Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Hydrocortone 10 mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 10 mg Hydrocortisone.

Excipient: Contains 191.1mg Lactose Monohydrate per tablet.
For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet.

White, oval-shaped tablets quartersected on one side and imprinted with 'HYD 10' on the other side.
The scoreline is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Corticosteroid.

For use as replacement therapy in primary, secondary or acute adrenocortical insufficiency.

Pre-operatively, and during serious trauma or illness in patients with known adrenal insufficiency or doubtful adrenocortical reserve.

4.2 Posology and method of administration

Dosage must be individualized according to the response of the individual patient. The lowest possible dosage should be used.

Patients should be observed closely for signs that might require dosage adjustment, including changes in clinical status resulting from remissions or exacerbations of the disease, individual drug responsiveness, and the effect of stress (e.g., surgery, infection, trauma). During stress it may be necessary to increase the dosage temporarily.

If the drug is to be stopped after more than a few days of treatment, it should be withdrawn gradually.

In chronic adrenocortical insufficiency, a dosage of 20-30 mg a day is usually recommended, sometimes together with 4-6 g of sodium chloride or 50-300 micrograms of fludrocortisone daily. When immediate support is mandatory, one of the soluble adrenocortical corticosteroid preparations (e.g., dexamethasone sodium phosphate), which may be effective within minutes after parenteral administration, can be life-saving.

Paediatric population: in chronic adrenocortical insufficiency, the dosage should be approximately 0.4 to 0.8 mg/kg/day in two or three divided doses, adjusted to the needs of the individual child.

Use in the elderly: treatment of elderly patients, particularly if long term, should be planned bearing in mind the more serious consequences of the common side effects of corticosteroids in old age, especially osteoporosis, diabetes, hypertension, susceptibility to infection and thinning of the skin.

4.3 Contraindications

- Hypersensitivity to the active substance or to any of the excipients.

- Acute infectious processes: viral infections and systemic fungal infections (bacterial infections, see also

'Special warnings and precautions for use).

-Tropical worm infections.

-After vaccination with live attenuated virus (see 4.4 'Special warnings and precautions for use').

4.4 Special warnings and precautions for use

Visual disturbance may be reported with systemic and topical corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, the patient should be considered for referral to an ophthalmologist for evaluation of possible causes which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids.

Hypertrophic cardiomyopathy was reported after administration of hydrocortisone to prematurely born infants, therefore appropriate diagnostic evaluation and monitoring of cardiac function and structure should be performed.

Corticosteroid therapy should be used only when simpler proven diagnosis and therapy is not feasible or has failed (unless there is a life-threatening situation). The lowest possible dosage of corticosteroids should be used to control the condition under treatment, and when reduction in dosage is possible, the reduction should be gradual.

Corticosteroids may exacerbate systemic fungal infections and therefore should not be used in the presence of such infections unless they are needed to control life-threatening drug reactions due to amphotericin. Moreover, there have been cases reported in which concomitant use of amphotericin and hydrocortisone was followed by cardiac enlargement and congestive failure.

Literature reports suggest an apparent association between use of corticosteroids and left ventricular free- wall rupture after a recent myocardial infarction; therefore, therapy with corticosteroids should be used with great caution in these patients.

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.

Drug-induced secondary adrenocortical insufficiency may result from too rapid a withdrawal of corticosteroids and may be minimised 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, corticosteroid therapy should be reinstated. If the patient is receiving steroids already, the dosage may have to be increased. Since mineralocorticoid secretion may be impaired salt and/or a mineralocorticoid should be administered concurrently (see 4.5 'Interaction with other medicinal products and other forms on interaction').

Following prolonged therapy, withdrawal of corticosteroids may result in symptoms including fever, myalgia, arthralgia, and malaise. This may occur in patients even without evidence of adrenal insufficiency.

Administration of live virus vaccines is contra-indicated in individuals receiving immunosuppressive doses of corticosteroids. If inactivated viral or bacterial vaccines are administered to individuals receiving immunosuppressive doses of corticosteroids, the expected serum antibody response may not be obtained. However, immunisation procedures may be undertaken in patients who are receiving corticosteroids as replacement therapy, i.e., for Addison's disease.

