Package leaflet: Information for the user

Dexamethasone 2 mg, 4 mg and 8 mg soluble tablets

Dexamethasone

Important information about this medicine
- **Dexamethasone is a steroid medicine**, prescribed for many different conditions including serious illnesses
- **You need to take it regularly** to get the maximum benefit
- **Don't stop taking this medicine** without talking to your doctor – you may need to reduce the dose gradually
- **Dexamethasone 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 straight 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, shingles or measles**, 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**

Now read the rest of this leaflet. 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 side effects not listed in this leaflet.

What is in this leaflet:

1. What Dexamethasone soluble tablets 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 soluble tablets are and what they are used for

Dexamethasone soluble tablets contain the active substance dexamethasone. Dexamethasone belongs to a group of medicines called steroids (the full name is 'corticosteroids'). Corticosteroids occur naturally in the body, and help to maintain health and well-being.

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

Dexamethasone is a synthetic glucocorticoid (adrenocortical hormone).

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

Dexamethasone soluble tablets are used for one of the following:
- where your natural corticosteroid levels have been reduced and you need to replace them
- where swelling of the brain has occurred
- if you are having tests for diseases which may decrease your natural corticosteroid level, such as Cushing's syndrome (a hormonal disorder)
- to reduce inflammation and suppress the immune system in:
  - allergy (hypersensitivity)
  - polymyalgia rheumatica (chronic inflammation of the larger arteries), polyarteritis nodosa (chronic inflammation of small and medium arteries)
  - blood disorders including haemolytic anaemia (disorder which breaks down red blood cells), leukaemia (cancer of the blood), myeloma (bone marrow tumour)
  - Crohn's disease, ulcerative colitis (inflammation of the bowel), hepatitis
  - polymyositis (inflammation of muscles)
  - increased pressure in the head not linked to tumours, worsening of multiple sclerosis
  - inflammation of the eye
  - inflammation of the kidney
  - breathing problems including chronic bronchial asthma and chronic obstructive pulmonary disease (COPD) which may show as shortness of breath during exercise, difficulty breathing in and out deeply, persistent cough and croup. (Disorders where there is inflammation of the lung).
  - rheumatoid arthritis (painful joint disease), rheumatism, inflammation of a wide area of the body
  - chronic and severe diseases of the skin (including Stevens-Johnson syndrome and a rare condition known as mycosis fungoides)
  - leukaemia of the lymphatic system, Hodgkin's and Non-Hodgkin's lymphoma, breast cancer that has spread around the body, Kahler's disease (cancer of blood cells) and high calcium levels caused by this disease
  - after organ transplants and to prevent nausea and vomiting following chemotherapy

Dexamethasone is used as a 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.

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 Dexamethasone soluble tablets:
- if you are **allergic** (hypersensitive) to dexamethasone or any of the other ingredients of Dexamethasone soluble tablets (listed in section 6) or you have ever had an unusual reaction to these substances. The signs of an allergic reaction include a rash, itching or shortness of breath.
- 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 have an infection with **worms** after travelling to a tropical area
- to treat a serious lung disease called Acute Respiratory Distress Syndrome if you have had this problem for more than 2 weeks.

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Dexamethasone soluble tablets.

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

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

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

Talk to your doctor or pharmacist before taking Dexamethasone soluble tablets:
- 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 tumor of the adrenal glands).

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

Mental health problems while taking Dexamethasone soluble tablets
Mental health problems can happen while taking steroids like Dexamethasone (see also section 4).
- 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**
- you have **high blood pressure, heart disease** or you have recently had a **heart attack**
- 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 in the past
- you have **glaucoma** (raised eye pressure) or there is a family history of glaucoma
- you have myasthenia gravis. The sign of this may be long term **tiredness (fatigue)** and **muscle weakness**
- 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 **mental** problems or you have had a mental illness which was made worse by this type of medicine such as "steroid psychosis"
- you have **epilepsy** (condition where you have repeated fits or convulsions)
- you have **migraines**
- had an **allergy** or unusual reaction to corticosteroids
- 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)
- you have **asthma**
- you have **stunted** growth
- symptoms of tumour lysis syndrome such as muscle cramping, muscle weakness, confusion, visual loss or disturbances or shortness of breath, in case you suffer from haematological malignancy

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 dentists) or you require a vaccination (particularly with 'live virus' vaccines) whilst taking or when you have finished taking Dexamethasone soluble tablets, 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 soluble tablets:
  - 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.
- **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.

Children
If a child is taking this medicine, it is important that the doctor monitors their growth and development regularly.
Dexamethasone soluble tablets should not be routinely given to premature babies with respiratory problems.

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).

Taking other medicines and Dexamethasone soluble tablets
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).

