ADAM™ 33

Composition
ADAM 33 tablet 5 mg: Each tablet contains Micronised Prednisolone USP 5mg.
ADAM 33 tablet 20 mg: Each tablet contains Micronised Prednisolone USP 20mg.

Characteristics
Prednisolone is a synthetic glucocorticoid which is easily absorbed from the gastrointestinal tract. It has 4 times the anti-inflammatory potency and 0.8 times the saltretaining potency of the natural adrenocortical hormone, hydrocortisone. Like other glucocorticoids, prednisolone also has anti-allergic, anti-toxic, anti-pyretic and immunosuppressive properties. Because of the biological half-life of prednisolone (12-36hours), ADAM 33 dosage can be easily adjusted to the physiological circadian rhythm, and consequently the risk for adrenal insufficiency is decreased.

Indications
1. Immuno-allergology : in some cases, especially in exacerbation, of systemic lupus erythematosus, nephrotic syndrome with minimal change lesions, periarteritis nodosa, mixed connective tissue disease, arteritis temporalis : hypersensitivity reactions to drugs or chemicals, serum sickness, transfusion reactions, insect stings and bites, angioneurotic oedema, severe hay-fever, Stevens-Johnson syndrome : for chronic immunosuppression in transplantation patients.
2. Rheumatology : in general as adjunctive therapy for short-term administration in serious cases of rheumatoid arthritis and rheumatic osteoarthritis, polymalgia rheumatica, acute rheumatic carditis only on recommendation of physician.
3. Endocrinology : primary or secondary adrenocortical insufficiency and adrenogenital syndromes (only if supplemented with mineralocorticoid therapy), polycystic ovary syndrome.
4. Dermatology : severe cases of pemphigas and pemphigoid exfoliative and other serious cases of dermatitis, mycosis fungoides, erythema multiforme, severe psoriasis.
5. Ophthalmology : Severe acute or chronic allergic inflammatory processes of the eye and its adnexa, such as allergic conjunctivitis, iritis, iridocyclitis, choroiditis, optic neuritis, sympathetic ophthalmia : scar-prevention in eye surgery and eye injuries.
6. Gastro-enterology : to induce remission of ulcerative colitis and regional enteritis ; in some cases of chronic hepatitis, especially the aggressive form with hyperimmunity ; oesophagitis corrosiva, in some cases of coeliac disease, eosinophylic (gastro) enteritis.
7. Cardiology : in some cases of pericarditis (idiopathic, postmyocardial infarction and postcommissurotomic syndrome).
8. Pulmonology : asthmatic pulmonary eosinophilia and allergic alveolitis, severe bronchial asthma and other chronic non-specific obstructive lung diseases ; diffuse interstitial pulmonary processes ; as part of the treatment of laryngotracheobronchitis ; in combination with tuberculostatic therapy in fulminating tuberculosis.
9. Haematology and oncology : idiopathic and secondary thrombocytopenic purpura, auto-immune haemolytic anaemia, idiopathic immuno-granulocytopenia (agranulocytosis), acute and chronic lymphocytic leukaemia, acute myelocytic leukaemia (blastemic crisis), Hodgkin's disease, other malignancies of the lymphoid and histiocytic tissue, multiple myeloma, macroglobulinaemia ; as an anti-emetic in anti-neoplastic regimens ; for palliative treatment in terminal stages of neoplastic disease.
10. Neurology : cerebral oedema, particularly those forms resulting from brain tumours, brain abscesses and neurosurgical interventions (in the later case also for prevention of brain oedema) ; myoclonic seizures in epilepsy, pseudotumor cerebri, severe myasthenia gravis resistant to anticholinesterase therapy and thymectomy, in some selected cases of acute multiple sclerosis and peripheral neuritis.
11. Other indications : in most cases of tuberculous meningitis, pericarditis, peritonitis and pleuritis (in combination with tuberculostatic therapy) ; severe trichinosis, hypercalcaemia such as associated with neoplastic diseases, hypervitaminosis-D, idiopathic infantile hypercalcaemia.

Dosage
1. In general, glucocorticoid dosage depends on the severity of the condition and the response of the patient. Under certain circumstances, for instance in stress and changed clinical picture, extra dosage adjustments may be necessary. If no favourable response is noted within a couple of days, continuation of glucocorticoid therapy is undesirable.
2. For primary and secondary adrenocortical insufficiency : 5-25 mg daily in divided doses. In adrenogenital syndromes 10-20mg/m^2 body surface daily in divided doses.
3. For other therapy, daily oral dosage of 5-30 mg are usually sufficient. In some patients higher dosages may be temporarily required, to control the disease. As soon as symptoms diminish, dosage should be reduced under continuous observation of the clinical picture to the lowest possible level, or tapered off completely. This should be done by giving one daily dose in the early morrning, preferably every other day.

Administration
ADAM 33 tablets should be taken orally preferably with some fluid.

Contraindications
- Gastric and duodenal ulcers.
- Systemic fungal infections.
- Certain viral infections, e.g. varicella and herpes genitalis infections.
- Glaucoma.
- Hypersensitivity to glucocorticoids.

In general no contraindications apply in conditions where the use of glucocorticoids may be life-saving.