The use of 'Hydrocortone' 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 prophylactic chemotherapy.

Corticosteroids should be used with caution in: non-specific 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, diabetes or in those with a family history of diabetes, congestive heart failure, previous steroid myopathy, glaucoma (or family history of glaucoma), osteoporosis, and myasthenia gravis. Signs of peritoneal irritation following gastro-intestinal perforation in patients receiving large doses of corticosteroids may be minimal or absent.

Fat embolism has been reported as a possible complication of hypercortisonism.

In cerebral malaria, the use of corticosteroids is associated with prolongation of coma and higher incidence of pneumonia and gastrointestinal bleeding.

There is an enhanced effect of corticosteroids in patients with hypothyroidism and in those with cirrhosis. Corticosteroids may increase or decrease motility and number of spermatozoa in some patients.
Corticosteroids may mask some signs of infection, and new infections may appear during their use. There may be decreased resistance and inability to localise infection in patients on corticosteroids.

Corticosteroids may activate latent amoebiasis or strongyloidiasis or exacerbate active disease. Therefore, it is recommended that latent or active amoebiasis and strongyloidiases be ruled out before initiating corticosteroid therapy in any patient at risk of or with symptoms suggestive of either condition.

Prolonged used 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.

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

Regular ophthalmic monitoring is recommended.

Patients who are on drugs which suppress the immune system are more susceptible to infections than healthy individuals. Chickenpox 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. The risk of developing a disseminated infection varies among individuals and may be related to the dose, route and duration of corticosteroid administration as well as to the underlying disease. Exposed patients should be advised to seek medical advice without delay. If exposed to measles, prophylaxis with pooled immunoglobulin (IG) may be indicated. If exposed to chickenpox, prophylaxis with varicella zoster immune globulin (VZIG) may be indicated. (See the respective package inserts for IG and VZIG for complete prescribing information.) If chickenpox develops, treatment with antiviral agents should be considered.

Caution should be exercised in immunocompromised patients.
Steroid therapy might impair prognosis in surgery by increasing the hazard of infection. If infection is suspected, appropriate antibiotic therapy must be administered, usually in larger than ordinary doses.

Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

Thyrotoxic Periodic Paralysis (TPP) can occur in patients with hyperthyroidism and with hydrocortisone-induced hypokalaemia. TPP must be suspected in patients treated with hydrocortisone presenting signs or symptoms of muscle weakness, especially in patients with hyperthyroidism.

If TPP is suspected, levels of blood potassium must be immediately monitored and adequately managed to ensure the restoration of normal levels of blood potassium.

*Children:*Corticosteroids cause growth retardation in infancy, childhood and adolescence, which may be irreversible. Treatment should be limited to the minimum dosage, for the shortest possible time in order to minimise suppression of the hypothalamo-pituitary-adrenal axis and growth retardation.

Growth and development of infants and children on prolonged corticosteroid therapy should be carefully monitored.

Patients and/or carers should be warned that potentially severe psychiatric adverse reactions **may**occur with systemic steroids (see section 4.8). Symptoms typically emerge within a few days or weeks of starting the treatment. Risks may be higher with high doses/systemic exposure (see also section 4.5 pharmacokinetic interactions that can increase the risk of side effects), although dose levels do not allow prediction of the onset, type, severity or duration of reactions. Most reactions recover after either dose reduction or withdrawal, although specific treatment may be necessary. Patients/carers should be encouraged to seek medical advice if worrying psychological symptoms develop, especially if depressed mood or suicidal ideation is

suspected. Patients/carers should also be alert to possible psychiatric disturbances that may occur either during or immediately after dose tapering/withdrawal of systemic steroids, although such reactions have been reported infrequently.

Particular care is required when considering the use of systemic corticosteroids in patients with existing or previous history of severe affective disorders in themselves or in their first degree relatives. These would include depressive or manic-depressive illness and previous steroid psychosis.