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In particular, tell your doctor if you are taking any of the following:
- medicines to treat **heart** and **blood problems**, such as warfarin, high blood pressure medicines, such as captopril or verapamil, a cholesterol lowering medicine called colestyramine and water tablets (diuretics)
- medicines to treat **infections**, such as amphotericin B iv injection, rifabutin, rifampicin, a medicine for fungal infections called ketoconazole, antibiotics including erythromycin, a medicine for worm infections called praziquantel and a medicine for tuberculosis called isoniazid
- medicines that control pain or lower inflammation, such as **aspirin** or similar non-steroidal anti-inflammatory drugs (NSAIDs), such as indometacin, **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
- rifabutin, rifampicin (**antibiotics** used to treat tuberculosis)
- medicines to treat stomach problem, such as **antacids,** charcoal and carbenoloxone. You should leave at least two hours between taking these medicines and dexamethasone
- **anti-cancer** treatments, such as aminoglutethimide and thalidomide, also used for leprosycarbenoxolone (used in the treatment of **stomach ulcers**)
- ephedrine which helps to tighten **blood vessels**
- medicines to treat epilepsy, such as phenytoin, carbamazepine, primidone, phenobarbital and acetazolamide, also use for glaucoma
- medicines for **HIV**: ritonavir, indinavir or saquinavir
- oestrogen and progestogen including the **contraceptive pill**
- tetracosactide (used in the test for adrenocortical function)
- medicines that **calm emotions** or for sleeping, such as barbiturates or sulpiride
- **ciclosporin** used to stop the rejection of organs after transplants
- **live vaccines** such as MMR, tuberculosis, yellow fever or oral typhoid
- medicines that help muscle movement in **myasthenia gravis**, such as neostigmine.
- **methotrexate** used for cancer or inflammatory problems
- medicines used to lower potassium levels

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

Pregnancy, breast-feeding and fertility
Ask your doctor or pharmacist for advice if you are pregnant, planning to get pregnant or breast-feeding.

There is not enough information on the use of dexamethasone during pregnancy to know the possible side effects. For this reason, the use of Dexamethasone soluble tablets **during pregnancy** is not recommended unless advised to you by your doctor.

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 Dexamethasone.

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 Dexamethasone soluble tablets
Dexamethasone soluble tablets 2 mg contains 14.96 mg of sodium per tablet, this is less than 1mmol sodium (23 mg) per 2 mg tablet, that is to say essentially 'sodium-free'. This should be taken into consideration by patients on controlled sodium diet.

Dexamethasone soluble tablets 4 mg contains 29.95 mg of sodium per tablet (main component of cooking/table salt). This is equivalent to 1.5% of the recommended maximum daily intake of sodium for an adult. This should be taken into consideration by patients on controlled sodium diet.

Dexamethasone soluble tablets 8 mg contains 60.5 mg of sodium per tablet (main component of cooking/table salt). This is equivalent to 3% of the recommended maximum daily intake of sodium for an adult. This should be taken into consideration by patients on a controlled sodium diet.

Dexamethasone contains Yellow Sunset (E110). This colouring agent may cause allergic reactions.

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.

Take Dexamethasone 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.

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.

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

The recommended dose is:

Adults:
The usual dose of Dexamethasone is 0.5 mg to 10 mg each day. If your doctor wishes you to take less than 2 mg per day, you will be prescribed a different dexamethasone product.

Children: a single dose on alternate days.

If Dexamethasone soluble tablets are being given to you as part of some hospital tests, the dose given will be 2 mg, for a short period of time.

Croup: Children: 0.15mg/kg-0.6 mg/kg in a single dose.

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

Important: 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 Dexamethasone soluble tablets than you should
If you take too much medicine contact a doctor or hospital straight away. Take the medicine pack with you so the doctor knows what you have taken. The following effects may happen:
- Swelling of the throat
- Skin reaction
- Difficulty breathing

If you forget to take Dexamethasone soluble tablets
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 Dexamethasone soluble tablets
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 people taking medicines like dexamethasone. These problems include:
- feeling depressed, including thinking about suicide
- feeling high (mania), very happy (euphoria) 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 or believing in things that are not real (delusions). Having strange and frightening thoughts, changing how you act or having feelings of being alone
- schizophrenia
- inability to sleep

If you notice any of these problems, **talk to a doctor straight away.**

Talk to your doctor immediately or go to hospital straight away if you experience any of the following side effects as they are signs of an allergic reaction:
- any kind of skin rash, flaking skin, boils or sore lips and mouth
- sudden wheezing, fluttering or tightness of the chest or collapse.
- puffy, swollen face, tongue or body, which may cause shortness of breath, shock and collapse.

If you get any of the following side effects, stop taking Dexamethasone soluble tablets and see your doctor as soon as possible.

