In this leaflet:
1. What Dexamethason 0.5 mg GALEN is and what it is used for
2. Before you take Dexamethason 0.5 mg GALEN
3. How to take Dexamethason 0.5 mg GALEN
4. Possible side effects
5. How to store Dexamethason 0.5 mg GALEN
6. Further information

1. WHAT DEXAMETHASON 0.5 MG GALEN IS AND WHAT IT IS USED FOR

Dexamethason 0.5 mg GALEN contains a synthetic glucocorticoid (corticosteroid) with an effect on metabolism, the electrolyte balance and on tissue functions.

Dexamethason 0.5 mg GALEN is used in diseases requiring systemic treatment with glucocorticoids. These include the following, depending on the symptoms and severity:

**Neurological disorders**
Brain swelling (only when increased brain pressure has been confirmed by CT scan) triggered by brain tumour, neurosurgery, brain abscess.

**Lung and respiratory tract disorders**
Severe acute asthma attack.

**Skin disorders**
Initial treatment of extensive acute severe skin conditions, such as erythroderma, pemphigus vulgaris, acute eczema.

**Immune system/rheumatological disorders**
Treatment of systemic rheumatic disorders (rheumatic disorders which can affect internal organs), such as systemic lupus erythematosus.

Active phases of certain types of blood vessel inflammation (systemic vasculitis), such as panarteritis nodosa (in patients who also have a positive hepatitis B serology, the duration of treatment should be restricted to two weeks).

Severe progressive forms of active rheumatic joint inflammation (rheumatoid arthritis), e.g. forms rapidly leading to the destruction of joints and/or when tissue outside the joints is affected.
Juvenile idiopathic arthritis (joint inflammation with no apparent cause, occurring in adolescence) running a severe systemic course (Still’s syndrome) or with an eye condition not responsive to local treatment (iritocyclitis).

Rheumatic fever also affecting the heart.

*Infectious diseases*
Severe infectious diseases with states similar to intoxication (e.g. in tuberculosis, typhoid fever; only together with appropriate anti-infective therapy).

*Tumour diseases*
For supportive treatment in malignant tumours

Prevention and treatment of vomiting after surgery or in cytostatic treatment.

*Hormone replacement therapy*
Poor or absent adrenal cortex function (adrenogenital syndrome) in adulthood.

2. **BEFORE YOU TAKE DEXAMETHASON 0.5 MG GALEN**

Do not take Dexamethason 0.5 mg GALEN
- if you are allergic (hypersensitive) to dexamethasone or any of the other ingredients of Dexamethason 0.5 mg GALEN.

Take special care with Dexamethason 0.5 mg GALEN

Treatment with glucocorticoids can lead to poor adrenal cortex function (insufficient production of glucocorticoids by the body) which, depending on the dose and duration of treatment, may persist for several months and, in individual cases, more than one year after discontinuation of glucocorticoids. If particular physical stress occurs during glucocorticoid treatment, such as feverish illness, accidents or surgery, the doctor must be notified or an emergency doctor must be informed about the ongoing treatment. A temporary increase in the daily dexamethasone dose may become necessary. Similarly, administration of glucocorticoids may be necessary in physical stress situations if poor adrenal cortex function persists after the end of treatment. During long-term treatment with dexamethasone, your doctor should therefore provide you with a corticosteroid safety card, which you should carry with you at all times.

In order to prevent acute, treatment-related adrenocortical sufficiency (poor adrenal cortex function), your doctor will set out a schedule for reducing the dose when your treatment is due to end, which you must follow at all times.

Treatment with Dexamethason 0.5 mg GALEN should only be started if your doctor considers it absolutely necessary for the following diseases. You may also have to take specific medicines targeted against the germs causing your disease:
- acute viral infections (chickenpox, shingles, herpes simplex infections, inflammation of the cornea caused by herpes viruses)
- HBsAg-positive chronic active hepatitis (infectious liver inflammation)
- approximately 8 weeks before and up to 2 weeks after preventive vaccinations with an attenuated pathogen (live vaccine)
- acute and chronic bacterial infections
- fungal disease with infestation of internal organs
- certain parasitic diseases (amoeba or worm infections).
- polio
- swollen lymph nodes after tuberculosis vaccination
- if you have a history of tuberculosis. You should only use this medicine together with anti-tuberculosis medication.

