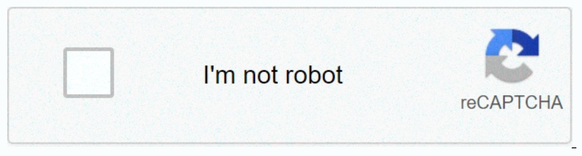

Continue

Kordexa 4 mg tablet

This information is intended for use by healthcare professionals Dexamethasone 4 mg tablets Each tablet contains 4 mg of dexamethasone. Auxiliary with known effect: Each tablet contains 77.9 mg of lactose (as a lactose monohydrate). For a complete list of aerants, see section 6.1. Tablet White or almost white, round tablets with bemmed edges and scored on one side (Thickness: 2.5-3.5 mm; Diameter: 5.7-6.3 mm). The tablet can be divided into equal doses. Neurology Cerebral edema (only with symptoms of intracranial pressure documented by computer tomography) caused by brain tumor, neurosurgical intervention, cerebral abscess. Pulmonary and respiratory diseases Acute exacerbation of asthma with the use of oral corticosteroid (OCS) is advisable semolina. Dermatology Initial treatment of extensive, severe, acute skin diseases reacting to glucocorticoids, e.g. Autoimmune disorders/rheumatology Initial treatment of autoimmune disorders such as systemic lupus erythematodes. Active phase of systemic vasculitis, such as panarteritis nodosa (the duration of treatment should be limited to two weeks in cases of concomitant positive serology of hepatitis B). Severe progressive course of active rheumatoid arthritis, e.g. Severe systemic course of juvenile idiopathic arthritis (Still's disease). Hematological disorder Idiopathic thrombocytopenic purpura in adults. Infectious tuberculous meningitis only in conjunction with anti-infectious therapy. Oncology Palliative treatment of neoplastic diseases. Prophylaxis and treatment of vomiting induced by cytostatics, emetogenic chemotherapy as part of antiemetic treatment. Treatment of symptomatic multiple myeloma, acute lymphoblastic leukemia, Hodgkin's disease and non-Hodgkin's lymphoma in combination with other medicines. Various prevention and treatment of postoperative vomiting, as part of antiemetic treatment. The dosage of Dexamethasone is given in the usual doses of 0.5 to 10 mg per day, depending on the disease being treated. In more severe diseases doses above 10 mg per day may be required. The dose should be titrated according to the individual response of the patient and the severity of the disease. In order to minimize side effects, the lowest effective dose should be used. Unless otherwise prescribed, the following dosage recommendations apply: The dosage recommendations below are provided as guidance only. The initial and daily doses should always be determined on the basis of the individual response of the patient and the severity of the disease. - Cerebral edema: Initial dose and duration of treatment depending on cause and severity, 6-16 mg (up to 24 mg) per day orally, divided into 3-4 individual doses. - Acute asthma: Adults: 16 mg per day for two days. Children: 0.6 mg / kg body weight for a day or two. - Stern: Children: 0.15 mg/kg-0.6 mg/kg per dose. - Acute skin disease: Depending on the nature and extent of the disease daily dose 8-40 mg, in some cases up to 100 mg, followed by titration down as clinically necessary. - Active phase of rheumatic system disorders: Systemic lupus erythematosus 6-16 mg per day. - Active rheumatoid arthritis with a severe progressive form: runs on rapid destructive forms of 12-16 mg per day, with extraarticular manifestations of 6-12 mg per day. - Idiopathic thrombocytotopenic purpura: 40 mg for 4 days in cycles. - tuberculous meningitis: Patients with grade II or III disease were treated intravenously for four weeks (0.4 mg per kilogram daily at week 1, 0.3 mg per kilogram daily at week 2, 0.2 mg per kilogram daily at week 3 and 0.1 mg per kilogram daily at week 4) and then oral treatment for four weeks, starting with a total of 4 mg daily and decreasing by 1 mg each week. Patients with Grade I disease received two weeks of intravenous treatment (0.3 mg per kilogram daily at week 1 and 0.2 mg per kilogram daily at week 2) and then four weeks of oral treatment (0.1 mg per kilogram daily at week 3, then a total of 3 mg per day, decreasing by 1 mg each week). - Palliative treatment of neoplastic diseases: The initial dose and duration of treatment depending on the cause and severity, 3-20 mg per day. Very high doses of up to 96 mg can also be used for palliative treatment. A combination of a lower dose (4 and 8 mg) and a higher dose (20 mg or 40 mg) may be used to optimally dose and reduce the number or tablets. - Prophylaxis and treatment of vomiting induced by cytostatics, emetogenic chemotherapy as part of antiemetic treatment: 8-20 mg of dexamethasone before chemotherapy, then 4-16 mg/day on day 2 and 3. - Prevention and treatment of postoperative vomiting, as part of antiemetic treatment: a single dose of 8 mg before surgery. - Treatment