



Dexamethasone 20mg Soluble Tablets

dexamethasone

The name of your medicine is Dexamethasone 20mg Soluble Tablets which will be referred to as Dexamethasone Soluble Tablets throughout the rest of this leaflet.

Important information about this medicine

- Dexamethasone Soluble Tablets is a steroid medicine, prescribed for many different conditions including serious illnesses.
- You need to take it regularly to get the maximum benefit.
- Do not stop taking this medicine without talking to your doctor – you may need to reduce the dose gradually.
- Dexamethasone Soluble Tablets can cause side effects in some people (read section 4: 'Possible side effects'). Some problems such as mood changes (feeling depressed, or 'high'), or stomach problems can happen taking away. If you feel unwell, in any way, keep taking your medicine, but see your doctor straight away.
- Some side effects only happen after weeks or months. These include weakness of arms and legs, or developing a rounder face (read section 4 for more information).
- If you take it for more than 3 weeks you will get a 'steroid card': always keep it with you and show it to any doctor or nurse treating you.
- Keep away from people who have chicken pox or shingles, if you have never had them. They could affect you severely. If you do come into contact with chicken pox or shingles, see your doctor straight away.

Read all of this leaflet carefully before you start taking 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 is and what it is used for
2. What you need to know before you take Dexamethasone Soluble Tablets
3. How to take Dexamethasone Soluble Tablets
4. Possible side effects
5. How to store Dexamethasone Soluble Tablets
6. Contents of the pack and other information

1 What Dexamethasone is and what it is used for

This medicine contains the active substance dexamethasone. This medicine belongs to a group of medicines called steroids ('corticosteroids'). Corticosteroids occur naturally in the body (produced by the cortex of the adrenal gland) and help to maintain health and well-being via anti-inflammatory, analgesic and anti-allergic effects which suppresses the immune system.

Boosting your body with extra corticosteroid (such as dexamethasone) is an effective way to treat various illnesses involving inflammation in the body.

Dexamethasone reduces this inflammation, which could otherwise go on making your condition worse. You must take this medicine regularly to get the maximum benefit from it.

This medicine is recommended for treating the following:

- rheumatic and autoimmune diseases (e.g. myositis)
- skin diseases (e.g. pemphigus vulgaris)
- blood disorders (e.g. idiopathic thrombocytopenic purpura in adults)
- treatment of symptomatic multiple myeloma, acute lymphoblastic leukaemia, Hodgkin's disease and non-Hodgkin's lymphoma in combination with other medicinal products
- metastatic spinal cord compression (pressure on the spinal cord nerves caused by a tumour)
- prophylaxis and treatment of nausea and vomiting caused by chemotherapy, within antiemetic treatment

You may be using this medicine for a different reason. Ask your doctor why this medicine has been prescribed for you.

2 What you need to know before you take Dexamethasone Soluble Tablets

Do not take this medicine:

- if you are allergic (hypersensitive) to dexamethasone sodium phosphate or any of the other ingredients of this medicine (listed in section 6) or you have ever had an unusual reaction to these substances
- if you have an infection (including fungal infections) that affects the whole body (unless you are receiving treatment)
- if you have a stomach or duodenal ulcer
- if you are going to have a vaccination by live vaccines.

Warnings and precautions

Treatment with this medicine may cause pheochromocytoma crisis, which can be fatal. Pheochromocytoma is a rare tumour of the adrenal glands. Crisis can occur with the following symptoms: headaches, sweating, palpitations, and hypertension. Contact your doctor immediately if you experience these signs.

Contact your doctor if you experience blurred vision or other visual disturbance.

Talk to your doctor or pharmacist before taking this medicine:

- if you have ever had severe depression or manic depression (bipolar disorder). This includes having had depression before or while taking steroid medicines like Dexamethasone.
- if any of your close family has had these illnesses.
- if the treatment is for a premature baby. Dexamethasone should not be routinely used in preterm neonates with respiratory problems.
- if you have or are suspected of having pheochromocytoma (a tumour of the adrenal glands).

