Your doctor is the best resource for medical advice and information. The health information contained herein is provided for educational / awareness purposes only and is not intended to replace discussions with a medical practitioner and/or medical advice or be construed as a promotional information.

Package Leaflet: Information for the user
Prednisolone Dispersible Tablets
WYSOLONE® DT

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- If you have any further questions, ask your doctor.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Wysolone DT (Prednisolone) is and what it is used for

Wysolone DT (Prednisolone) is a dispersible tablet containing Prednisolone I.P. (5 mg, 10 mg, 20 mg). Prednisolone, a synthetic glucocorticoid and is used primarily as anti-inflammatory, immunosuppressant agent.

Wysolone DT (Prednisolone) 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 mineral corticoids where applicable; in infancy mineral corticoids supplement is of particular importance); congenital adrenal hyperplasia; non-suppurative thyroiditis; hypercalcemia associated with cancer.

2. Rheumatic Disorders

As adjunctive therapy for short-term administration (to assist the patient during an acute episode or exacerbation) in: psoriatic arthritis; rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy); ankylosing

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spondylitis; acute and subacute bursitis; acute non-specific 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; systemic dermatomyositis (polymyositis).

4. Dermatologic Diseases

Pemphigus; bullous dermatitis herpetiformis, severe erythema multiforme (Stevens Johnson syndrome); exfoliative dermatitis, mycosis fungoides, severe psoriasis, severe seborrheic dermatitis lichen planus, unresponsive to local treatment.

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 conjunctivitis, keratitis, allergic corneal margin ulcers, herpes zoster ophthalmicus, iritis and iridocyclitis, chorioretinitis, anterior segment inflammation, diffuse posterior uveitis and choroiditis, optic neuritis, sympathetic ophthalmia.

7. Respiratory Diseases

Symptomatic sarcoidosis; Loeffler's syndrome not manageable by other means, berylliosis, fulminating or disseminated pulmonary tuberculosis when used concurrently with appropriate antituberculous chemotherapy; aspiration pneumonitis.

8. Hematologic Disorders

Idiopathic thrombocytopenic purpura in adults; secondary thrombocytopenia purpura in adults; acquired (autoimmune) hemolytic anemia; erythroblastopenia (red blood cell anemia); congenital (erythroid) hypoplastic anemia.

9. Neoplastic Diseases

For palliative management of leukemias and lymphomas in adults; acute leukemia of childhood.

10. Edematous States

To induce a diuresis or remission of proteinuria in the nephrotic syndrome, without uremia, of the idiopathic or that due to lupus erythematosus.

11. Gastrointestinal Diseases

To assist the patient during a critical period of the disease in: ulcerative colitis; regional enteritis.

12. Hepatic Diseases

Subacute hepatic necrosis: chronic active hepatitis; alcoholic hepatitis; non-alcoholic cirrhosis in women when ascites is not present.

13. Nervous System

Acute exacerbations of multiple sclerosis.

14. Miscellaneous

Tuberculosis meningitis with subarachnoid block or impending block when used concurrently with appropriate antituberculosis chemotherapy; trichinosis with neurologic or myocardial involvement; adjunctive therapy in severe typhoidal toxemia when the patient is responsive to conventional therapy; concomitantly with other immunosuppressive drugs to prevent rejection of transplanted organs.

2. What you need to know before you take Wysolone DT (Prednisolone)

Do not use Wysolone DT (Prednisolone)

- if you are allergic to prednisolone or any of the other ingredients of this medicine (listed in section 6).
- if you have a fungal infection.

You must not be vaccinated with a live vaccine while taking immunosuppressive doses of corticosteroids.

Warnings and precautions

Talk to your doctor or pharmacist before taking Wysolone DT (Prednisolone) if you have:

- an infection or if you get an infection during prednisolone treatment
- an underactive thyroid (also known as hypothyroidism)
- liver disease or renal failure
- or have had seizures
- myasthenia gravis (an illness that weakens the muscles)
- tuberculosis or have ever been treated for tuberculosis
- stomach ulcers duodenal ulcers or an inflammatory intestinal disease (e.g. ulcerative colitis or diverticulitis)
- diabetes
- heart disease, e.g. heart failure or high blood pressure
- had previous blood clots (such as venous thrombosis) or predisposition to them
- mood swings or tendency to psychosis
- any drug allergy
- brittle bones (osteoporosis)
- a tumour in the adrenal gland (pheochromocytoma)
- newly created blood vessels or intestinal anastomoses

- scleroderma (also known as systemic sclerosis, an autoimmune disorder).
  Abnormal muscle breakdown which can lead to kidney problems (Rhabdomyolysis)

Contact your doctor if during the treatment:

- you experience serious psychiatric side effects, e.g. depression and suicidal thoughts. These may also occur when you stop taking prednisolone.
- you experience blurred vision or other vision disorders.
- you are exposed to unusually severe physical or mental stress of any type (e.g. infection, surgery, trauma) during the period when you are treated with prednisolone. The dose may need to be increased.