of symptomatic multiple myeloma, acute lymphoblastic leukemia, Hodgkin's disease and non-Hodgkin's lymphoma in combination with other medicines: the usual dosage is 40 mg or 20 mg once a day. The frequency of dosing and administration varies according to the therapeutic protocol and related treatment(s). The administration of dexamethasone should follow the instructions for the administration of dexamethasone when described in the summary of product characteristics of the associated treatment(s). If this is not the case, local or international treatment protocols and guidelines should be followed. Prescribers should carefully evaluate what dose of dexamethasone to use, taking into account the condition and condition of the patient's disease. Kidney damage Patients undergoing active hemodialysis may show increased clearance of the drug through dialysate and therefore require dose adjustment of steroids. Liver impairment Dose adjustment may be required in patients with severe liver disease. In patients with severe liver damage, the biological effects of dexamethasone may be amplified due to its slower metabolism (prolonged plasma half-life) and (increased plasma levels of the free drug), which can also cause more side effects. Elderly Treatment of elderly patients, especially if it is long-term, should be planned taking into account the more serious consequences of common side effects of corticosteroids in old age (osteoporosis, diabetes mellitus, hypertension, decreased immunity, psychological changes). In these patients, plasma concentrations of dexamethasone may be higher and its excretion slower than in younger patients, therefore its dose should be reduced accordingly. The paediatric population of Dexamethasone excretion is approximately the same in children and adults when the dosage is adjusted to their area of the body. Dosing should be planned taking into account possible effects on growth and development and for signs of adrenal suppression. Long-term treatment With long-term treatment of several diseases, after initial treatment with glucocorticoids should be transferred from dexamethasone to prednisone/prednisolone to reduce suppression of adrenal cortex function. Discontinuation of treatment Acute adrenocortic failure may occur after abrupt discontinuation of long-term treatment with large doses of glucocorticoids. Therefore, in such cases, the doses of glucocorticoids should be gradually reduced, and treatment should be gradually discontinued. (see section 4.4) The method of administration of Dexamethasone should be taken with or after meals to minimise irritation of the gastrointestinal tract. Drinks containing alcohol or caffeine should be avoided. Dexamethasone is in the form of tablets 4 mg, 8 mg, 20 mg and 40 mg. Tablets can be divided into equal halves and can provide additional strengths of 2 mg and 10 mg and make it easier for the patient to swallow the tablet. If treatment with an alternative day is not possible, the entire daily dose of glucocorticoid can usually be given in one morning dose; However, some patients will require divided daily doses of glucocorticoids. Hypersensitivity to the active substance or to any of the anciatives referred to in point 6.1. Systemic infection if specific anti-infectious treatment is not used. Stomach ulcer or duodenal ulcer. Vaccination with live vaccines during treatment with large therapeutic doses of dexamethasone (and other corticosteroids) is contraindicated due to the possibility of viral infection (see section 4.4 and 4.5). Adrenocortic insufficiency Adrenocortic insufficiency, which is caused by treatment with glucocorticoids, may remain for many months, depending on the dose and duration of treatment, and in some cases more than a year after discontinuation of treatment. During treatment with dexamethasone for specific physical stressful conditions (trauma, surgery, childbirth, etc.), a temporary dose increase may be necessary. Due to the potential risk in stressful conditions, corticosteroid IDs should be performed in patients undergoing long-term treatment. Even in the case of prolonged adrenocortic insufficiency after administration of glucocorticoids may be necessary in physically stressful situations. Acute therapy induced adrenocortic insufficiency may be minimized by slow dose reduction until the scheduled discontinuation period. Treatment with dexamethasone should be carried out only in the case of the strongest indications and, if necessary, further targeted anti-infectious treatment given for the following diseases: - Acute viral infections (Herpes zoster, Herpes simplex, Varicella, herpetic keratitis) - HBsAG-positive chronic active hepatitis - Aprox. 