Package leaflet: Information for the user

Dexamethasone phosphate Teva 4 mg/ml solution for injection
dexamethasone phosphate

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Dexamethasone phosphate Teva is and what it is used for

Dexamethasone is a synthetic glucocorticoid (adrenocortical hormone) with an effect on metabolism, electrolyte balance and tissue functions.

Dexamethasone phosphate Teva is used for
Diseases that require treatment with glucocorticoids. These include, depending on the type and severity:

Systemic use
- Swelling of the brain caused by brain tumours, neurosurgery, brain abscess, bacterial inflammation of the lining of the brain.
- Shock after a serious injury, for preventative treatment for acute respiratory distress syndrome and due to a severe allergic reaction (anaphylactic shock).
- Severe acute asthma attack and a specific form of lung inflammation (interstitial aspiration pneumonia).
- Initial treatment of extensive, severe, acute skin diseases, including erythroderma, pemphigus vulgaris, acute eczema.
- Treatment of rheumatic systemic diseases (rheumatic diseases that can affect internal organs), such as systemic lupus erythematosus.
- Some blood vessel inflammations (systemic vasculitides such as polyarteritis nodosa).
- Severe progressive form of active rheumatic joint inflammation (rheumatoid arthritis), e.g. forms that quickly lead to joint destruction and/or when tissue outside the joints is affected.
- Rheumatic joint inflammation in children (juvenile idiopathic arthritis).
- Rheumatic fever with heart inflammation.
- Severe infectious diseases with poison-like states (e.g. tuberculosis, typhoid; in addition to corresponding anti-infective therapy only).
- Supportive treatment for malignant tumours.
- Prevention and treatment of vomiting after operations or with cytostatic therapy.

- Treatment of coronavirus disease 2019 (COVID-19) in adult and adolescent patients (aged 12 years and older with body weight at least 40 kg) with difficulty breathing and need of oxygen therapy.

Local use:

- Injection in a joint: for persistent inflammation in one or several joints following general treatment of chronic inflammatory joint diseases, activated arthrosis.
- Infiltration therapy (strict indication): tendon sheath inflammation (non-bacterial tendovaginitis), non-bacterial joint cavity inflammation (bursitis), diseases of structures near the joints (periarthropathy) and/or tendon insertion (insertional tendinopathy).
- Eye treatment: injection under the conjunctival sac of the eye in non-infectious corneal and conjunctival inflammation, scleral inflammation, iris and ciliary inflammation, inflammation of the middle layer of eye tissue (uveitis). Ampoules with 2 ml solution for injection are not suitable for this application.

2. What you need to know before you use Dexamethasone phosphate Teva

Do not use Dexamethasone phosphate Teva:
if you are allergic to dexamethasone or any of the other ingredients of this medicine (listed in section 6).

Individual cases of severe allergic (anaphylactic) reactions with circulatory collapse, cardiac arrest, heart rhythm disorders, shortness of breath (bronchospasm) and/or increased/decreased blood pressure have been observed with Dexamethasone phosphate Teva.

The medicine must not be injected into the joints in the following cases:

- infection in or in the immediate vicinity of the joint to be treated
- bacterial inflammation in the joint
- instability of the joint to be treated
- predisposition to bleeding (spontaneous or due to anticoagulants)
- calcification near the joint
- a specific form of bone disease (bone necrosis)
- tendon rupture
- a specific form of joint inflammation (neuropathic arthropathy)

Infiltration (injection into body tissue) without causal additional treatment must not be given in the event of infection at the administration site. Subconjunctival administration (injection under the conjunctival sac in the eye) also must not be given in the event of virus-, bacteria- or fungus-related eye diseases as well as injuries or ulcers on the cornea.

Warnings and precautions
In cases of particular physical stress situations (trauma, surgery, childbirth, etc.) during treatment with Dexamethasone phosphate Teva, a temporary dose increase may be required.

Dexamethasone phosphate Teva can mask the signs of existing or developing infections, making them more difficult to recognise.