Prednisolone treatment may impair your resistance to different infections, may mask some signs of infections, make current infections worse, or cause old, hidden infections to come back or get worse. New infections may also appear during Prednisolone use Different infections may therefore occur more easily during the treatment. These infections may be mild or can be severe and at times lead to death. Your doctor will monitor you closely, for the development of infection and consider stopping treatment or reducing the dose as needed. Chickenpox and measles can be more serious when you are taking a cortisone product. If you have not previously had these diseases, you must therefore avoid exposure to chickenpox or measles during treatment and talk to your doctor if this still occurs.

If you have to be vaccinated during prednisolone treatment, you must inform the doctor of your treatment before receiving the vaccination.

Corticosteroids cause growth inhibition in infants, children and adolescents and, therefore, long-term treatment should be avoided. If prolonged therapy is necessary, the growth and development of infants and children will be closely monitored by your doctor.

Other medicines and Wysolone DT (Prednisolone)

Tell your doctor if you are using, have recently used or might use any other medicines, including medicines obtained without a prescription.

The effect of treatment may be affected if this medicine is taken at the same time as certain other medicines. It is especially important for your doctor to know if you use any of the following medicines:

- Rifampin, isoniazid (used for treatment of tuberculosis)
- oral anticoagulants (medicines taken by mouth to prevent blood clotting) of the vitamin K antagonists class, such as warfarin, acenocoumarol, fluindione
- Carbamazepine, phenobarbital, phenytoin (epilepsy medicines)
- Anticholinergic medicines (medicines that counteract the effect of the body's own substance acetylcholine, used to treat Parkinson's disease and asthma, for example)
- Cholinesterase inhibitors (used to treat myasthenia gravis and Alzheimer's disease)
- Insulin and diabetes medicines in tablet form. Cortisone products may impair the blood sugar lowering effect of antidiabetics
- Aprepitant, Fosaprepitant (antiemetics)

- Itraconazole, Ketoconazole (used to treat fungal infections)
- Indinavir, ritonavir (antiviral medicine to treat HIV infection)
- Aminoglutethimide, diltiazem, cyclosporine
- Estrogens (used e.g. in contraceptive pills)
- Grapefruit juice, cyclophosphamide, tacrolimus
- Clarithromycin, erythromycin, Troleandomycin
- Acetylsalicylic acid (aspirin) and other such nonsteroidal anti-inflammatory agents (NSAIDs) (used to treat pain and inflammation). The risk of gastric ulcer may increase in combination with cortisone products
- Thiazides, furosemide, ethacrynic acid (potassium-depleting diuretics)
- Xanthines (e.g. theophylline, used to treat asthma)
- beta-2 agonists
- Amphotericin B (antibiotic for fungal infection).

If you need to be vaccinated inform the doctor that you use Wysolone DT (Prednisolone).

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant, or are planning to have a baby, ask your doctor for advice before taking this medicine.

Pregnancy

There is a risk of harm to the foetus. Since adequate human reproduction studies have not been done with prednisolone, this medicinal product should be used during pregnancy only after a careful assessment of the benefit-risk ratio to the mother and fetus.

Breast-feeding

Wysolone DT (Prednisolone) passes into human milk and should be used during breast feeding only after a careful assessment of the benefit-risk ratio to the mother and infant.

Fertility

Corticosteroids have been shown to impair fertility in animal studies.

Driving and using machines

Undesirable effects, such as dizziness, vertigo, visual disturbances and fatigue are possible after treatment with corticosteroids. If affected, patients should not drive or operate machinery.

Wysolone DT (Prednisolone) contains lactose

If you do not tolerate certain types of sugar, you should contact your doctor before taking this medicine.

3. How to take Wysolone DT (Prednisolone)

Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

The dose is determined by the doctor, who will adjust it individually for you.

Treatment usually starts with a higher dose which is then decreased to a fixed maintenance dose once a satisfactory effect has been obtained. When it is time to cease treatment, the dose should be slowly decreased and eventually stop completely. Do not discontinue treatment without consulting your doctor.

If you take more Wysolone DT (Prednisolone) than you should
If you have taken more medicine than you should or if a child has taken medicine by accident, contact a doctor, for assessment of the risk and advice.

If you forget to take Wysolone DT (Prednisolone)
Do not take a double dose to make up for a forgotten dose. Also, please consult your doctor.

If you stop taking Wysolone DT (Prednisolone)
If you have taken Wysolone DT (Prednisolone) for a longer period, the treatment must be gradually reduced according to the doctor's instructions. Do not stop suddenly, as this can lead to severe side effects.