Furthermore, Dexamethason 0.5 mg GALEN should be taken for the following disorders only if your doctor considers it absolutely necessary and if these disorders are being treated as necessary at the same time:

- gastrointestinal ulcers
- severe osteoporosis (brittle-bone disease)
- difficult-to-manage high blood pressure
- difficult-to-manage diabetes mellitus
- psychiatric illnesses (including a history thereof)
- increased inner eye pressure (narrow and wide-angle glaucoma)
- corneal lesions and corneal ulceration of the eye.

Due to the risk of bowel wall perforation with peritonitis, Dexamethason 0.5 mg GALEN may only be used on compelling medical grounds, together with appropriate monitoring, in the following cases:

- severe inflammation of the large intestine (ulcerative colitis) with imminent perforation, with abscesses or purulent (pus-filled) inflammation,
- diverticulitis (inflamed bulges on the bowel wall),
- after certain types of bowel surgery (intestinal anastomosis), immediately after the operation.

Signs of peritoneal irritation after perforation of a gastrointestinal ulcer may be absent in patients receiving high doses of glucocorticoids.

The metabolism must be regularly checked if diabetes is also present; a possibly increased need for medicines to treat diabetes (insulin, oral antidiabetics) should be taken into account.

Patients with severe high blood pressure and/or severe heart failure should be carefully monitored, as there is a risk of deterioration.

Dexamethason 0.5 mg GALEN can mask the signs of infection, thereby making it more difficult to detect an existing or developing infection.

Long-term use of even small amounts of dexamethasone leads to an increased risk of infection by microorganisms that otherwise rarely cause infections (known as opportunistic infections).

In principle, vaccinations with vaccines made from pathogens that have been “killed off” (inactivated vaccines) are possible. However, it should be remembered that the immune response and hence successful vaccination may be compromised at higher corticosteroid dosages.

During long-term treatment with dexamethasone, regular medical check-ups (including eye check-ups) are required.

Particularly during prolonged treatment with high doses of dexamethasone, adequate potassium intake (e.g. vegetables, bananas) and restricted salt intake must be ensured and blood potassium levels monitored.

Depending on the dosage and duration of treatment, a negative effect on calcium metabolism must be considered and hence osteoporosis prevention is recommended. This particularly applies if there are other existing risk factors, such as family predisposition, advanced age, insufficient protein and calcium intake, heavy smoking, excessive alcohol consumption, after the menopause and lack of physical exercise.

Prevention consists of adequate calcium and vitamin D intake, as well as physical exercise. If you already have osteoporosis, your doctor may consider additional medication-based therapy.

When ending or, if necessary, discontinuing long-term administration of glucocorticoids, the following risks
should be considered: flare-up or worsening of the underlying disease, acute adrenocortical insufficiency (poor adrenal cortex function), cortisone withdrawal syndrome.

Viral diseases (e.g. measles, chickenpox) may become particularly severe in patients treated with Dexamethason 0.5 mg GALEN. At particular risk are children with a weakened immune system and persons who have never had measles or chickenpox. If these persons should come into contact with people with measles or chickenpox during treatment with Dexamethason 0.5 mg GALEN, they should consult their doctor immediately, who will start up preventive treatment as necessary.

Children
In children, Dexamethason 0.5 mg GALEN should be used only if there are compelling medical reasons, due to the risk of growth inhibition, and height gain should be regularly monitored during long-term treatment with glucocorticoids.

Elderly
A careful benefit/risk assessment should also be performed in elderly patients, due to the increased risk of osteoporosis.

Effects if misused for doping purposes
The use of Dexamethason 0.5 mg GALEN can lead to positive results in doping tests. The consequences on health of using Dexamethason 0.5 mg GALEN as a doping agent cannot be predicted. Serious health hazards cannot be ruled out.