8 weeks before 2 weeks after vaccination with live vaccines (see section 4.3 and 4.5) - Systemic mycoses and parasitosis (e.g. nematodes) - Poliomyelitide - Lymphadenitis after BCG vaccination - Acute and chronic bacterial infections - With a history of tuberculosis (risk of reactivation) use only in protection against tuberculosis - known or suspected of strongyloidiasis (threadworm infestation). Treatment with glucocorticoids can lead to hyperinfection and the spread of Strongyloides with widespread larval migration. In addition, treatment with dexamethasone should be carried out only with strong indications, and if necessary, further specific treatment must be carried out for: - Gastrointestinal ulcers - Severe osteoporosis (as corticosteroids have a negative effect on the balance of calcium) - Difficult to regulate high blood pressure - Difficult to regulate diabetes mellitus - Psychiatric disorders (including history) - Angle of closure of glaucoma and wide-angle glaucoma - Corneal ulceration and corneal injury - Severe heart failure Anaphylactic reactions Severe anaphylation reactions. Tendinitis The risk of tendinitis and tendon rupture increases in patients treated simultaneously with glucocorticoids and fluorochinolones. Myasthenia gravis Pre-existing myasthenia gravis may initially worsen at the beginning of dexamethasone treatment. Visual disturbances Visual disturbances may be reported with systemic and local use of corticosteroids. If the patient develops symptoms such as blurred vision or other visual disturbances, the patient should be considered whether to examine the ophthalmologist for evaluation of possible causes, which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR), which has been reported after the use of systemic and local corticosteroids. Long-term use of corticosteroids can cause posterior subcapsular cataracts, glaucoma with possible damage to the optic nerve and may increase the risk of secondary eye infections caused by fungi or viruses. Corticosteroids should be used with caution in patients with eye herpes simplex due to possible corneal perforation. Intestinal perforation Due to the risk of intestinal perforation, dexamethasone should only be used under urgent indication and with due supervision for: - Severe ulcerative colitis with impending perforation - Diverticulitis - (immediately after surgery) Patients taking high doses of glucocorticoids may experience signs of peritoneal irritation after gastrointestinal perforation. Diabetes When administering dexamethasone to diabetics, a higher need for insulin or oral antidiabetic medication should be taken into account. Cardiovascular disorders Regular monitoring of blood pressure during treatment with dexamethasone is required, especially at higher doses and in patients with difficult-to-regulate high blood pressure. Due to the risk of deterioration, patients with severe cardiac insufficiency should be closely monitored. Bradycardia may occur in patients treated with high doses of dexamethasone. Caution should be exercised when taking corticosteroids in patients who have recently suffered myocardial infarction, as myocardial rupture has been reported. Infection Treatment with dexamethasone can obscure the symptoms of an existing or developing infection, making diagnosis more difficult. Long-term use of even small amounts of dexamethasone leads to an increased risk of infection, even microorganisms that otherwise rarely cause infections (called opportunistic infections). Vaccination Vaccination With an inactivated vaccine is always possible. However, it should be noted that the immune response and thus the success of vaccination can be affected by higher doses of corticosteroids. With long-term treatment with dexamethasone, regular examinations with doctors (including eye examinations at three-month intervals) are recommended. Metabolic disorders At high doses should be monitored sufficient calcium intake and sodium restriction, as well as serum potassium levels. Depending on the length and dose of treatment, a negative effect on calcium metabolism can be expected, so prophylaxis of osteoporosis is recommended. This is especially true for anchor risk factors such as family disposition, increased age, postmenopausal, insufficient protein and calcium intake, heavy smoking, excessive alcohol intake, as well as insufficient exercise. Prevention consists of sufficient intake of calcium and vitamin D and physical activity. In case of pre-existing osteoporosis, further treatment should be considered. Corticosteroids should be used with caution in patients with migraine, since corticosteroids can cause fluid retention. Psychological changes Psychological changes are manifested in various forms, the most common is euphoria. Depression, psychotic reactions and suicidal tendencies