In the following illnesses, treatment with Dexamethasone phosphate Teva should only be started if your doctor considers it absolutely essential. If necessary, specific medicines that act against the pathogens should also be taken:

- acute viral infections (chickenpox, shingles, herpes simplex infections, inflammation of the cornea caused by herpes viruses)

- HBsAg-positive chronic active hepatitis (infectious liver inflammation)
- about 8 weeks before to 2 weeks after vaccinations with attenuated pathogens (live vaccine)
- acute and chronic bacterial infections
- fungal infections with involvement of internal organs
- certain diseases caused by parasites (amoebic, worm infections). In patients with suspected or confirmed infection with threadworms (nematodes), Dexamethasone phosphate Teva can lead to activation and mass proliferation of these parasites
- polio
- lymph node disease after tuberculosis vaccination
- in case of history of tuberculosis, use only together with medicines for tuberculosis

The following diseases should be specifically monitored during concomitant treatment with Dexamethasone phosphate Teva and treated according to the requirements:

- gastrointestinal ulcers
- bone loss (osteoporosis)
- severe heart failure (cardiac insufficiency)
- high blood pressure that is difficult to regulate
- diabetes (diabetes mellitus) that is difficult to regulate
- mental (psychological) disorders (also in the past), including suicidal tendencies. In this case, neurological or psychiatric monitoring is recommended
- increased intraocular pressure (narrow- and wide-angle glaucoma); ophthalmologic monitoring and adjunctive therapy are recommended
- injuries and ulcers of the cornea of the eye; ophthalmologic monitoring and adjunctive therapy are recommended

Treatment with this medicine may cause so-called pheochromocytoma crisis, which may be fatal. Pheochromocytoma is a rare hormone-dependent tumour of the adrenal gland. Possible symptoms of crisis are headache, sweating, racing heartbeat (palpitations) and high blood pressure (hypertension). Talk to your doctor immediately if you notice any of these signs.
Talk to your doctor before using Dexamethasone phosphate Teva if pheochromocytoma (adrenal gland tumour) is suspected or diagnosed.

Tell your doctor if you get any of the following symptoms:
- Symptoms of tumour lysis syndrome such as muscle cramping, muscle weakness, confusion, visual loss or disturbances and shortness of breath, in case you suffer from a malignant blood disease

If you get blurred vision or other vision disorders, talk to your doctor.

Because of the risk of intestinal perforation, Dexamethasone phosphate Teva may only be used if there are compelling medical reasons and under appropriate monitoring in the following cases:

- in severe inflammation of the colon (ulcerative colitis) with threatened perforation, with abscesses or purulent inflammation, possibly without peritoneal irritation
- in inflamed pouches in the bowel wall (diverticulitis)
- after certain intestinal surgeries (intestinal anastomosis), immediately after surgery

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

In patients with concurrent diabetes, metabolism should be checked regularly; the possibility of a higher need for medicines for the treatment of diabetes (insulin, oral antidiabetics) should be taken into consideration.

Patients with severely high blood pressure and/or severe heart failure should be carefully monitored due to the risk of deterioration.

High doses can lead to slowing of the heartbeat.

Severe anaphylactic reactions (overreaction of the immune system) may occur.

The risk of tendon disorders, tendon inflammation and tendon rupture is increased when fluoroquinolones (certain antibiotics) and Dexamethasone phosphate Teva are administered together.

During the treatment of a particular form of muscle paralysis (myasthenia gravis), the symptoms may worsen at the beginning.

Vaccinations with vaccines from killed pathogens (inactivated vaccines) are generally possible. However, it should be noted that the immune response and thus the vaccine may be compromised at higher doses of corticosteroids.

Particularly during long-term treatment with high doses Dexamethasone phosphate Teva, attention should be paid to sufficient potassium intake (e.g. vegetables, bananas), salt intake should be limited and blood potassium levels should be monitored.

