for patients in whom long-term pharmacologic corticoid therapy is anticipated.
3. In less severe disease processes in which corticoid therapy is indicated, it may be possible to initiate treatment with ADT. More severe disease states usually will require daily divided high dose therapy for initial control of the disease process. The initial suppressive dose level should be continued until satisfactory clinical response is obtained, usually four to ten days in the case of many allergic and collagen diseases. It is important to keep the period of initial suppressive dose as brief as possible particularly when subsequent use of alternate day therapy is intended. Once control has been established, two courses are available: (a) change to ADT and then gradually reduce the amount of corticoid given every other day **or** (b) following control of the disease process reduce the daily dose of corticoid to the lowest effective level as rapidly as possible and then change over to an alternate day schedule. Theoretically, course (a) may be preferable.
4. Because of the advantages of ADT, it may be desirable to try patients on this form of therapy who have been on daily corticoids for long periods of time (e.g., patients with rheumatoid arthritis).Since these patients may already have a suppressed HPA axis, establishing them on ADT may be difficult and not always successful. However, it is recommended that regular attempts be made to change them over. It may be helpful to triple or even quadruple the daily maintenance dose and administer this every other day rather than just doubling the daily dose if difficulty is encountered. Once the patient is again controlled, an attempt should be made to reduce this dose to a minimum.
5. As indicated above, certain corticosteroids, because of their prolonged suppressive effect on adrenal activity, are not recommended for alternate day therapy (e.g., dexamethasone and betamethasone).
6. The maximal activity of the adrenal cortex is between 2 am and 8 am, and it is minimal between 4 pm and midnight. Exogenous corticosteroids suppress adrenocortical activity the least, when given at the time of maximal activity (am).
7. In using ADT it is important, as in all therapeutic situations to individualize and tailor the therapy to each patient.

Complete control of symptoms will not be possible in all patients. An explanation of the benefits of ADT will help the patient to understand and tolerate the possible flare-up in symptoms which may occur in the latter part of the off-steroid day. Other symptomatic therapy maybe added or increased at this time if needed.

8. In the event of an acute flare-up of the disease process, it may be necessary to return to a full suppressive daily divided corticoid dose for control. Once control is again established alternate day therapy may be reinstituted.
9. Although many of the undesirable features of corticosteroid therapy can be minimized by ADT, as in any therapeutic situation, the physician must carefully weigh the benefit-risk ratio for each patient in whom corticoid therapy is being considered.

Adverse Effects

Fluid and Electrolyte Disturbances

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

Musculoskeletal

- Muscle weakness
- Loss of muscle mass
- Steroid myopathy
- Osteoporosis
- Tendon rupture, particularly of the Achilles tendon
- 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

Increases in alanine transaminase (ALT, SGPT), aspartate transaminase (AST, SGOT), and alkaline phosphatase have been observed following corticosteroid treatment. These changes are usually small, not associated with any clinical syndrome and are reversible upon discontinuation.

Dermatologic

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

Increased sweating

Neurological

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

Endocrine

- 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
- Menstrual irregularities
- Decreased carbohydrate tolerance
- Manifestations of latent diabetes mellitus
- Increased requirements of insulin or oral hypoglycemic agents in diabetics

Ophthalmic

- Posterior subcapsular cataracts
- Increased intraocular pressure
- Glaucoma
- Exophthalmos

Metabolic

- Negative nitrogen balance due to protein catabolism

The following additional reactions have been reported following oral as well as parenteral therapy:

Urticaria and other allergic, anaphylactic or hypersensitivity reactions.

Pregnancy Comments

Pregnancy Category B.

Since adequate human reproduction studies have not been done with corticosteroids, the use of these drugs in pregnancy, nursing mothers or women of child-bearing 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.

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.

Administration of live or live, attenuated vaccines is contraindicated in patients receiving immunosuppressive doses of corticosteroids. Killed or inactivated vaccines may be administered to patients receiving immunosuppressive doses of corticosteroids; however, the response to such vaccines may be diminished. Indicated immunization procedures may be undertaken in patients receiving nonimmunosuppressive doses of corticosteroids.