Mental health problems while taking this medicine

Mental health problems can happen while taking steroids like Dexamethasone.

- These illnesses can be serious.
- Usually they start within a few days or weeks of starting the medicine.
- They are more likely to happen at high doses.
- Most of these problems go away if the dose is lowered or the medicine is stopped. However, if problems do happen, they might need treatment.

Talk to a doctor if you (or someone taking this medicine), show any signs of mental health problems. This is particularly important if you are depressed, or might be thinking about suicide. In a few cases, mental health problems have happened when doses are being lowered or stopped.

Talk to your doctor before taking this medicine if:

- you have a cancer of the blood because you may be at risk of a very rare, potentially life-threatening condition resulting from a sudden breakdown of tumour cells
- you have a bacterial or viral infection (such as hepatitis, poliomyelitis) or an infection with parasites
- you have kidney or liver problems (liver cirrhosis or chronic liver failure)
- you have high blood pressure, heart disease or you have recently had a heart attack (myocardial rupture has been reported)
- you have diabetes or there is a family history of diabetes
- you have osteoporosis (thinning of the bones), particularly if you are a female who has been through the menopause
- you have suffered in the past from muscle weakness with this or other steroids
- you have glaucoma (raised eye pressure) or there is a family history of glaucoma, cataract (clouding of the lens in the eye leading to a decrease in vision)
- you have myasthenia gravis (a condition causing weak muscles)
- you have a bowel disorder (ulcerative colitis or diverticulitis), have recently had an operation on your bowel or a stomach ulcer (peptic or gastrointestinal ulcer)
- you have psychiatric problems, or you have had a psychiatric illness which was made worse by this type of medicine
- you have epilepsy (convulsions where you have repeated fits or convulsions)
- you have migraines
- you have an underactive thyroid gland
- you have tuberculosis (TB) or have recently had a reaction to a vaccination for TB
- you have septicaemia

- you have a fungal or viral infection in the eye, an injury to your eye or an ulcer on the surface of your eye (corneal ulceration)
 - you have cerebral malaria
 - you have herpes (cold sores or genital herpes and ocular herpes simplex because of possible corneal perforation)
 - you have asthma
 - you have stunted growth
 - you have a tumour of the adrenal gland (pheochromocytoma)
 - you have a parasitic infection
 - you are treated for a blockage of blood vessels by blood clots (thromboembolism)
 - you have corneal ulcerations and corneal injuries
- This may affect the dose you are given, or your doctor may want you to take other medicines at the same time.

More important information about taking this medicine

- Taking this medicine may increase your risk of getting an infection. It may also mask the symptoms of an existing or developing infection and make it harder to find out what is wrong. If you develop an infection whilst on this medicine, you should talk to your doctor.
- If you have an accident, are ill, require surgery (even at the dentist's) or you require a vaccination (particularly with 'live virus' vaccines) whilst taking or when you have finished taking Dexamethasone, you should inform the person treating you that you are taking or have taken steroids.
- If you have an allergy test, a suppression test (test for hormone levels) or a test for an infection, you should inform the person performing the test that you are taking Dexamethasone as it may interfere with the results.
- If you need a vaccination tell your doctor as it may not be effective or you may have a greater chance of getting an infection from a 'live' vaccine such as MMR, tuberculosis (TB), yellow fever or oral typhoid.
- If you have a doping test when taking this medicine, you may get a positive result.
- Your doctor may want to perform regular check ups on you while you are taking Dexamethasone:
 - they may be more frequent if you have other health problems (such as diabetes or kidney problems) or if you are elderly as any side effects may be more serious for you.
 - if a child is taking this medicine, it is important that their growth and development is checked at frequent intervals as Dexamethasone can cause children to grow more slowly.
 - if you are taking this medicine for a long time, regular (every 3 months) checks of your vision are recommended.
 - if you are taking high doses your doctor may monitor the levels of potassium in your blood. You may also find that your doctor will reduce the amount of salt in your diet and give you a potassium supplement whilst you are taking this medicine.
- If you take this medicine for more than 3 weeks, you should always carry a 'steroid card' which gives clear guidance on the special care to be taken when you are taking this medicine. Show this to any doctor, dentist or person who may be giving you treatment. Even after your treatment has finished you must tell anyone who is giving you treatment that you have taken steroids in the past.
- Talk to your doctor if you have 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 haematological malignancy.
- Chickenpox, shingles and measles. It is important that whilst you are taking this medicine you avoid contact with anybody who has chickenpox, shingles or measles. If you think you may have had exposure to any of these diseases, you should consult your doctor immediately.
 - You should also inform your doctor if you have ever had infectious diseases such as measles or chickenpox and if you have had any vaccinations for these diseases in the past.