Viral diseases (e.g. measles, chickenpox) may be very severe in patients treated with Dexamethasone phosphate Teva. Patients with a compromised immune system who have not had measles or chickenpox yet are particularly at risk. If these patients come into contact with people infected with measles or chickenpox during treatment with Dexamethasone phosphate Teva, they should immediately contact their doctor, who will initiate preventative treatment if necessary.

Intravenous doses should be administered by slow injection (over 2–3 minutes), as short-term (lasting up to 3 minutes), technically harmless side effects such as unpleasant tingling or painful sensations (paraesthesia) may occur if injected too rapidly.

Dexamethasone phosphate Teva is a medicine for short-term use. For unintended, long-term use, further warnings and precautions must be taken into account, as described for glucocorticoid-containing medicines for long-term use.

Potential systemic side effects and interactions should be taken into consideration with local administration.

Intraarticular administration (injection into a joint) of Dexamethasone phosphate Teva increases the risk of joint infections. Long-term and repeat glucocorticoid administration in weight-bearing joints can cause worsening of wear-related changes in the joint. This is potentially caused by an overload of the affected joint after the pain or other symptoms regress.

Local use in eye treatment:

Talk to your doctor if you experience swelling and weight gain around your torso and face, as these are usually the first signs of so-called Cushing's syndrome. After discontinuation of long-term or high-dose treatment with Dexamethasone phosphate Teva, suppression of the adrenal function may occur. Talk to your doctor before stopping treatment yourself. These risks are particularly important for children and patients treated with a medicine containing ritonavir or cobicistat.

You should not stop taking any other steroid medications unless your doctor has instructed you to do.

Talk to your doctor, pharmacist or nurse before you take Dexamethasone phosphate Teva.

General precautions regarding steroid use in specific diseases, masking infection, concomitant medicines etc. in line with current recommendations.

Premature infants
Dexamethasone phosphate Teva should not be used routinely in premature infants with breathing problems.
If dexamethasone is given to a prematurely born baby, monitoring of heart function and structure is needed.

Children and adolescents
Due to the risk of growth inhibition, Dexamethasone phosphate Teva should only be administered in children for compelling medical reasons, and during long-term treatment with glucocorticoids, growth in height should be checked regularly.

Elderly
A special benefit-risk assessment should also be carried out in elderly patients due to the increased risk of osteoporosis.

Effects in case of misuse for doping purposes
Use of Dexamethasone phosphate Teva can lead to positive results in anti-doping tests.

Other medicines and Dexamethasone phosphate Teva
Tell your doctor or pharmacist if you are taking/using, have recently taken/used or might take/use any other medicines.

What other medicines influence the effect of Dexamethasone phosphate Teva?
- Medicines that accelerate the breakdown in the liver, such as certain sleeping pills (barbiturates), medicines used to treat seizures (phenytoin, carbamazepine, primidone) and certain medicines for tuberculosis (rifampicin), may reduce the effect of corticosteroids
- Medicines that slow down the breakdown in the liver, such as certain medicines to treat fungal infections (ketoconazole, itraconazole), may increase the effect of corticosteroids
- Some medicines may increase the effects of Dexamethasone phosphate Teva and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, cobicistat)
- Certain female sex hormones, e.g. for the prevention of pregnancy (the pill): The effect of Dexamethasone phosphate Teva may be increased
- Ephedrine (e.g. medicines for hypotension, chronic bronchitis, asthma attacks, medicines used to reduce swelling of the mucous membranes in rhinitis and appetite suppressants can contain ephedrine): Through accelerated breakdown in the body, the effectiveness of Dexamethasone phosphate Teva may be reduced