The use of methylprednisolone tablets in active tuberculosis should be restricted to those cases of fulminating or disseminated tuberculosis in which the corticosteroid is used for the management of the disease in conjunction with an appropriate antituberculous regimen.

If corticosteroids are indicated in patients with latent tuberculosis or tuberculin reactivity, close observation is necessary as reactivation of the disease may occur. During prolonged corticosteroid therapy, these patients should receive chemoprophylaxis.

Persons who are on drugs which suppress the immune system are more susceptible to infections than healthy individuals. Chicken pox and measles, for example, can have a more serious or even fatal course in non-immune children or adults on corticosteroids. In such children or adults who have not had these diseases particular care should be taken to avoid exposure. How the dose, route and duration of corticosteroid administration affects the risk of developing a disseminated infection is not known. The contribution of the underlying disease and/or prior corticosteroid treatment to the risk is also not known. If exposed, to chicken pox, prophylaxis with varicella zoster immune globulin (VZIG) may be indicated. If exposed to measles, prophylaxis with pooled intramuscular immunoglobulin (IG) may be indicated. (See the respective package inserts for complete VZIG and IG prescribing information.) If chicken pox develops, treatment with antiviral

agents may be considered. Similarly, corticosteroids should be used with great care in patients with known or suspected Strongyloides (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.

Warnings & Precautions

In patients on corticosteroid therapy subjected to unusual stress, increased dosage of rapidly acting corticosteroids before, during, and after the stressful situation is indicated. Corticosteroids may mask some signs of infection, and new infections may appear during their use. Infections with any pathogen including viral, bacterial, fungal, protozoan or helminthic infections, in any location of the body, may be associated with the use of corticosteroids alone or in combination with other immunosuppressive agents that affect cellular immunity, humoral immunity, or neutrophil function.

These infections may be mild, but can be severe and at times fatal. With increasing doses of corticosteroids, the rate of occurrence of infectious complications increases.[2] There may be decreased resistance and inability to localize infection when corticosteroids are used. 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.

General Precautions

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. Steroids should be used with caution in nonspecific ulcerative colitis, if there is a probability of impending perforation, abscess or other pyogenic infection; 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. Kaposi's sarcoma has been reported to occur in patients receiving corticosteroid therapy. Discontinuation of corticosteroids may result in clinical remission. Although controlled clinical trials have shown corticosteroids to be effective in speeding the resolution of acute exacerbations of multiple sclerosis, they do not show that corticosteroids affect the ultimate outcome or natural history of the disease. The studies do show that relatively high doses of corticosteroids are necessary to demonstrate a significant effect. Since complications of treatment with glucocorticoids are dependent on the size of the dose and the duration of treatment, a risk/benefit decision must be made in each individual case as to dose and duration of treatment and as to whether daily or intermittent therapy should be used.

Drug Interactions:

The pharmacokinetic interactions listed below are potentially clinically important. Mutual inhibition of metabolism occurs with concurrent use of cyclosporin and methylprednisolone; therefore, it is possible that adverse events associated with the individual use of either drug may be more apt to occur. Convulsions have been reported with concurrent use of methylprednisolone and cyclosporin. Drugs that induce hepatic enzymes such as phenobarbital, phenytoin and rifampin may increase the clearance of methylprednisolone and may require increases in methylprednisolone dose to achieve the desired response. Drugs such as troleandomycin and ketoconazole may inhibit the metabolism of methylprednisolone and thus decrease its clearance. Therefore, the dose of methylprednisolone should be titrated to avoid steroid toxicity.

Methylprednisolone may increase the clearance of chronic high dose aspirin. This could lead to decreased salicylate serum levels or increase the risk of salicylate toxicity when methylprednisolone is withdrawn. Aspirin should be used

cautiously in conjunction with corticosteroids in patients suffering from hypoprothrombinemia.

The effect of methylprednisolone on oral anticoagulants is variable. There are reports of enhanced as well as diminished effects of anticoagulant when given concurrently with corticosteroids. Therefore, coagulation indices should be monitored to maintain the desired anticoagulant effect.

Information for the Patient

Persons 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.