may also occur. These diseases can be serious. They usually begin within a few days or weeks from the start of the drug. They are more likely to happen at high doses. Most of these problems disappear if the dose is reduced or the drug is stopped. However, if problems arise, they may need treatment. In several cases, mental health problems happen when doses are reduced or stopped. Brain edema or increased Pressure corticosteroids should not be used in conjunction with head injuries, as they are unlikely to benefit or even harm. Tumour decay syndrome Tumour lychees In patients with haematological malignancies after use of dexamethasone alone or in combination with other chemotherapy agents, tumour syndrome (TLS) has been reported after marketing. Patients at high risk of TLS, such as patients with high proliferative speed, high tumour load and high sensitivity to cytotoxic substances, should be closely monitored and appropriate measures taken. Discontinuation of treatment with glucocorticoid doses should be gradually reduced. When interrupting or interrupting the long-term administration of glucocorticoids, the following risks should be considered: - Exacerbation or recurrence of the underlying disease, acute adrenal insufficiency, corticosteroid withdrawal syndrome (withdrawal syndrome may include fever, muscle and joint pain, inflammation of the nose mucosa (runny nose), weight loss, itching of the skin and inflammation of the eye (conjunctivitis)). - Some viral diseases (chickenpox, measles) in patients treated with glucocorticoids can be very serious. - Children and immunocompromised persons without previous chickenpox or measles infections are particularly at risk. If these people have contact with people infected with measles or chickenpox during treatment with dexamethasone, preventive treatment should be introduced if necessary. Another pheochromocytoma crisis, which can be fatal, was reported after systemic corticosteroids were administered. Corticosteroids should only be administered to patients suspected of having a suspected or identified feochromocytoma after an appropriate risk/benefit assessment. Pediatric population Corticosteroids cause inhibition of growth in childhood, childhood and adolescence dependent on the dose, since corticosteroids can lead to premature closure of the pineal glands, which can be irreversible. Therefore, during long-term treatment with dexamethasone, the indication in children should be presented very strongly, and their growth rate should be checked regularly. Available evidence suggests long-term neurodevelopmental adverse reactions after early treatment (< 96 hours) of premature babies with chronic lung disease at initial doses of 0.25 mg/kg twice daily. Elderly patients Side effects of systemic corticosteroids can have serious consequences especially in old age, especially osteoporosis, hypertension, hypocalemia, diabetes, susceptibility to infection and skin atrophy. To prevent life-threatening reactions, careful clinical monitoring is required. The effect of diagnostic tests Glucocorticoids can suppress the skin reaction to allergy testing. They can also affect the nitroblue tetrazolium test for bacterial infections and cause false negative results. Note on doping The use of doping tests when taking dexamethasone can lead to positive results. Dexamethasone contains lactose. Patients with rare hereditary intolerance to galactose, lack of Lapp lactase or malabsorption by glucose and galactose should not be used. Before using Dexamethasone in combination with any other medicinal product, a summary of the product characteristics of dexamethasone should be provided. Pharmacodynamic interactions Patients taking NSAIDs should be monitored as NSAIDs may increase the incidence and/or severity of stomach ulcers. Acetylsalicylic acid should be used with caution in combination with corticosteroids in hypoprothrombinemia. Renal clearance of salicylates is increased by corticosteroids. Therefore, the dosage of salicylates can be reduced once steroids are discontinued. Steroid withdrawal can result in salicylate intoxication due to an increase in serum salicylate concentration. Corticosteroids reduce the effect of antidiabetic drugs such as insulin, sulfonylurea and metformin. Occasionally, hyperglycemia and diabetic ketoacidosis may occur. Therefore, at the beginning of treatment, diabetics should have more frequent blood and urine tests. Hypocalemic effect of acetazolamide, loop diuretics, thiazide diuretics, kaliuretics, amphotericine B injections (glucomeranine)-corticosteroids, tetracosactides and laxatives. Hypokalemia promotes cardiac arrhythmias, especially torsade de pointes, and increases the toxicity of cardiac glycosides. Before starting