Older people

Some of the side effects of Dexamethasone may be more serious in older people. Your doctor may need to monitor you more closely for the following:

- diabetes
- getting infections
- thinning of the skin
- high blood pressure
- thinning of the bones (osteoporosis)
- low potassium levels in the blood (hypokalaemia).

Children

If a child is taking this medicine, it is important that the doctor monitors their growth and development at frequent intervals. Dexamethasone should not be used routinely in preterm neonates with respiratory problems.

Taking other medicines and this medicine

Please tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines you buy without a prescription, including herbal medicines. This is because some medicines may increase the effects of Dexamethasone and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, cobicistat).

In particular, tell your doctor if you are taking any of the following:

- anticoagulant medicines which thin the blood (e.g. warfarin, coumarin).
- medicines that control pain or lower inflammation, such as aspirin (acetylsalicylic acid) or similar non-steroidal anti-inflammatory drugs (NSAIDs), such as indomethacin, hydrocortisone, cortisone and other corticosteroids. You should be carefully monitored if you are taking NSAIDs at the same time as taking Dexamethasone because you are more likely to get stomach or gut ulcers.
- medicines used to treat diabetes such as insulin, metformin or sulfonylureas such as chlorpropamide
- medicines used to treat high blood pressure such as captopril or verapamil diuretics (water tablets)
- amphotericin B injection (used to treat infections)
- phenytoin, carbamazepine, (epilepsy medication)
- rifabutin, rifampicin, isoniazid (antibiotics used to treat tuberculosis)
- antacids or charcoal. You should leave at least two hours between taking these medicines and dexamethasone
- barbiturates (medication used to aid sleep and relieve anxiety and also for epilepsy)
- aminoglutethimide (anti-cancer treatment)
- carbenoxolone (used in the treatment of stomach ulcers)
- ephedrine (nasal decongestant)
- acetazolamide (used for glaucoma and epilepsy)
- ketoconazole, itraconazole (for fungal infections)
- medicines for HIV: ritonavir, cobicistat
- antibiotics including erythromycin, fluoroquinolones
- colestyramine (for high cholesterol levels)
- oestrogen hormones including the contraceptive pill
- tetracosactide (used in the testing for adrenocortical function)
- adrenergic (used to calm emotions)
- ciclosporin (used to prevent rejection after transplants)
- thalidomide (anti-cancer treatment and leprosy)
- praziquantel (given for certain worm infections)
- isoniazid for tuberculosis
- live vaccines such as MMR, tuberculosis, yellow fever or oral typhoid
- medicines to treat viral infections and HIV such as indinavir and saquinavir
- medicines that help muscle movement in myasthenia gravis, such as neostigmine.
- methotrexate used for cancer or inflammatory problems.
- diuretics (water tablets)
- chloroquine, hydroxychloroquine and mefloquine (medicines used to treat malaria)
- somatotropin
- protirelin

You must read the package leaflet of all medicinal products to be taken in combination with Dexamethasone for information related to these medicines before starting treatment with Dexamethasone. When thalidomide, lenalidomide or pomalidomide is used, particular attention to pregnancy testing and prevention requirement is needed.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking Dexamethasone Soluble Tablets.