Section 3. COMPOSITION / INFORMATION ON INGREDIENTS

Component	Exposure limit	CAS no.
Principle component		
Methyl Prednisolone	Not found	83-43-2
Inactive ingredients		
Lactose Monohydrate	Not found	5989-81-1
Microcrystalline cellulose	Not found	9004-34-6
Pregelatinised starch	Not found	9057-07-2
Sodium starch glycolate	Not found	9063-38-1
Magnesium stearate	Not found	557-04-0

Section 4. FIRST -AID MEASURES

Swallowed	Immediately give a glass of water. First aid is not generally required. If in doubt, contact a Poisons Information Centre or a doctor.
Eye	If this product comes in contact with the eyes: Wash out immediately with fresh running water. Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids. If pain persists or recurs seek medical attention. Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.
Skin	If skin contact occurs: Immediately remove all contaminated clothing, including footwear Flush skin and hair with running water (and soap if available). Seek medical attention in event of irritation.
Inhaled	If fumes or combustion products are inhaled remove from contaminated area. Lay patient down. Keep warm and rested. Prostheses such as false teeth, which may block airway, should be removed, where possible, prior to initiating first aid procedures. Apply artificial respiration if not breathing, preferably with a demand valve resuscitator, bag-valve mask device, or pocket mask as trained. Perform CPR if necessary. Transport to hospital, or doctor
Notes to physician	treat symptomatically.

Section 5. FIRE FIGHTING MEASURES

Flammability of the Product: May be combustible at high temperature.
Auto-Ignition Temperature: Not available.
Flash Points: Not available.
Flammable Limits: Not available.
Products of Combustion: These products are carbon oxides (CO, CO2).
Fire Hazards in Presence of Various Substances: Not available.
Explosion Hazards in Presence of Various Substances:

Risks of explosion of the product in presence of mechanical impact: Not available. Risks of explosion of the product in
presence of static discharge: Not available.
Fire Fighting Media and Instructions:
SMALL FIRE: Use DRY chemical powder. LARGE FIRE: Use water spray, fog or foam. Do not use water jet.
Special Remarks on Fire Hazards: Not available.
Special Remarks on Explosion Hazards: Not available.
Personal protective equipment Gloves, boots (chemical resistant).
Breathing apparatus.

Section 6. ACCIDENTAL RELEASE MEASURES

Small Spill:
Use appropriate tools to put the spilled solid in a convenient waste disposal container. Finish cleaning by spreading water on
the contaminated surface and dispose of according to local and regional authority requirements.
Large Spill:
Use a shovel to put the material into a convenient waste disposal container. Finish cleaning by spreading water on the
contaminated surface and allow to evacuate through the sanitary system.

Treatment and Disposal	Decontaminate equipment. Dispose of protective clothing with spilled material.
Environmental precautions	Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Avoid discharge into drains, water courses or onto the ground. Inform appropriate managerial or supervisory personnel of all environmental releases.

Section 7. HANDLING AND STORAGE

Storage	Store at 20° to 25° C (68° to 77° F)
Precautions for safe handling	Keep locked up. Keep away from heat. Keep away from sources of ignition. Empty containers pose a fire risk; evaporate the residue under a fume hood. Ground all equipment containing material. Do not ingest. Do not breathe dust. Wear suitable protective clothing. If ingested, seek medical advice immediately and show the container or the label. Avoid contact with skin and eyes

Section 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Engineering Controls:
Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended
exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants
below the exposure limit.
Personal Protection:
Splash goggles. Lab coat. Dust respirator. Be sure to use an approved/certified respirator or equivalent. Gloves.
Personal Protection in Case of a Large Spill:
Splash goggles. Full suit. Dust respirator. Boots. Gloves. A self contained breathing apparatus should be used to avoid
inhalation of the product. Suggested protective clothing might not be sufficient; consult a specialist BEFORE handling this
product.
Exposure Limits: Not available.