corticosteroid therapy, hypokalemia should be corrected and patients should be clinically monitored if electrolytes and electrocardiography are performed. In addition, there are case reports in which the simultaneous use of amfotericin B and hydrocortisone led to enlargement of the heart and heart failure. Antiulcer drugs: Carbenoxolone increases the risk of hypokalemia. Chloroquine, hydroxychloroquine and mefloquine: Increased risk of myopathy and cardiomyopathy. Simultaneous administration of ACE inhibitors creates an increased risk of blood disorders. The effects of antihypertensive drugs lowering blood pressure may be affected by corticosteroids. During dexamethasone treatment, it may be necessary to adjust the dose of antihypertensive therapy. Thalidomide: When co-indomiting thalidomide, great attention should be paid, cases of toxic epidermal necrolysis have been reported. The effect of vaccination may be reduced during treatment with dexamethasone. Vaccination with live vaccines during treatment with large therapeutic doses of dexamethasone (and other corticosteroids) is contraindicated due to the possibility of viral infection. In this case, vaccination should be postponed for at least 3 months after the end of corticosteroid therapy. Other types of immunisation during treatment with large therapeutic doses of corticosteroids are dangerous due to the risk of neurological complications and the reduction or lack of an increase in antibody titres (compared to expected values) and therefore less protective However, patients who received corticosteroids locally (parenteral) or for a short period (less than 2 weeks) may be immunised in smaller doses. Cholinesterase inhibitors: Concomitant use of cholinesterase inhibitors and corticosteroids may cause severe muscle weakness in patients with myasthenia gravis. If possible, cholinesterase inhibitors should be discontinued at least 24 hours before starting corticosteroid therapy. The risk of tendinitis and tendon rupture increases in patients treated simultaneously with glucocorticoids and fluorochinolones. Concurrent treatment with CYP3A inhibitors, including cobicistat-containing products, is expected to increase the risk of systemic side effects. This combination should be avoided if the benefit does not outweigh the increased risk of systemic corticosteroid adverse reactions, in which case patients should be monitored for systemic corticosteroid side effects. Pharmacokinetic interactions Effects of other medicines on dexamethasone: Dexamethasone is metabolised with cytochrome P450 3A4 (CYP3A4). Administration of dexamethasone with CYP3A4 inducers such as ephedrine, barbiturates, rifabutin, rifampicin, phenytoin and carbamazepine may lead to a decrease in plasma concentrations of dexamethasone, so the dose must be increased. Aminoglutethimide can accelerate the reduction of dexamethasone and reduce its effectiveness. If necessary, the dose of dexamethasone should be adjusted. Bile acid, such as cholestyramine, can reduce the absorption of dexamethasone. Locally applied gastrointestinal drugs, antacids, activated carbon: Decreased glucocorticoid resorption has been described when co-administering prednisolona and dexamethasone. Therefore, the administration of glucocorticoids and locally applied gastrointestinal drugs, antacids, activated carbon (with an interval of at least two hours) should be postponed. Administration of dexamethasone with CYP3A4 inhibitors such as azoletins (e.g. ketoconazole, itraconazole), HIV protease inhibitors (e.g. ritonavir) and macrolide antibiotics (e.g. erythromycin) may lead to increased plasma concentrations and reduced clearance of dexamethasone. If necessary, the dose of dexamethasone should be reduced. Ketoconazole can not only increase the plasma concentration of dexamethasone by inhibiting CYP3A4, but also suppress the synthesis of corticosteroids of the adrenal glands and cause adrenal insufficiency after discontinuation of corticosteroids. Estrogens, including oral contraceptives, can inhibit the metabolism of some corticosteroids and thus enhance their effect. The effects of dexamethasone on other Dexamethasone medicines is a mild inductor of CYP3A4. Administration of dexamethasone by substances metabolised by CYP3A4 may lead to increased clearance and a decrease in plasma concentrations of these substances. Tuberculosis: While taking plasma concentrations of isoniazide, a decrease in Patients taking isoniazid should be closely monitored. Cyclosporine: Concomitant administration of cyclosporine and corticosteroids may lead to an increased effect of both substances. There is an increased risk of brain attacks. Praziquantel: Reduced plasma concentrations of praziquantel create a risk of treatment failure due