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.

Dexamethasone should only be prescribed **during pregnancy**, particularly in the first trimester, if the benefit outweighs the risks for the mother and child. If you **become pregnant** during the use of the product, do not stop using it, but tell your doctor immediately that you are pregnant.

Dexamethasone is excreted in breast milk. It may influence the growth of your baby or cause other unwanted effects. Tell your doctor if you intend to breast-feed while taking this medicine.

Driving and using machines

You may experience dizziness when taking this medicine (see section 4: 'Possible side effects'). This may affect your ability to drive. If this happens, do not drive or use tools or machinery.

Important information about some of the ingredients of this medicine

Dexamethasone 20mg Soluble Tablets contain 65.6mg of sodium per tablet (main component of cooking/table salt). This is equivalent to 3.3% of the recommended maximum daily dietary intake of sodium for an adult.

Dexamethasone 20mg Soluble Tablets contain 18mg of benzoate salt per tablet.

Benzoate salt may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).

3 How to take Dexamethasone Soluble Tablets

Dexamethasone Soluble Tablets are only to be taken by mouth. Your doctor will prescribe the most appropriate dose to treat your condition.

The tablets should be taken as a drink after dissolving them in a glass of water. Take your tablets as a **single dose each morning**, unless your doctor has told you otherwise.

Dexamethasone Soluble Tablets should be taken with or after food to minimise irritation to the gastrointestinal tract. Drinks containing alcohol or caffeine should be avoided.

Always take this medicine exactly as your doctor has told you. These instructions will have been added to the dispensing label by your pharmacist. Check with your doctor or pharmacist if you are not sure.

Please be aware that this is a high dosage medical product.

Dexamethasone is recommended to be used at the lowest effective dose, recommended by your doctor.

Adults:

The usual dose of Dexamethasone is 0.5mg to 10mg daily, depending on the disease being treated. In more severe disease conditions, doses above 10mg per day may be required. The dose should be titrated to the individual patient response and disease severity. In order to minimise side effects, the lowest effective possible dose should be used. Your doctor will decide your exact dose based on how serious your illness is.

Unless otherwise prescribed, the following dosage recommendations apply:

The below mentioned dosing recommendations are given for guidance only. The initial and daily doses should always be determined based on individual patient response and disease severity.

- **Pemphigus:** initial dose of 300mg for three days followed by down titration according to clinical need.
- **Myositis:** 40mg for 4 days in cycles.
- **Idiopathic thrombocytopenic purpura:** 40mg for 4 days in cycles.
- **Metastatic spinal cord compression:** initial dose and duration of treatment depending on the cause and severity. Very high doses up to 96mg may be used for palliative treatment. For optimal dosing and reduction of the number of tablets the combination of lower dose strengths (4 and 8 mg) and higher dose strengths (20mg or 40mg) can be used.
- **Prophylaxis and treatment of emesis induced by cytotoxic, emetogenic chemotherapy within antiemetic treatment:** 8-20mg (one 20mg tablet or one half of 40mg tablet) prior to chemotherapy treatment, then 4-16mg/day on day 2 and 3.
- **Treatment of symptomatic multiple myeloma, acute lymphocytic leukaemia, acute lymphoblastic leukaemia, Hodgkin's disease and non-Hodgkin's lymphoma in combination with other medicinal products:** the usual posology is 40mg or 20mg once per day.

The dose and administration frequency varies with the therapeutic protocol and the associated treatment(s). Dexamethasone administration should follow instructions for dexamethasone administration 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. Prescribing physicians should carefully evaluate which dose of dexamethasone to use, taking into account the condition and disease status of the patient.