Using other medicines
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Which other medicines influence the effect of Dexamethason 0.5 mg GALEN?
- Medicines that speed up metabolism in the liver, such as certain sleeping pills (barbiturates), medicines for seizures (phenytoin, carbamazepine, primidone) and certain medicines for tuberculosis (rifampicin) can reduce the corticosteroid effect.
- Medicines that slow down metabolism in the liver, such as certain medicines for fungal disease (ketoconazole, itraconazole), can enhance the corticosteroid effect.
- Certain female sex hormones, e.g. those used as contraceptives (the “Pill”), can enhance the corticosteroid effect.
- The use of medicines to lower stomach acid production (antacids) in patients with chronic liver disease can reduce the corticosteroid effect.
- Medicines containing ephedrine to reduce swelling of the mucous membranes can speed up the breakdown of glucocorticoids, thereby making them less effective.

How does Dexamethason 0.5 mg GALEN influence the effect of other medicines?
Dexamethason 0.5 mg GALEN
- can increase the risk of abnormal blood counts if used together with certain medicines for high blood pressure (ACE inhibitors):
- can enhance the effect of medicines used to strengthen the heart (cardiac glycosides) due to potassium deficiency.
- can increase potassium excretion caused by water tablets (saluretics) or laxatives.
- can reduce the blood sugar-lowering effect of oral antidiabetics and insulin.
- can weaken the effect of medicines used to prevent blood clotting (oral anticoagulants, coumarins).
- can increase the risk of stomach ulcers and gastrointestinal bleeding if used at the same time as medicines for inflammation and rheumatism (salicylates, indomethacin and other non-steroidal anti-inflammatory drugs).
- can prolong the muscle-relaxing effect of certain medicines (non-depolarising muscle relaxants).
- can enhance the effect of certain medicines used to increase inner eye pressure (atropine and other anticholinergics).
- can reduce the effect of medicines for worm infestations (praziquantel).
- can increase the risk of muscle disease or heart muscle disease (myopathy, cardiomyopathy) if used at the same time as medicines for malaria or rheumatic disorders (chloroquine, hydroxychloroquine, mefloquine).
- can reduce the effect of growth hormone (somatropin), particularly at high doses.
- can lessen the rise in thyroid-stimulating hormone (TSH) after administration of protirelin (a hormone of the hypothalamus in the brain).
- can increase the blood level of ciclosporin (a medicine used to suppress the body’s immune system), thereby increasing the risk of seizures.

Effect on testing methods:
Glucocorticoids can suppress skin reactions to allergy tests.

**Pregnancy and breast-feeding**

Ask your doctor or pharmacist for advice before taking any medicine.

**Pregnancy**
During pregnancy, especially in the first three months, treatment should be administered only after careful benefit/risk assessment. Women should therefore tell their doctor if they are or become pregnant.

In long-term treatment with glucocorticoids during pregnancy, growth impairment in the unborn child cannot be ruled out. If glucocorticoids are taken at the end of pregnancy, adrenocortical insufficiency (poor adrenal cortex function) may develop in the newborn infant.

**Breast-feeding**
Glucocorticoids, including dexamethasone, are excreted in human milk. No harm to infants has been reported to date. Nevertheless, the need for administration during breast-feeding should be very carefully assessed. If higher doses are required on medical grounds, you should stop breast-feeding.

**Driving and using machines**
To date, there is no evidence that Dexamethason 0.5 mg GALEN affects the ability to drive vehicles or use machines. This also applies to working without suitable safeguards.

**Important information about some of the ingredients of Dexamethason 0.5 mg GALEN**

This medicine contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

**3. HOW TO TAKE DEXAMETHASON 0.5 MG GALEN**

1. Always take Dexamethason 0.5 mg GALEN exactly as your doctor has told you.
2. Your doctor will individually set the dexamethasone dose for you.
3. Please follow the directions for use at all times, as Dexamethason 0.5 mg GALEN may otherwise not work properly.
4. You should check with your doctor or pharmacist if you are not sure.

*(Translator: text box illegible)*

Tablets for oral use.
The tablets can be manually divided into equal halves.

**Unless otherwise prescribed by the doctor, the usual dose is:**
Dexamethason 0.5 mg GALEN is mainly used for tapering off higher-dose dexamethasone therapy and for congenital adrenogenital syndrome in adulthood.

Dexamethason GALEN tablets are available in strengths of 0.5 mg, 1.5 mg, 4 mg and 8 mg.

Neurological disorders
Brain swelling:
Initially for acute forms, depending on the cause and severity: 8-10 mg (up to 80 mg) dexamethasone into a vein (IV), followed by 16-24 mg (up to 48 mg) dexamethasone per day, divided into 3-4 (up to 6) single doses into a vein or as a tablet for 4-8 days.