4.5 Interaction with other medicinal products and other forms of interaction

Phenytoin, ephedrine, rifabutin, carbamazepine, aminoglutethimide, barbiturates, and rifampicin may enhance the metabolic clearance of corticosteroids, resulting in decreased blood levels and lessened physiological activity, thus requiring adjustment in corticosteroid dosage.

The prothrombin time should be checked frequently in patients who are receiving corticosteroids and coumarin anticoagulants at the same time because of reports that corticosteroids have altered the response to these anticoagulants. Studies have shown that the usual effect produced by adding corticosteroids in inhibition of response to coumarins, although there have been some conflicting reports of potentiation not substantiated by studies.

Ketoconazole alone can inhibit adrenal corticosteroid synthesis and may cause adrenal insufficiency during corticosteroid withdrawal (see 4.4 'Special warnings and precautions for use').

When corticosteroids are administered concomitantly with potassium-depleting diuretics, patients should be observed closely for development of hypokalaemia. Moreover, corticosteroids may affect the nitrobluetetrazolium test for bacterial infection and produce false negative results.

Acetylsalicylic acid should be used cautiously in conjunction with corticosteroids in hypopropthrombinaemia.

Hydrocortisone, in combination with diuretics increases the risk of hypokalemia.

Glucocorticoids may increase the necessary quantity of insulin or oral antidiabetics.

Additive ulcerogenic effects should be considered when taking hydrocortisone with ulcerogenic agents (e.g. NSAIDs).

Co-treatment with CYP3A inhibitors, including cobicistat-containing products, is expected to increase the risk of systemic side-effects. The combination should be avoided unless the benefit outweighs the increased risk of systemic corticosteroid side-effects, in which case patients should be monitored for systemic corticosteroid effects.

4.6 Fertility, pregnancy and lactation

Since human reproduction studies have not been done with corticosteroids, the use of these drugs in pregnancy, 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 foetus. Hydrocortisone crosses the placenta. Infants born of mothers who have received substantial doses of corticosteroids during pregnancy should be carefully observed for signs of hypoadreanalism.

Corticosteroids appear in breast milk and could suppress growth, interfere with endogenous corticosteroid production, or cause other unwanted effects. Mothers taking pharmacological doses of corticosteroids should be advised not to breast-feed.

4.7 Effects on ability to drive and use machines

There are some side effects associated with this product that may affect some patients' ability to drive and operate machinery. When driving vehicles or operating machinery, it should be taken into account the possibility of the occurrence of muscle weakness, muscle atrophy, and mood changes (euphoria, depression).

4.8 Undesirable effects

The frequencies of adverse events are ranked according to the following: very common (

≥

1/10), common (

≥

1/100 to < 1/10), uncommon (

≥

1/1,000 to < 1/100), rare (

≥

1/10,000 to < 1/1,000), very rare (< 1/10,000), not known (cannot be estimated from the available data).

There are not many side effects or complications, but undesirable effects are inherent to the corticosteroid therapy. With a good dose of hydrocortisone replacement therapy, the risk of the following side effects is low.

Infections and infestations
Not known: Reduced resistance, which increases the risk of infections (opportunistic), an unfavourable course of infections (sepsis and reactivation of latent tuberculosis and parasitic infections such as amoebiasis and strongyloidiasis)
Masking of warning symptoms of sepsis and perforation

Blood and lymphatic system disorders
Not known: Erythrocytosis and granulocytosis, lymphoma and eosinopenia

Immune system disorders
Not known: Hypersensitivity or anaphylactic reactions

Endocrine disorders
Not known: Inhibition of hypothalamic-pituitary-adrenal axis function (due to negative feedback by exogenous steroid) with risk of adrenal insufficiency when the patient is exposed to stress (trauma, surgery, infection)
Development of Cushing's syndrome

Metabolism and nutrition disorders
Not known: Sodium and fluid retention, potassium decrease with hypokalemic alkalosis
Centripetal obesity (face, trunk) enhanced by increased appetite