Other side effects may include:
- **stomach and gut problems:** inflamed food pipe (oesophagus), ulcers in the food pipe or gut that may split and bleed, feeling sick (nausea) or being sick (vomiting), stomach ache or a swollen stomach, having more of an appetite than usual, hiccups, diarrhoea, tearing of the bowel, particularly if you have inflammatory bowel disease
- **inflamed pancreas:** this may cause severe pain in the back or tummy
- **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), rhythm disorder, loss of protein and calcium balance, unmask diabetes symptoms, increased cholesterol levels and triglycerides in the blood (hypercholesterolemia and hypertriglyceridaemia)
- **heart and blood problems:** heart failure in people who are likely to have heart problems, high blood pressure, blood clots (signs of this may include redness, pain or numbness, throbbing, a burning feeling or swelling). Raised or lowered levels of red and white blood cells in your body. Some types of blood tests will show this affecting you. Problems with the muscles in your heart after a recent heart attack
- **bone problems:** thinning of the bones with more risk of fractures, also hip, arm and leg bone problems, ruptured tendons, muscle wasting, myopathy, muscle weakness, early stoppage of bone growth (premature epiphyseal closure).
- **recurring infections:** that get worse each time. This may be a sign that your immune system is low. Recurrence of TB (tuberculosis) if you have already had it before. You may also get thrush
- **skin problems:** wounds that heal more slowly, thinned, delicate skin, unusual purple spots on the skin or bruising, redness and inflammation of the skin, weaker reaction to skin tests, stretch marks, acne, sweating more than usual, skin rash or swollen small veins under the skin, thinning of hair, excessive hair growth, pigment disorders, weakened capillaries that rupture easily, observed as bleeding under the skin (increased capillary fragility), skin irritation around mouth (perioral dermatitis)
- **eye problems:** cataracts, increased pressure in the eye, swelling of the eye including glaucoma, swelling inside the eye, blurred vision, thinning of the eyeball, bacterial infections, worsening of symptoms associated with corneal ulcers, eye infections that you may already have can become worse, bulging of the eye balls. Frequency rare: blurred vision. Frequency not known: visual disturbances, loss of vision
- **reproductive system problems**: impotence
- **hormonal problems:** impairment of the body's regulation of hormones growth of extra body hair (particularly in women), irregular or missing periods, changes in the levels of protein and calcium in your body (which could be detected by a blood test), stunted growth in children and teenagers, swelling and weight gain of the body and face (called Cushingoid state). Dexamethasone soluble tablets may affect your diabetes and you may notice you start needing higher doses of the medicine you take for diabetes. While taking Dexamethasone soluble tablets your body may not be able to respond normally to sever stress such as accidents, surgery, childbirth or illness
- **nervous system problems:** fits and worsening of epilepsy, dizziness, headache with visual disturbances linked with withdrawal of treatment
- **other side effects:** While taking Dexamethasone your body may not be able to respond normally to severe stress such as accidents, surgery or illness, withdrawal effects (fever, muscle and joint pain, inflammation of the eye or nose, itchy skin and weight loss, inflammation of the eye (conjunctivitis). It may make you feel generally unwell. If you are a man, this medicine can affect the amount of sperm and their movement.

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 package in order to protect from moisture.

Do not use this medicine after the expiry date printed on the bottle label and carton after EXP. The expiry date means 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 Dexamethasone soluble tablets contain
The active substance is dexamethasone.

Each 2 mg tablet contains 2 mg of dexamethasone (as dexamethasone sodium phosphate).
Each 4 mg tablet contains 4 mg of dexamethasone (as dexamethasone sodium phosphate).
Each 8 mg tablet contains 8 mg of dexamethasone (as dexamethasone sodium phosphate).

The other ingredients are: sodium bicarbonate, disodium citrate 1.5 hydrate, povidone K 30, sodium saccharin, sodium benzoate, yellow sunset (E110).

What Dexamethasone soluble tablets look like and contents of the pack
Dexamethasone 2 mg soluble tablets are salmon, oblong tablets
Dexamethasone 4 mg soluble tablets are salmon, biconvex, round tablets
Dexamethasone 8 mg soluble tablets are salmon, biconvex, engraved '8', round tablets

Dexamethasone soluble tablets are available in blisters containing 10, 30, 50 or 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
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PRODUCT :	Colours:	Fonts: (Artwork)	Approval :
Dexamethasone 2 mg, 4 mg and 8 mg soluble tablets ALL UK	Cutter Guide Black	Times New Roman ALL 9 pts body copy (min)	**Internal proof approval** **Signed (digitally)** **External proof approval** **Signed (digitally)**

Job No:

Date:

Component: Leaflet (PIL)

Dimensions: 330x350 mm

Spellcheck: Y