"Steroid withdrawal syndrome" may also occur following abrupt discontinuance of Wysolone DT (Prednisolone). This syndrome includes symptoms such as loss of appetite, nausea, vomiting, tiredness, headache, fever, joint pain, peeling skin, muscle pain, weight loss, and/or low blood pressure. Contact your doctor if you experience any of these symptoms after you have stopped taking Wysolone DT (Prednisolone).

If you have any further questions on the use of this medicine, ask your doctor.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Side effects occur primarily during long-term treatment, but also depend on the size of the dose and individual sensitivity.

Contact a doctor immediately if any of the following serious side effects occur:
Severe allergic reaction, including angioedema (may affect an unknown number of users). The symptoms can include:

- swelling of the face, tongue or throat
- difficulty swallowing
- hives and difficulty breathing
- fever
- drop in blood pressure.

Other side effects:

- infections, the immunosuppressant effect of prednisolone may also lead to infections flaring up again (e.g. tuberculosis)
- lower concentration of certain hormones, Cushingoid appearance, growth inhibition in children
- low levels of potassium, sodium accumulation in the body, increased sugar content in the blood and urine, brittle bones
- swelling due to fluid retention, high blood pressure

- thinning of the skin, poor wound healing
- muscle wasting
- activation of mental disorders (at high doses)
- cataract, glaucoma
- depression
- mania in patients with no prior history of mental illness
- benign increase in pressure in the skull
- breakdown of bone tissue, tendon rupture
- increased numbers of white blood cells (leukocytosis)
- hypersensitivity to the medicine
- withdrawal syndrome during tapering (see section 3)
- reduced pH value of the blood, reduced quantity of potassium in the blood, increased blood lipids, impaired tolerance to glucose, exacerbated diabetes, accumulation of fatty tissue at isolated places on the body, increased appetite (which may results in increased weight)
- emotional symptoms (including euphoria, emotional instability, medicine dependency), psychotic disorder (including delusions, hallucination, and schizophrenia), personality change, confusion, anxiety, mood swings, abnormal behaviour, sleep problems, irritability
- seizure, memory problems, intellectual disorder, dizziness, headache, increased fat around the spinal cord
- vision impairment (central serous chorioretinopathy), protruding eyes, blurred vision
- heart failure (in sensitive patients), slow heart rate
- blood clots
- hiccups
- gastric ulcer, perforation in the intestine, inflammation in the pancreas, inflammation and ulcer in the oesophagus, swollen abdomen, stomach pains, diarrhoea, digestive problems, nausea
- increased body hair in women, bleeding in the skin, bruising, reddening of the skin, sweating, stretch marks (blue-red marks on the chest and abdomen), itching, hives, acne
- muscle weakness, muscle pain, bone fractures without prior trauma, joint disintegration, joint pain
- irregular menstruation
- fatigue, malaise
- increased calcium in urine, increased liver values (alanine aminotransferase, aspartate aminotransferase) increased alkaline phosphatase in the blood, increased blood urea levels (seen in blood test results), reduced reaction to skin tests.
- Abnormal muscle breakdown which can lead to kidney problems (Rhabdomyolysis)

Reporting of side effects
If you get any side effects talk to your doctor. This includes any possible side effects not listed in this leaflet.

5. How to store Wysolone DT (Prednisolone)

Store at room temperature. Protect from light.

Keep out of reach of children.

6. Contents of the pack and other information

What Wysolone DT (Prednisolone) contains

Wysolone DT 5: Each uncoated dispersible tablet contains Prednisolone I.P. 5 mg.

Wysolone DT 10: Each uncoated dispersible tablet contains Prednisolone I.P. 10 mg.

Wysolone DT 20: Each uncoated dispersible tablet contains Prednisolone I.P. 20 mg.

List of Excipients

Lactose IP, Microcrystalline Cellulose IP, Indion 234 IH, Colloidal Silicon Dioxide IP, Magnesium Stearate IP.

All strengths/presentations mentioned in this document might not be available in the market.

What Wysolone DT (Prednisolone) looks like and contents of the pack

Wysolone DT 5 - Clean round tablets with beveled edges engraved '5' on one side and break line on the other side.

Wysolone DT 10 - Clean round tablets with beveled edges engraved '10' on one side and break line on the other side.

Wysolone DT 20 - Clean round tablets with beveled edges engraved '20' on one side and break line on the other side.

Contents of the pack

15 tablets are blister packed using rear printed Aluminum foil and Amber coloured PVC foil.

Details of Manufacturer:

Pfizer Limited, Plot No. L-137, Phase III A, Verna Industrial Estate, Verna, Salcete - Goa, India.

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