Psychiatric disorders
Not known: Euphoric mood, anxiety, depression, psychosis

Nervous system disorders
Not known: Increased intracranial pressure with papilledema (pseudotumor cerebri), particularly in children during or shortly after rapid withdrawal
Insomnia

Eye disorders
Not known: Posterior subcapsular cataract
Glaucoma
Vision blurred (see also section "Special warnings and precautions for use")

Cardiac disorders
Not known: Congestive heart failure in predisposed patients, hypertrophic cardiomyopathy in prematurely born infants

Vascular disorders
Not known: Hypertension,thromboembolism

Gastrointestinal disorders
Not known: Oesophagitis, peptic ulcer with increased risk of bleeding and (masked) perforation, pancreatitis

Skin and subcutaneous tissue disorders
Not known: Skin atrophy with large bruising ("easy bruising")
Erythema of the face, acne and hirsutism
Impaired wound healing
Suppressed skin reactions to skin tests
Allergic reactions such as urticaria

Musculoskeletal and connective tissue disorders
Not known: Muscle weakness and muscle atrophy (steroid myopathy), risk of osteoporosis with compression fractures of vertebrae, aseptic bone necrosis, especially of the femoral head.
Growth retardation in children

Reproductive system and breast disorders
Not known: Menstrual cycle abnormal

Investigations
Not known: Decreased glucose tolerance, resulting in latent diabetes, increased need for oral hypoglycaemic agents or insulin in diabetics
Negative nitrogen balance due to protein degradation, weight increased

A wide range of psychiatric reactions including affective disorders (such as irritable, euphoric, depressed and labile mood, and suicidal thoughts), psychotic reactions (including mania, delusions, hallucinations, and aggravation of schizophrenia), behavioural disturbances, irritability, anxiety, sleep disturbances and cognitive dysfunction including confusion and amnesia have been reported. Reactions are common and may occur in both adults and children. In adults, the frequency of severe reactions has been estimated to be 5-6%. Psychological effects have been reported on withdrawal of corticosteroids; the frequency is unknown.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance website: www.hpra.ie

4.9 Overdose

Anaphylactic and hypersensitivity reactions may be treated with adrenaline, positive-pressure artificial respiration and aminophylline. The patient should be kept warm and quiet.

Treatment is probably not indicated for reactions due to chronic poisoning unless the patient has a condition that would render him unusually susceptible to ill effects from corticosteroids. In this case, symptomatic treatment should be instituted as necessary.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: corticosteroids for systemic use
ATC Code: H02AB09.

Hydrocortisone is a glucocorticoid. Glucocorticoids are adrenocortical steroids, both naturally-occurring and synthetic, which are readily absorbed from the gastro-intestinal tract.

Hydrocortisone is believed to be the principal corticosteroid secreted by the adrenal cortex. Naturally-occurring glucocorticosteroids (hydrocortisone and cortisone), which also have salt-retaining properties, are used as replacement therapy

in adrenocortical deficiency states. They are also 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.

5.2 Pharmacokinetic properties

Hydrocortisone is readily absorbed from the gastro-intestinal tract and 90% or more of the drug is reversibly bound to protein.

The binding is accounted for by two protein fractions. One, corticosteroid-binding globulin is glycoprotein; the other is albumin.

Hydrocortisone is metabolised in the liver and most body tissues to hydrogenated and degraded forms such as tetrahydrocortisone and tetrahydrocortisol which are excreted in the urine, mainly conjugated as glucuronides, together with a very small proportion of unchanged hydrocortisone.

5.3 Preclinical safety data

No relevant information.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose Monohydrate
Magnesium stearate
Maize starch

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Store below 25°C. Store in the original package.

6.5 Nature and contents of container

Blister packs of opaque PVC lidded with aluminium foil containing 30 tablets, presented in an outer carton.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Teva B.V.
Swensweg 5
2031GA Haarlem
Netherlands

8 MARKETING AUTHORISATION NUMBER

PA1986/054/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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