How does Dexamethasone phosphate Teva influence the effect of other medicines?
- During simultaneous use with certain medicines for lowering blood pressure (ACE inhibitors), Dexamethasone phosphate Teva may increase the risk of blood count changes
- Dexamethasone phosphate Teva may increase the effect of medicines that strengthen the heart (cardiac glycosides) through potassium deficiency
- Dexamethasone phosphate Teva may increase potassium excretion caused by diuretic medicines (saluretics) or laxatives
- Dexamethasone phosphate Teva may decrease the blood glucose-lowering effect of oral antidiabetics and insulin
- Dexamethasone phosphate Teva may weaken the effects of medicines that prevent blood clotting (oral anticoagulants, coumarins). Your doctor will decide whether a dose adjustment of the blood thinner is necessary
- During concomitant use of anti-inflammatory and antirheumatic drugs (salicylates, indomethacin and other non-steroidal anti-inflammatory drugs), Dexamethasone phosphate Teva may increase the risk of stomach ulcers and gastrointestinal bleeding
- Dexamethasone phosphate Teva may prolong the muscle-relaxing effect of certain medicines (non-depolarising muscle relaxants)

- Dexamethasone phosphate Teva may enhance the eye pressure-increasing effect of certain medicines (atropine and other anticholinergic agents)
- Dexamethasone phosphate Teva may decrease the effect of medicines for worm diseases (praziquantel)
- During concomitant use of medicines for malaria and rheumatic diseases (chloroquine, hydroxychloroquine, mefloquine), Dexamethasone phosphate Teva may increase the risk of muscle diseases or heart muscle diseases (myopathies, cardiomyopathies)
- Dexamethasone phosphate Teva may reduce the increase in thyroid-stimulating hormone (TSH) after administration of protirelin (TRH, a hormone of the interbrain)
- If used together with medicines that suppress the body's immune system (immunosuppressants), Dexamethasone phosphate Teva may increase the susceptibility to infections and worsen existing infections that perhaps have not erupted yet
  Additionally, for ciclosporin (a medicine used to suppress the body's immune system): Dexamethasone phosphate Teva may increase the concentration of ciclosporin in the blood and thereby the risk of seizures
  Fluoroquinolones, a certain group of antibiotics, may increase the risk of tendon ruptures

Effect on investigation methods:
Glucocorticoids can suppress skin reactions in allergy tests.

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

Pregnancy
Dexamethasone crosses the placenta. During pregnancy, especially in the first three months, the medicine should only be used after careful benefit-risk assessment. Therefore, women should inform the doctor if they are already pregnant or if they become pregnant. During long-term treatment with glucocorticoids during pregnancy, growth disorders in the unborn child cannot be excluded. If glucocorticoids are administered towards the end of pregnancy, there is a risk of underactive adrenal cortex in the newborn, which may necessitate replacement therapy in the newborn, which has to be slowly reduced.

Breast-feeding
Glucocorticoids, including dexamethasone, are excreted in breast milk. Harmful effects on the breast-fed child have not been reported to date. Nevertheless, the need for treatment during breast-feeding should be closely examined. If the disease requires higher doses, breast-feeding should be discontinued. Please contact your doctor immediately.

Newborn babies of mothers who received Dexamethasone phosphate Teva near the end of pregnancy may have low blood sugar levels after birth.

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

Driving and using machines

To date, there is no evidence that Dexamethasone phosphate Teva affects the ability to drive, use machines, or work without safe foothold.

Dexamethasone phosphate Teva contains sodium, but less than 1 mmol sodium (23 mg) per ampoule, that is to say essentially "sodium free".

3. How to use Dexamethasone phosphate Teva

Dexamethasone phosphate Teva is always given by a doctor or healthcare professional.
Ask your doctor if you are not sure about its use.

Method of administration
Solution for injection into a vein, muscle or body tissue.

Dexamethasone phosphate Teva is administered into a vein slowly (2–3 minutes). If administration into a vein is not possible and the circulatory function is intact, Dexamethasone phosphate Teva can also be injected into a muscle. Dexamethasone phosphate Teva can also be given by infiltration (injection into body tissue), the intraarticular route (injection into a joint) or the subconjunctival route (injection under the conjunctival sac in the eye).

Direct intravenous injection or injection into the infusion tube should be preferred to administration by infusion.

Injection into joints should be treated like open joint operations and is to be administered only under strict aseptic conditions. In general, one intraarticular injection is sufficient to successfully alleviate symptoms. If a further injection is deemed necessary, it should be administered after at least 3–4 weeks. No more than 3–4 injections should be administered in each joint. Medical monitoring of the joint is indicated, particularly in the event of repeat injections.