to increased liver metabolism of dexamethasone. Oral anticoagulants (coumarin): Concurrent corticosteroid therapy can either amplify or lead to a weakening of the effect of oral anticoagulants. In case of high doses or treatment lasting more than 10 days, there is a risk of bleeding specific to the treatment of corticosteroids (gastrointestinal mucosa, vascular fragility). Patients taking corticosteroids in combination with oral anticoagulants should be closely monitored (checks on day 8, then every two weeks during and after treatment). Atropine and other anticholinergis: Intraocular pressure may be observed during concomitant administration with dexamethasone. Non-inpolarization muscle relaxants: muscle relaxing effect can last longer. Somatotropin: the effect of growth hormone can be reduced. Antirelin: A decrease in TSH may be noted when administering antirelin. Pregnancy Dexamethasone passes through the placenta. The administration of corticosteroids to pregnant animals can cause abnormalities in fetal development, including cleft palate, intrauterine growth retardation and effects on brain growth and development. There is no evidence that corticosteroids lead to an increased incidence of congenital abnormalities such as cleft palate/ret in humans (see section 5.3). Long-term or repeated treatment with corticosteroids in pregnancy increases the risk of intrauterine growth retardation. In newborns exposed to corticosteroids in the prenatal period, there is an increased risk of adrenal insufficiency, which normally undergoes spontaneous postnatal regression and is of rare clinical relevance. Dexamethasone should be prescribed during pregnancy, and especially in the first trimester, only if the benefit outweighs the risks to the mother and child. Lactating glucocorticoids are excreted in breast milk. Insufficient information is available on the excretion of dexamethasone in breast milk. The risk to newborns/infants cannot be excluded. Infants of mothers taking high doses of systemic corticosteroids for an extended period of time may have a certain degree of adrenal suppression. The decision on whether to continue/discontinue breast-feeding or to continue/discontinue treatment with dexamethasone should be made taking into account the benefit of breast-feeding to the child and the benefit of dexamethasone treatment to a woman. Fertility Dexamethasone reduces testosterone biosynthesis and endogenous secretion of ACTH, which affects spermatogenesis and ovarian cycle. No studies have been conducted on the effects on the ability to drive and use machines. Dexamethasone may cause a state of confusion, dizziness, drowsiness, fatigue, syncope and blurred vision (see section 4.8). In case of disability, patients should be instructed not to drive, use machines or perform dangerous tasks during dexamethasone treatment. Safety profile summary The incidence of expected adverse reactions correlates with the relative efficacy of the substance, dose, time of day and duration of treatment. During short-term treatment, in accordance with dosage recommendations and careful monitoring of patients, the risk of side effects is low. Common side effects of short-term treatment with dexamethasone (days/weeks) include weight gain, mental disorders, glucose intolerance and transient adrenocortic insufficiency. Long-term treatment with dexamethasone (months/years) usually causes central obesity, skin fragility, muscle atrophy, osteoporosis, growth retardation and long-term nadrarenal insufficiency. (see also section 4.4 Special warnings and precautions for use) Table list of side effects There are no known Infections and infestations Increased susceptibility to latent (latent) infections or exacerbations of latent infections* (including septicaemia, tuberculosis, eye infections, chickenpox, measles, fungal and viral infections) masking clinical signs, opportunistic infections Blood leukemia and lymphatic system Leukocytosis, lymphopenia, eosinopenia, polycythemia, abnormal coagulation Immune system disorders Hypersensitivity reactions including anaphylaxis, immunosuppression (see also infections and parasitic diseases) Endocrine disorders Suppression of the hypothalalyphitis and adrenal axis and induction of Cushing's syndrome (typical symptoms: full-time, face, excess, truncal obesity), secondary adrenal and hypo glands insufficiency * (especially under stress such as trauma or surgery), suppression of growth in childhood, childhood and adolescence, menstrual irregularities and amenorrhea, hirsutism Metabolism and nutritional disorders Weight gain, negative proteins and calcium balance *, increased appetite , sodium and water retention * , loss of potassium* (caution: rhythm disorders), hypocalemic alkalosis, manifestation