Long-term treatment

For the long-term treatment of several conditions, after initial therapy, glucocorticoid treatment should be switched from dexamethasone to prednisone/prednisolone to reduce suppression on the function of the adrenal cortex.

Use in children: a single dose on alternate days.

Important: if a child is taking this medicine, it is important that the doctor monitors their growth and development at frequent intervals.

If you are unsure how much medicine to take, please contact your doctor or pharmacist for advice.

Do not exceed or take less than the stated dose.

Do not take it more or less often than prescribed.

If you take more of this medicine than you should

If you take too much medicine contact a doctor or hospital immediately.

If you forget to take this medicine

If you forget to take a dose, take it as soon as you remember unless it is almost time for the next dose.

Do not take a double dose to make up for a forgotten dose.

If you stop taking this medicine

It can be dangerous to stop taking this medicine abruptly. The symptoms that have been reported when **treatment has been stopped too quickly** include low blood pressure and sometimes, relapse of the disease for which the medicine was given. A 'withdrawal syndrome' may also occur which includes fever, muscle and joint pain, inflammation of the nose lining (rhinitis), weight loss, itchy skin and inflammation of the eye (conjunctivitis). If your treatment is to be stopped follow your doctor's advice. He/she may tell you to reduce the amount of medicine you are taking gradually until you stop taking it altogether.

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.

Serious side effects, tell a doctor straight away if you experience serious mental health problems.

They can affect about 5 in every 100 people taking medicines like dexamethasone. These problems include:

- feeling depressed, including thinking about suicide
- feeling high (mania) or moods that go up and down
- feeling anxious or irritable, having problems sleeping, difficulty in thinking or being confused and losing your memory
- feeling, seeing or hearing things that do not exist. Having strange and frightening thoughts, changing how you act or having feelings of being alone.

Talk to your doctor immediately or go to hospital straight away if you experience any of the following side effects:

- severe abdominal pains, nausea, vomiting, diarrhoea, profound muscle weakness and fatigue, extremely low blood pressure, weight loss and fever as these may be signs of adrenocortical insufficiency
- sudden abdominal pain, tenderness, nausea, vomiting, fever and blood in stool as these may be signs of tearing of the bowel particularly if you have or have had a bowel disease.

This medicine may worsen your existing heart problem. If you experience shortness of breath or ankle swelling, consult your doctor straight away.

Other side effects may include

(frequency not known):