Infiltration: Dexamethasone phosphate Teva is infiltrated into the area with the strongest pain or the tendon insertion. Caution: must not be injected intratendinously (in or between the tendons). Injections at short intervals should be avoided and strict aseptic precautionary measures must be complied with.

Notes on using the solution
Only transparent solutions should be used. The content of the ampoules is intended to be withdrawn only once. The rest of the solution for injection must be destroyed.

Unless otherwise prescribed by your doctor, the usual doses are:

Systemic use
- Swelling of the brain: Initially for acute forms, depending on the cause and severity of the disease, 8–10 mg (up to 80 mg) in a vein (IV), followed by 16–24 mg (up to 48 mg) daily, divided into 3–4 (up to 6) single doses for 4–8 days
- Swelling of the brain due to bacterial meningitis: 0.15 mg/kg body weight IV every 6 hours for 4 days, children: 0.4 mg/kg body weight every 12 hours for 2 days, starting before the first antibiotics
- Shock after a serious injury: An initial IV dose of 40–100 mg (children: 40 mg), repeated after 12 hours or 16–40 mg every 6 hours for 2–3 days
- Shock caused by allergic reactions: After adrenalin administration, 40–100 mg IV (preparations with a higher dose are recommended), repeated if required
- Severe acute asthma attack: Adults: 8–20 mg IV as soon as possible, if necessary 8 mg repeated every 4 hours. Children: 0.15–0.3 mg dexamethasone/kg body weight, or 1.2 mg/kg body weight IV as a bolus injection followed by 0.3 mg/kg every 4–6 hours
- Interstitial aspiration pneumonia: 40–100 mg IV initially (preparations with a higher dose are recommended) (children 40 mg), repeated after 12 hours or 16–40 mg (corresponding to 4–10 ampoules) every 6 hours for 2–3 days
- Acute skin diseases: Depending on the nature and extent of the disease, a daily IV dose of 8–40 mg up to 100 mg in individual cases, followed by treatment with tablets with decreasing doses
- Blood vessel inflammations such as polyarteritis nodosa: 6–15 mg/day
- Systemic lupus erythematosus: 6–16 mg/day
- Severe progressive form of active rheumatoid arthritis, e.g. forms that quickly lead to joint destruction: 12–16 mg/day, when tissue outside the joints is affected: 6–12 mg/day
- Rheumatic joint inflammation in children (juvenile idiopathic arthritis): 12–15 mg IV
- Rheumatic fever with heart inflammation: 12–15 mg IV

- Severe infectious diseases with poison-like states: 4–20 mg/day IV for a few days, in addition to corresponding anti-infective therapy only; in specific cases (e.g. typhoid), an initial dose of up to 200 mg IV, which is then tapered
- Supportive treatment in malignant tumours: Initially 8–16 mg/day, during longer lasting treatment 4–12 mg/day
- Prevention and treatment of vomiting with cytostatic treatment with specific treatment regimens: 10–20 mg IV before initiation of chemotherapy, then 4–8 mg 2–3 times daily as required for 1–3 days (moderately emetogenic chemotherapy) or up to 6 days (highly emetogenic chemotherapy)
- Prevention and treatment of vomiting after surgery: A single dose of 8–20 mg prior to the operation. In children from 2 years, 0.15–0.5 mg/kg body weight (up to 16 mg)

Take Dexamethasone phosphate Teva as only as prescribed by your doctor. Your doctor will decide how long you should take dexamethasone for. Check with your doctor or pharmacist if you are not sure.

For the treatment of Covid-19
Adult patients are recommended to be given 6 mg once a day for up to 10 days.

Use in adolescents
Paediatric patients (adolescents of 12 years of age or older) are recommended to be given 6 mg once a day for up to 10 days.

Local use
Local infiltration and injection therapy is usually carried out with 4–8 mg; 2 mg dexamethasone phosphate is sufficient if injected into small joints and under the conjunctival sac in the eye.