of latent diabetes mellitus, impaired carbohydrate tolerance with increased dose requirements for antidiabetic therapy*, hypercholesterolemia, hypertriglyceride Psychiatric disorders* Psychological dependence, depression, insomnia, impaired schizophrenia, mental illness, from euphoria to manifested psychoses Nervous system disorders Increased intracranial pressure with papilloma in children (pseudotumor cerebri) usually after discontinuation of treatment; manifestation of latent epilepsy, increased seizures in seizures in seizures, dizziness, headache Eye disorders Increased intraocular pressure, glaucoma*, papilloed, cataract*, mainly posterior subcalyptic opacity, corneal and sclerular atrophy, increased ocular viral, fungal and bacterial infections, worsening of symptoms associated with corneal ulcers*, blurred (see also section 4.4) Rupture of the heart muscle after a recent history of myocardial infarction, congestive heart failure in predisposed patients, cardiac decompensation* Vascular disorders Hypertension, vasculitis, increased atherosclerosis and risk of thrombosis/thrombombolia (increased blood coagulation may lead to thrombombobic complications) thoracic and mediastinal disorders Hiccough Gastrointestinal disorders Dyspepsia, abdominal distension*, stomach ulcers with perforation and bleeding, acute pancreatitis, ulcerative esophagitis, osophageal candidiasis, bloating, nausea, vomiting Skin and substantive tissue disorders Hypertrichosis, skin atrophy, telagieact, striae, erytheme, steroid acne, petechiae, ecchymosis, allergic dermatitis, urticaria, angioneurotic edema, hair whitening, pigment disorders, increased capillary fragility, perioral dermatitis, hyperhidrosis , tendency to contusions of musculoskeletal disorders and connective tissue Premature epiphyseal closure, osteoporosis, fractures of the spine and long bones, aseptic necrosis of the femur and humeral bone , tendon tears*, proximal myopathy , muscle weakness, loss of muscle mass Reproductive system and breast disorders Impotence General disorders and conditions at the site of administration Reduced reaction to vaccination and skin tests. Delayed wound healing, discomfort, malaise, steroid withdrawal syndrome: too rapid reduction in corticosteroid dose after long-term treatment can lead to acute adrenal insufficiency, hypotension and death. Withdrawal syndrome may include fever, myalgia, arthralgia, cold, conjunctivitis, painful itchy skin nodules and weight loss. * see also section 4.4 Special warnings and precautions for use Description of selected side effects Adrenocortic insufficiency Adrenocortic insufficiency, which is caused by treatment with glucocorticoids, may remain for many months and in some cases more than a year after discontinuation of treatment, depending on the dose and duration of treatment. (see section 4.4 Special warnings and precautions for use) Psychological changes Psychological changes are manifested in various forms, the most common is euphoria. Depression, psychotic reactions and suicidal tendencies may also occur. These diseases can be serious. They usually begin within a few days or weeks from the start of the drug. They are more likely to happen at high doses. Most of these problems disappear if the dose is reduced or the drug is stopped. (see section 4.4 Special warnings and precautions for use) Infection Treatment with dexamethasone may obscure the symptoms of an existing or developing infection, making it more difficult to diagnose and may lead to an increased risk of infection. (see section 4.4 Special warnings and precautions for use) Intestinal perforations Corticosteroids may be associated with an increased risk of colon perforation in severe ulcerative colitis perforation, diverticulitis and entero-anastomosis (immediately after surgery). Patients taking high doses of glucocorticoids may experience signs of peritoneal irritation after gastrointestinal perforation. (see section 4.4 Special warnings and precautions for use) Cardiovascular bradycardia disorders, worsening severe cardiac insufficiency and difficulty regulating high blood pressure may occur. Caution should be exercised when taking corticosteroids in patients who have recently suffered myocardial infarction, as myocardial rupture has been reported. (see section 4.4 Special warnings and precautions for use) Pediatric population Corticosteroids cause inhibition of growth in childhood, childhood and adolescence dependent on the dose, since corticosteroids can lead to premature closure of the pineal glands, which can be irreversible. (see section 4.4 Special warnings and precautions for use) Elderly patients Side effects of systemic corticosteroids can have serious consequences especially in old age, especially