Use during pregnancy and breast-feeding
There are insufficient data on the use of this drug during human pregnancy to assess potential harm to the foetus. However, there are indications for a harmful effect in animal experiments. Infants whose mothers received substantial doses of glucocorticoids during pregnancy should be carefully observed for signs of adrenal insufficiency. Glucocorticoids appear in breast milk in very small quantities, but it is unknown whether this can adversely affect the infant. However, the potential gain should be assessed over the harm and decision should be taken accordingly.

Warnings and precautions
- Patients with any of the following conditions should be monitored :
  - Latent or overt cardiac failure, renal dysfunction, hypertension epilepsy or migraine, since glucocorticoids may induce fluid retention ;
  - osteoporosis, since glucocorticoids have a negative effect on the calcium balance ;
  - a history of psychotic illness ;
  - latent tuberculosis, since glucocorticoids may induce reactivation ;
  - certain parasitic infestations, in particular amoebiasis;
  - incomplete statural growth, since glucocorticoids on prolonged administration may accelerate epiphyseal closure.
- Glucocorticoid therapy is non-specific, suppresses the symptoms and signs of disease and decrease the resistance to infections. Appropriate antimicrobial therapy should accompany glucocorticoid therapy when necessary, e.g. in tuberculosis, and viral and fungal infections of the eye.
- Patients on long-term glucocorticoid therapy should be regularly examined for increased intra-ocular pressure and posterior subcapsular cataracts.
- Patients on long-term glucocorticoid therapy should be regularly examined for increased intra-ocular pressure and posterior subcapsular cataracts.
- Before, during and after stressful situations, dosage may need to be increased in patients currently on glucocorticoids or resumed in patients who have undergone prolonged glucocorticoid treatment in the previous year.
- Discontinuation of prolonged therapy should be carried out by gradual reduction of dosage and under strict medical supervision, since withdrawal may results in acute exacerbation of the disease and acute adrenocortical insufficiency.
- The use of corticosteroids may influence the results of certain laboratory tests.

Interactions
- Concomitant use of glucocorticoids with any of the following drugs or substances may lead to the occurrence of clinically relevant interactions :
  - diuretics and/or cardiac glycosides
    (potassium loss may be enhanced which is a particular risk in patients using cardiac glycosides, since hypokalaemia increases the toxicity of these drugs).
  - antidiabetics
    (glucocorticoids may impair glucose tolerance, thereby increasing the need for antidiabetic drugs).
  - non-steroidal anti-inflammatory drugs
    (the incidence and / or severity of gastrointestinal ulceration may increase).
  - Oral anticoagulants
    (glucocorticoids may alter the need for these drugs).
  - active vaccines
    (glucocorticoids may suppress the immune response of the body ; extra caution should be excercised with live vaccines).
- Glucocorticoids may be less effective when used concomitantly with liver enzyme-inducing drugs, such as rifampicin, ephedrine, barbiturates, phenytoin and primidone.
- If patients undergoing long-term therapy with glucocorticoids are concomitantly given salicylates, any reduction in glucocorticoid dosage should be made with caution, since salicylate intoxication has been reported in such cases.

Adverse reactions
- Adverse reactions, associated with prolonged systemic glucocorticoid therapy, are unlikely when high doses are administered over a short period of time. Nevertheless, gastric and duodenal ulceration, with possible perforation and haemorrhage, may occasionally occur.
- The following adverse reactions have been associated with prolonged systemic glucocorticoid therapy :
  - Endocrine and metabolic disturbances : Cushing-like syndrome, hirsutism, menstrual irregularities, premature epiphyseal closure, secondary adrenocortical and pituitary unresponsiveness, decreased glucose tolerance, negative nitrogen and calcium balance.
  - Fluid and electrolyte disturbances : sodium and fluid retention, hypertension, potassium loss, hypokalaemic alkalosis.
  - Musculo-skeletal effects : myopathy, abdominal distension, osteoporosis, aseptic necrosis of femoral and humeral heads.
  - Gastro-intestinal effects : gastric and duodenal ulceration, perforation and haemorrhage.
  - Dermatologic effects : impaired wound healing, skin atrophy striae, petechiae and ecchymosses, bruising, facial erythema, increased sweating, acne.
  - C.N.S. effects : psychic disturbances ranging from euphoria to frank psychotic manifestations, convulsions, in children pseudotumor cerebri (benign intracranial hypertension) with vomiting and papilloedema.
  - Ophthalmic effects : glaucoma, increased intraocular pressure, posterior subcapsular cataracts.
  - Immunosuppressive effects : increased susceptibility to infections, decreased responsiveness to vaccination and skin test.

Overdosage
In animal experiments the acute oral toxicity of prednisolone has been shown to be very low. Symptoms of acute overdosage are unlikely, except perhaps nausea and vomiting. Treatment is probably not required, apart from fluids by month.

Storage Condition
Store below 30°C, dry place & protect from light.

Commercial Pack
ADAM 33 tablet 5 mg: Each box contains 30 x 10's in Alu-PVC blister strip.
ADAM 33 tablet 20 mg: Each box contains 5 x 10's in Alu-PVC blister strip.

Manufactured by:
Nuvista Pharma Limited
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A subsidiary of Beximco Pharmaceuticals Ltd.

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