Section 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance of Dosage form

Physical state	Tablets
Description	**4 mg** Methylprednisolone tablets USP, 4 mg are white to off-white, oval-shaped, flat-faced, beveled-edge tablets, debossed with '916' on one side and quadrisect on other side and are supplied as follows: NDC 68382-916-01 in bottle of 100 tablets NDC 68382-916-05 in bottle of 500 tablets NDC 68382-916-34 in unit-of-use cartons of 21 tablets **8 mg** Methylprednisolone tablets USP, 8 mg are white to off-white, oval-shaped, biconvex tablets, debossed with '917' on one side and bisect on other side and are supplied as follows: NDC 68382-917-11 in bottle of 25 tablets NDC 68382-917-01 in bottle of 100 tablets NDC 68382-917-05 in bottle of 500 tablets

NDC 68382-917-77 in unit-dose blister cartons of 100 (10 x 10) unit-dose tablets.

16 mg

Methylprednisolone tablets USP, 16 mg are white to off-white, oval-shaped, biconvex tablets, debossed with '918' on one side and quadrisect on other side and are supplied as follows:

NDC 68382-918-18 in bottle of 50 tablets
NDC 68382-918-01 in bottle of 100 tablets
NDC 68382-918-05 in bottle of 500 tablets
NDC 68382-918-77 in unit-dose blister cartons of 100 (10 x 10) unit-dose tablets

32 mg

Methylprednisolone tablets USP, 32 mg are white to off-white, oval-shaped, biconvex tablets, debossed with '919' on one side and bisect on other side and are supplied as follows:

NDC 68382-919-11 in bottle of 25 tablets
NDC 68382-919-01 in bottle of 100 tablets
NDC 68382-919-05 in bottle of 500 tablets
NDC 68382-919-77 in unit-dose blister cartons of 100 (10 x 10) unit-dose tablets

Pure/Mixture Mixture

Section 10. STABILITY AND REACTIVITY

Stability: The product is stable.

Section 11. TOXICOLOGICAL INFORMATION

Routes of Entry: Dermal contact. Eye contact. Inhalation. Ingestion.
Toxicity to Animals:
LD50: Not available. LC50: Not available.
Chronic Effects on Humans: Not available.
Other Toxic Effects on Humans: Hazardous in case of skin contact (irritant, permeator), of ingestion, of inhalation.
Special Remarks on Toxicity to Animals: Not available.
Special Remarks on Chronic Effects on Humans: Not available.
Special Remarks on other Toxic Effects on Humans: Not available.

Section 12. ECOLOGICAL INFORMATION

Do not discharge into sewer or waterways..

Section 13. DISPOSAL CONSIDERATION

All waste must be handled in accordance with local, state and federal regulations.
Legislation addressing waste disposal requirements may differ by country, state and/ or territory. Each user must refer to laws operating in their area. In some areas, certain wastes must be tracked.
A Hierarchy of Controls seems to be common - the user should investigate:

- Reduction
- Reuse
- Recycling
- Disposal (if all else fails)

This material may be recycled if unused, or if it has not been contaminated so as to make it unsuitable for its intended use. Shelf life considerations should also be applied in making decisions of this type. Note that properties of a material may change in use, and recycling or reuse may not always be appropriate.
DO NOT allow wash water from cleaning equipment to enter drains. Collect all wash water for treatment before disposal.

- Recycle wherever possible.
- Consult manufacturer for recycling options or consult Waste Management Authority for disposal if no suitable treatment or disposal facility can be identified.

Section 14. TRANSPORT INFORMATION

The product is not hazardous when shipping via air (IATA), ground (DOT), or sea (IMDG).

Section 15. REGULATORY INFORMATION

Generic Medicine, ANDA Number – 204331

Section 16. OTHER INFORMATION

NFPA (National Fire Protection Association (U.S.A).) Rating: These ratings are based on NFPA code 704 and are intended for use by emergency personnel to determine the immediate hazards of a material

Health: 2
Flammability: 1
Reactivity: 0
Specific hazard:
Protective Equipment:
Gloves. Lab coat. Dust respirator. Be sure to use an approved/certified respirator or equivalent. Splash goggles.

HMIS (U.S.A.):
Health Hazard: 2
Fire Hazard: 1
Reactivity: 0
Personal Protection: E

Date of issue: 20th January,2018 **Supersedes edition:** New Edition

The information presented in the safety data sheet is, to the best our knowledge, accurate and reliable. It characterizes the product with regard to the appropriate safety precautions. It does not represent a guarantee of the properties of the product.