Lung and respiratory tract disorders
Severe acute asthma attack:
8-20 mg dexamethasone as soon as possible, as a tablet or IV; if needed, repeated doses of 8 mg dexamethasone every 4 hours.

Children: 0.15-0.3 mg dexamethasone/kg body weight as a tablet or 1.2 mg dexamethasone/kg IV, then 0.3 mg dexamethasone/kg every 4-6 hours.

Skin disorders
Acute skin conditions:
Depending on the nature and extent of the disease, daily doses of 8-40 mg dexamethasone; in individual cases up to 100 mg. Followed by continued treatment with decreasing doses.

Rheumatic disorders/autoimmune disease
Rheumatic fever with heart inflammation: 12-16 mg dexamethasone.

Juvenile arthritis running a severe systemic course (Still’s syndrome) or with an eye condition not responsive to local treatment (iritidocyclitis): starting dose 12-16 mg dexamethasone.

Systemic lupus erythematosus: 6-16 mg dexamethasone.

Severe progressive forms of active rheumatoid arthritis, e.g. forms rapidly leading to destruction of joints: 12-16 mg dexamethasone and/or if tissue outside the joints is affected: 6-12 mg dexamethasone.

Infectious diseases
Severe infectious diseases with states similar to intoxication: 4-20 mg dexamethasone per day IV or as a tablet over a few days, only together with appropriate anti-infective therapy; in individual cases (e.g. typhoid fever) at starting doses up to 200 mg IV, then taper off.

Tumour diseases
Supportive treatment in malignant tumours: initially 8-16 mg dexamethasone/day; 4-12 mg dexamethasone/day for longer-term therapy.

Prevention and treatment of vomiting during cytostatic treatment as part of certain regimens.

Hormone replacement therapy
Congenital adrenogenital syndrome in adulthood:
0.25-0.75 mg (equivalent to ½ to 1½ Dexamethason 0.5 mg GALEN tablets/day as a single dose. If required, additional administration of a mineralocorticoid (fludrocortisone). In cases of particular physical stress, such as feverish infection, accident, surgery or childbirth, the dose should be temporarily increased as instructed by the doctor.

In patients with an underactive thyroid or liver cirrhosis, even lower dosages may be sufficient or a dose reduction may be required.
Method and duration of administration

Take the tablets with or after a meal. Swallow whole (not chewed) with sufficient liquid.

If possible, the daily dose should be taken as a single dose in the morning. However, for diseases requiring high-dose therapy, repeated daily dosing is often needed to achieve a maximum effect. Your doctor will assess the possibility of alternate-day treatment (dosing only on every other day), depending on the symptoms and your response to treatment.

The duration of treatment depends on the underlying disease and how it progresses. For this, your doctor will set out a treatment plan that you should follow exactly at all times. As soon as a satisfactory treatment outcome is achieved, the dose will be reduced to a maintenance dose or discontinued. In general, the dose should always be decreased gradually.

Please talk to your doctor or pharmacist if you have the impression that the effect of Dexamethason 0.5 mg GALEN is too strong or too weak.

If you take more Dexamethason 0.5 mg GALEN than you should

In general, Dexamethason 0.5 mg GALEN is tolerated without complications even when large amounts have been taken over the short term. No specific measures are required. If you notice any enhanced or unusual side effects, you should ask your doctor for advice.

If you forget to take Dexamethason 0.5 mg GALEN

You can make up for the missed dose during the day and continue taking the dose prescribed by your doctor as usual on the next day.
If several doses have been missed, the disease being treated may possibly flare up again or get worse. In such cases, you should contact your doctor, who will review the treatment and adjust it as necessary. Do not take a double dose to make up for a forgotten dose.

If you stop taking Dexamethason 0.5 mg GALEN

Always follow the dosing schedule prescribed by your doctor. Dexamethason 0.5 mg GALEN must never be stopped without consulting a doctor, as prolonged treatment in particular can suppress the production of glucocorticoids by the body (adrenocortical insufficiency). Situations of marked physical stress without sufficient glucocorticoid production may be life-threatening.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Dexamethason 0.5 mg GALEN can cause side effects, although not everybody gets them.