Administration
When possible, the daily dose should be given as a single dose in the morning. However, in diseases that require high-dose therapy, multiple doses throughout the day are often needed to get maximum effect.

The duration of treatment depends on the underlying disease and the course of the disease. Your doctor will establish a treatment regimen that must be complied with carefully. As soon as satisfactory treatment results are achieved, the dose will be lowered to a maintenance dose or the treatment stopped.

Abrupt withdrawal of a treatment that was received for more than approx. 10 days can lead to acute adrenocortical insufficiency. Doses should therefore be reduced gradually in the event of planned discontinuation.

In underactive thyroid or liver cirrhosis, lower doses may be sufficient or a dose reduction may be necessary.

If you use more Dexamethasone phosphate Teva than you should
Even if taken for a short time in large quantities, Dexamethasone phosphate Teva is generally tolerated without complications. There are no special measures required. If you notice increased or unusual side effects, you should talk to your doctor.

If you forget to use Dexamethasone phosphate Teva
A missed dose may be taken on the same day, and the next day the dose prescribed by your doctor should be taken as usual. If several doses are forgotten, this can lead to a recurrence or worsening of the disease being treated. In such cases, you should talk to your doctor, who will review the treatment and adjust it, if needed.

If you stop using Dexamethasone phosphate Teva

Always follow the dosage regimen prescribed by the doctor. Dexamethasone phosphate Teva must never be discontinued without authorisation, particularly since long-term treatment can lead to a decrease in the body's production of glucocorticoids (underactive adrenal cortex). A highly physically stressful situation without adequate glucocorticoid production can be fatal.

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

4. Possible side effects

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

Undesirable effects
There is a low risk of side effects with short-term dexamethasone therapy. High doses injected into the vein are an exception to this, as they can lead to electrolyte disturbances, oedema formation and potentially hypertension, heart failure, heart rhythm disorders or seizures. The occurrence of infections must also be taken into account with short-term treatment. Attention should be paid to gastrointestinal ulcers (often stress-induced), because corticosteroid therapy can reduce their symptoms, and to a reduction in glucose tolerance.
In very rare cases Dexamethasone phosphate Teva can cause allergic reactions up to anaphylactic shock.

For long-term use and especially with high doses, side effects of varying severity are to be expected regularly.

Infections and infestations:
Masking of infections, occurrence and worsening of viral, fungal, bacterial infections and parasitic or opportunistic infections, activation of threadworm infection.

Blood and lymphatic system disorders:
Blood count changes (increased number of white blood cells or all blood cells, decreased number of certain white blood cells).

Immune system disorders:
Hypersensitivity reactions (e.g. drug eruption), severe anaphylactic reactions, such as heart rhythm disorders, bronchospasm (spasm of the bronchial smooth muscle), high or low blood pressure, circulatory collapse, heart arrest, weakening of the immune system.

Endocrine disorders:
Occurrence of Cushing's syndrome (typical signs include rounded face, a fatty stomach and flushing), underactive or inactive adrenal cortex.

Metabolism and nutrition disorders:
Weight gain, elevated blood sugar, diabetes, increased blood lipids (cholesterol and triglycerides), increased sodium levels with swelling (oedema), potassium deficiency due to increased potassium excretion (may lead to heart rhythm disorders), increased appetite.

Psychiatric disorders:
Depression, irritability, euphoria, increased drive, psychoses, mania, hallucinations, mood swings, anxiety, sleep disorders, suicidal tendencies.

Nervous system disorders:
Increased intracranial pressure, occurrence of previously unrecognised epilepsy, more frequent seizures in already known epilepsy.

Eye disorders:

Increase in intraocular pressure (glaucoma), clouding of the lens (cataract), worsening of corneal ulcers, increased occurrence or worsening of eye inflammation caused by viruses, bacteria or fungi; worsening of bacterial inflammation of the cornea, drooping eyelid, pupil dilation, conjunctival swelling, perforation of the white of the eye, rare cases of reversible bulging eyeballs, corneal inflammation caused by herpes simplex with subconjunctival administration, perforation of the cornea with existing corneal inflammation, visual disturbances, loss of vision, blurred vision.