- **mental health problems:** a feeling of dependence, severe unusual headache with visual problems usually in children (normally after treatment has been stopped), fits and worsening of epilepsy, dizziness, worsening of schizophrenia (where you may sense, see or hear things that do not exist, become withdrawn or have mistaken beliefs or suspicions), extreme mood swings, depression, inability to sleep
- **stomach and bowel problems:** nausea, vomiting, hiccups, increased appetite, stomach discomfort, swollen abdomen, bloating, inflammation and ulcers in the oesophagus, heartburn, stomach ulcers that may bleed, inflamed pancreas (causing pain in the back and abdomen), tearing of the bowel particularly if you have inflammatory bowel disease, unusual fat deposits, flatulence, oesophageal candidiasis
- **metabolism and problems with salt levels:** weight gain, salt imbalances, water retention in the body, potassium loss due to low carbon dioxide levels (hypokalaemic alkalosis), loss of protein and calcium balance, unmask diabetes symptoms, increased need for diabetic medication, increased cholesterol and triglyceride levels in the blood (hypercholesterolaemia and hypertriglyceridaemia)
- **heart and blood problems:** blood clots (signs of this may include redness, pain or numbness, throbbing, a burning feeling or swelling), congestive heart failure in people who are likely to have heart problems, heart muscle rupture (especially if you have recently had a heart attack), high blood pressure, raised or lowered levels of red and white blood cells, inflammation and thickening of the veins or arteries, cardiac decompensation
- **muscle, bone and skin problems:** thinning of the bones with an increased risk of fractures (osteoporosis), also hip, arm and leg bone problems, bone necrosis, tendonitis, ruptured tendons, muscle wasting, myopathy, muscle weakness, excess body hair (particularly in women), slow wound healing, thinned delicate skin, unusual marks on the skin, bruising, redness and inflammation of the skin, stretch marks, visible swollen capillaries, acne, increased sweating, swelling, impaired reaction to skin tests, skin rash, thinning of the hair, water retaining in the body, pigment disorders, weakened capillaries that rupture easily – observed as bleeding under the skin (increased capillary fragility), skin irritation around the mouth (perioral dermatitis), discomfort, malaise, impaired reaction to vaccination and skin test
- **immune system problems:** greater chance of picking up infections, including viral and fungal infections e.g. thrush; recurrence of tuberculosis or some other infections, e.g. eye infections if you have already had it; blood disorders due to infection
- **eye problems:** cataracts, increased pressure in the eye, swelling of the eye, thinning of the eye membranes, worsening of existing eye infections, protrusion of the eyeballs, visual disturbances, loss of vision, blurred vision, papilloedema, increased eye viral, fungal and bacterial infections, worsening of symptoms associated with corneal ulcers
- **reproductive system problems:** irregular or lack of menstruation (periods), impotence, changes to the number and movement of sperm
- **hormonal problems:** impairment of the body's regulation of hormones, slow growth in children and teenagers, swelling and weight gain of the body and face (Cushingoid state), change in effectiveness of endocines following stress and trauma, surgery, childbirth or illness, development of excess body hair (particularly in women)
- **nervous system problems:** fits and worsening of epilepsy, dizziness, headache
- **allergic reactions:** allergic reaction to the medicine, including serious, potentially life-threatening allergic reaction (which may show as a rash and swelling of the throat or tongue and in severe cases difficulty in breathing or dizziness)
- **other general effect:** while taking this medicine your body may not be able to respond normally to severe stress such as accidents, surgery, childbirth or illness withdrawal effects (fever, muscle and joint pain, inflammation of the eye (conjunctivitis) or nose lining (rhinitis), itchy skin and weight loss). It may make you feel generally unwell. If you are a man, this medicine can affect the amount of sperm and their movement.

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 the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Dexamethasone Soluble Tablets

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

Store below 25°C.

Store in the original packaging to protect from moisture.

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

Do not throw away any medicines via wastewater or household waste. 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 this medicine contains

The active substance is dexamethasone.

Each tablet contains 20mg of dexamethasone (as dexamethasone sodium phosphate).

The other ingredients are sodium hydrogen carbonate, disodium hydrogen citrate, erythrosine (E127), povidone (K30), sodium saccharin, sodium benzoate (E211). See section 2: 'Dexamethasone Soluble Tablets contains sodium'.

What this medicine looks like and contents of the pack

Dexamethasone 20mg Soluble Tablets are pink, round, biconvex tablets (Thickness: 3.5 – 4.1mm; Diameter: 9.8 – 10.2mm).

Dexamethasone Soluble Tablets are available in blister foils containing 10, 28, 30, 50, 56, 60, and 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Aspire Pharma Limited
Unit 4, Rotherbrook Court
Bedford Road
Petersfield
Hampshire
GU32 3QG
United Kingdom

Manufacturer

Rafarm S.A.
Agiou Louka
Paiania
Attiki
TK19002
Greece

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Carrying a steroid card

If your doctor asks you to carry a steroid card, be sure to keep it with you always.

Show it to any doctor, dentist, nurse or midwife or anyone else who is giving you treatment. Even after your treatment has finished tell any doctor, dentist, nurse, midwife or anyone else who is giving you treatment that you have had steroid treatment.

A steroid card may be obtained from your doctor, pharmacist or local Family Health Service Authority. In Scotland, steroid cards are available from the Scottish Office of Home and Health.

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