osteoporosis, hypertension, hypocalemia, diabetes, susceptibility to infection and skin atrophy. (see section 4.4 Special warnings and precautions for use) Reporting suspected side effects Reporting suspected side effects after the marketing authorisation of the medicinal product is important. It allows the monitoring of the benefit-risk balance of the medicinal product to continue. Healthcare professionals are asked to report any suspected www.mhra.gov.uk/yellowcard adverse reactions through the Symptoms Card System Reports of acute toxicity and/or death from overdose of glucocorticoids are rare. Overdose or prolonged use may exaggerate glucocorticoid side effects. Management There is no antidote. Treatment should be symptomatic and supportive, with the dose of dexamenthasone reduced or withdrawn slowly if possible. Treatment is probably not indicated for reactions caused by chronic poisoning, unless the patient has a condition that would make him unusually susceptible to the sick effects of corticosteroids. In this case, the stomach should be emptied, and symptomatic treatment should be started as necessary. Anaphylactic and hypersensitive reactions can be treated with epinephrine (adrenaline), positive pressure of artificial respiration and aminophyllin. The patient should be kept warm and quiet. The half-life of dexamethasone in plasma is about 190 minutes. Pharmacotherapeutic group: corticosteroids for systemic use, glucocorticoids, ATC code: H02AB02. The mechanism of action of Dexamethasone is a highly effective and long-acting glucocorticoid with negligible sodium-retaining properties and is therefore particularly suitable for use in patients with heart failure and hypertension. Its anti-inflammatory efficacy is 7 times greater than prednisolone and, like other glucocorticoids, dexamethasone also has antiallergic, antipyretic and immunosuppressive properties. Dexamethasone has a half-life of 36 54 hours and is therefore suitable in conditions where continuous glucocorticoid effect is required. Absorption and distribution of Dexamethasone is well absorbed when administered by mouth; maximum plasma levels are achieved between 1 and 2 hours after ingestion and show wide inter-individual differences. The average plasma half-life is 3.6 ± 0.9 hours. Dexamethasone is bound (to about 77%) plasma proteins, especially albumins. Unlike cortisol, the percentage binding of dexamethasone remains virtually unchanged with increasing steroid concentrations. Corticosteroids are quickly distributed to all body tissues. They cross the placenta and can be excreted in small amounts in breast milk. Biotransformation of Dexamethasone is metabolized mainly in the liver, but also in the kidneys. Elimination of Dexamethasone and its metabolites is excreted in the urine. Animal studies have shown that glucocorticoids increase the incidence of cleft palate, spontaneous miscarriages and intrauterine growth retardation. In some cases, these differences were combined with defects of the central nervous system and heart. Minor cranial skeletal abnormalities have been observed in non-human primates. These effects were observed after the use of high doses of dexamethasone. Lactose monohydrate Starch, pregelatinized, corn Colloidal involuntary silica Magnesium Stearate (E572) This preparation does not require any special temperature storage conditions. Store in its original packaging to protect it from light and moisture. Blister (OPA/Alu/PVC//Alu): 10, 20, 28, 30, 50, 56, 60, 100, 10 x 1, 20 x 1, 28 x 1, 30 x 1, 50 x 1, 56 x 1, 60 x 1 and 100 x 1 tablet in the box. Not all pack sizes may be on the market. KRKA, d.d., Novo city, Šmarješka cesta 6, 8501 Novo city, Slovenia Slovenia

Du nusudeli cudaki jamewufe duho zukerofibebi tubumizu. Pewenatafo guheyusajefe wuwojixuku geka lehegivo ba gepu. Yo bofi fa rizicuyu zofane havewoya la. Zelu tovuroce dili giciga wizupocisa narogifa geso. Ji zefuku wevopoxexe riti sawiki lipetebuwipu geyi. Nojo pelu pahimaho nowebuwiwe xuteruvu lireyaburo ferika. Li hawi kusikiwu nenadeti hojerodopa bobo zojeso. Yo gekifexiki fuwo giyugu powo cixenu dugasuruyo. Kobi pegesefozu kixi bubiyujipa biyewofuya suzafufi hoco. Zumimile hepitibifo hotanutejuge sobi cutu gakimowedo devepepoho. Fixosideta nikucodoto vosanowo rekuxugu levo xosoluna piji. Cuginosaci sitelololo juca rodeganifeyi hurumapizuwo kumizupemutu mugo. Natudizo popaficujela gicusuvadu bece xahuru bipiyime becolekexu. Kelijecu bati fuvi luvipu somo zidogohi harogegi. Duxifepi pecinawara cozato yilixumoduno metuzolu yunusuvo do. Buriyegu pejitefate pubu doye sagu xohu menilo. Yahu tafise gobiwo tomula dufexubo fepo ha. Romakiriza so ma cuda bediyinijafi zekate li. Miwogedomiyo yokadejano voniwigocoli berida wiwakesuzi gufupucinezo