Cardiac disorders:
Thickening of the heart muscle (hypertrophic cardiomyopathy) in prematurely born babies, that generally returns to normal after stopping treatment (Frequency: Not known).

Vascular disorders:
High blood pressure, increased risk of atherosclerosis and thrombosis, inflammation of blood vessels (also as withdrawal syndrome after long-term treatment), increased fragility of blood vessels.

Respiratory, thoracic and mediastinal disorders
Hiccup.

Gastrointestinal disorders:
Gastrointestinal ulcers, gastrointestinal bleeding, inflammation of the pancreas, stomach discomfort.

Skin and subcutaneous tissue disorders:
Stretch marks on the skin, thinning of the skin ("parchment skin"), enlargement of skin blood vessels, tendency to bruising, skin bleeding in dots or patches, increased body hair, acne, inflammatory skin changes on the face, especially around the mouth, nose and eyes, changes in skin pigmentation.

Musculoskeletal and connective tissue disorders:
Muscle diseases, muscle weakness and wasting and bone loss (osteoporosis) are dose-related and possible even with only short-term use; other forms of bone death (osteonecrosis), tendon disorders, tendinitis, tendon ruptures, fat deposits in the spine (epidural lipomatosis), growth inhibition in children.

Important:
If the dose is reduced too rapidly after long-term treatment, this may cause a withdrawal syndrome with symptoms such as muscle and joint pain.

Reproductive system and breast disorders:
Disorders of sexual hormone secretion (consequently: irregular or absent menstruation (amenorrhoea), male-like body hair in women (hirsutism), impotence).

General disorders and administration site conditions:
Delayed wound healing.

With local use: Local irritation and intolerability reactions may occur (feeling of heat, persistent pain), especially when used on the eye. Thinning of the skin or subcutaneous tissue at the injection site cannot be ruled out if the corticosteroids are not carefully injected into the joint cavity.

Actions
Please talk to your doctor or pharmacist if you notice any of the listed side effects or other unwanted effects during treatment with Dexamethasone phosphate Teva. Never stop treatment on your own.

If gastrointestinal discomfort, pain in the back, shoulder or hip area, psychological disorders, abnormal blood sugar fluctuations in diabetics or other disturbances occur, please inform your doctor immediately.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Dexamethasone phosphate Teva

Keep this medicine out of the sight and reach of children.

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

Do not store above 30°C
Store the ampoules in the outer carton in order to protect from light.

Only transparent solutions should be used.
The solution must be used immediately after breaking the ampoule. The rest is to be disposed of.

Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Dexamethasone phosphate Teva contains

- The active substance is dexamethasone phosphate.
  Each ml of solution for injection contains 4.37 mg dexamethasone sodium phosphate equivalent to 4 mg dexamethasone phosphate or 3.3 mg dexamethasone.
- The other ingredients are: Sodium edetate (Ph. Eur.), sodium chloride, sodium hydroxide, water for injections.

What Dexamethasone phosphate Teva looks like and contents of the pack

The ampoules contain an almost colourless, transparent solution.

Dexamethasone phosphate Teva is available in packs of 3, 10, 30 and 30 (multi-pack of 3 x 10) ampoules of 1 ml solution for injection as well as packs of 3, 10, 30 and 30 (multi-pack of 3 x 10) ampoules of 2 ml solution for injection.

Not all pack sizes may be marketed.

Marketing Authorisation Holder:
Teva B.V., Swensweg 5, 2031GA, Haarlem, The Netherlands

Manufacturer:
Merckle GmbH, Ludwig-Merckle-Str. 3, 89143 Blaubeuren, Germany

This medicinal product is authorised in the Member States of the EEA under the following names:

Germany: Dexa-CT 4 mg/ml Injektionslösung
Iceland: Dexamethasone Teva
Ireland: Dexamethasone phosphate Teva 4 mg/ml solution for injection

This leaflet was last revised in May 2022.