In hormone replacement therapy, the risk of unwanted side effects is low when the recommended dosage is respected. However, during prolonged use of particularly high doses, side effects of varying degrees of severity can be routinely expected.

Blood and lymphatic system disorders
Abnormal blood counts (moderate leucocytosis, lymphopenia, eosinopenia, polyglobulia).
Nervous system disorders
Increased pressure within the brain, manifestation of previously unrecognised epilepsy, more frequent seizures in patients with known epilepsy.

Eye disorders
Increased inner eye pressure (glaucoma), clouded lens (cataract), worsening of corneal ulcers, onset or deterioration of viral, fungal and bacterial eye inflammation may be promoted.

Gastrointestinal disorders
Gastrointestinal ulcers, gastrointestinal bleeding, pancreatitis.

Skin and subcutaneous tissue disorders
Stretch marks, thinning of the skin (“parchment skin”), dilated blood vessels of the skin, easy bruising, pinpoint or superficial bleeding of the skin, increased body hair, acne, delayed wound healing, inflammatory skin changes of the face, particularly around the mouth, nose and eyes, changes in skin pigmentation, hypersensitivity reactions, e.g. skin rash.

Musculoskeletal and connective tissue disorders
Muscle weakness and muscle wasting, brittle-bone disease (osteoporosis), other forms of bone degeneration (osteonecrosis of the humeral and femoral heads), tendon rupture.

Hormonal disorders
Development of Cushing syndrome (typical signs are rounded face (“moon face”), upper body obesity and facial redness), poor function or atrophy (shrinkage) of the adrenal cortex, growth inhibition in children, sex hormone disorders (irregular or absent menstrual bleeding, impotence), raised blood sugar levels, diabetes.

Metabolism and nutrition disorders
Weight gain, increase in blood fat levels (cholesterol and triglycerides), tissue fluid accumulation (oedema), potassium deficiency caused by increased potassium excretion (may lead to heart rhythm disorders).

Vascular disorders
High blood pressure, increased risk of arteriosclerosis and thrombosis, inflamed blood vessels (including as a withdrawal syndrome after long-term therapy).

Immune system disorders
Weakening of the immune system, masking of existing infections, outbreak of latent infections, allergic reactions.

Psychiatric disorders
Depression, irritability, euphoria, increased drive and appetite, psychosis, sleep disorders.

Note:
If the dose is reduced too rapidly after long-term treatment, conditions such as withdrawal syndrome may occur, which can manifest as symptoms such as muscle pain and joint pain.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist. Do not stop treatment of your own accord under any circumstances.

If you experience gastrointestinal complaints, pain in the back, shoulder or hip joint region, psychiatric problems, noticeable fluctuations in blood sugar levels (for patients with diabetes) or any other disorders, please tell your doctor immediately.
5. HOW TO STORE DEXAMETHASON 0.5 MG GALEN

Keep out of the reach and sight of children.

Do not use this medicine after the expiry date which is stated on the box and tube label after “EXP”. The expiry date refers to the last day of that month.

Storage conditions:

Store Dexamethason 0.5 mg GALEN in the original container below 30°C.

After opening, the tablets have a shelf-life of 12 months.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Dexamethason 0.5 mg GALEN contains

The active substance is: dexamethasone
1 tablet contains 0.5 mg dexamethasone.

The other ingredients are: lactose monohydrate, sodium starch glycolate (Type A) (Ph.Eur.), hyprolose, magnesium stearate (Ph.Eur.), colloidal anhydrous silica

What Dexamethason 0.5 mg GALEN looks like and contents of the pack

Round, white tablets with a deep score line on one side, in a white tube with stopper and red flip top.

Dexamethason 0.5 mg GALEN is available in packs of 20 (N1), 50 (N2) and 100 (N3) tablets.

Marketing Authorisation Holder

GALENpharma GmbH
Wittland 13, 24109 Kiel, Germany
PO Box 3764, 24036 Kiel, Germany

Manufacturer
Artesan Pharma GmbH & Co. KG
Wendlandstrasse 1, 29439 Lüchow, Germany
PO Box 1142, 29431 Lüchow, Germany

This leaflet was last revised in November 2011.

GPH-04 GALEN