Patient Information Leaflet

Dexsol® 2mg/5ml Oral Solution
Dexamethasone

Important information about this medicine

- **Dexsol 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
- **Dexsol 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, in the UK, you will get a blue '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.**

Now read the rest of the leaflet. It includes other important information on the safe and effective use of this medicine that might be especially important for you.
This leaflet was last updated on 08/2025.

- Read all of this leaflet carefully before you start taking this medicine.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or your pharmacist.
- This medicine has been prescribed only for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of these side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

What is in this leaflet:

1. What Dexsol is and what it is used for
2. What you need to know before you take Dexsol
3. How to take Dexsol
4. Possible side effects
5. How to store Dexsol
6. Contents of the pack and other information

1. What Dexsol is and what it is used for

The name of your medicine is Dexsol. It contains dexamethasone sodium phosphate. This belongs to a group of medicines called Corticosteroids. Dexamethasone is a synthetic glucocorticoid (adrenocortical hormone).

Corticosteroids are hormones that are found naturally in your body that help to keep you healthy and well. Boosting your body with extra corticosteroid, such as Dexsol, is an effective way to treat various illnesses involving inflammation in the body. Dexsol lowers inflammation, which could otherwise go on making your condition worse. You must take this medicine regularly to get maximum benefit from it.

Dexsol 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.

Dexsol can be used for:
- replacing natural corticosteroids when levels have been reduced
- reducing swelling of the brain which is not caused by a head injury
- treating swelling (inflammation) and certain allergies
- treating cancer
- controlling how well your adrenal glands work. These are glands that are next to your kidneys
- croup in babies and children. This affects the windpipe and the two airways that branch off from it to the lungs. The top of the airway is slightly blocked causing a barking cough, hoarse voice, a harsh sound (known as 'stridor') and breathing difficulties.

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 Dexsol

Do not take Dexsol and tell your doctor if:
- you are allergic to dexamethasone or any of the other ingredients of this medicine (listed in Section 6). The signs of an allergic reaction include a rash, itching or shortness of breath
- you have an infection (including fungal infections) that affects the whole body, unless you are being treated for the infection
- you have an ulcer in your stomach (peptic ulcer) or digestive tract area (duodenal ulcer)
- you have an infection with tropical worms
- you have a parasitic infection
- you need to have a vaccination, particularly with "live virus" vaccines.

Do not take this medicine if any of the above apply to you, talk to your doctor or pharmacist before taking Dexsol.

Check with your doctor first:
- If you have ever had severe depression or manic depression (bipolar disorder). This includes having had depression before while taking steroid medicines like dexamethasone.
- If any of your close family has had these illnesses.

If either of these applies to you, **talk to a doctor before taking this medicine.**

Mental problems while taking Dexsol
Mental health problems can happen while taking steroids like Dexsol (see also section 4: Possible side effects).
- 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 problems. This is particularly important if you are depressed, or might be thinking about suicide. In a few cases, mental problems have happened when doses are being lowered or stopped.

Warnings and precautions

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 following symptoms: headaches, sweating, palpitations, and hypertension. Contact your doctor immediately if you experience these signs.

Talk to your doctor, pharmacist or nurse before taking Dexsol. This is particularly important if you have:
- kidney or liver problems
- high blood pressure, heart disease or you have recently had a heart attack
- diabetes or there is a family history of diabetes
- thinning of the bones (osteoporosis), particularly if you are a female who has been through the menopause
- had muscle weakness with this or other steroids in the past
- raised eye pressure (glaucoma) or there is a family history of glaucoma
- a condition causing muscle weakness (myasthenia gravis)
- a bowel problem or a stomach (peptic) ulcer
- disease of the muscles (glucocorticoid-induced myopathy)
- mental problems or you have had a mental illness which was made worse by this type of medicine such as “steroid psychosis”
- epilepsy
- migraines
- had an allergy or unusual reaction to corticosteroids
- an underactive thyroid gland
- an infection with parasites
- tuberculosis, septicaemia or a fungal infection in the eye

- malaria that affects the brain (cerebral malaria)
- herpes, including cold sores or genital herpes
- asthma
- you have stunted growth
- 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
- 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
- if you have or are suspected of having pheochromocytoma (a tumor of the adrenal glands).

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

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before using Dexsol.

More important information about taking this kind of medicine

- Taking this medicine can cause problems with your kidneys. This means that you must stop taking this medicine gradually if you have been taking it for a long time.
- Tell your doctor if you get ill, injured or have an operation while you are taking this medicine. This is because they may need to increase your dose during this time.
- If you develop an infection while you are taking this medicine, you should talk to your doctor.
- Please tell any doctor, dentist or person who may be giving you treatment that you are currently taking steroids or have taken them in the past.
- You should not stop taking any other steroid medications unless your doctor has instructed you to do.

If you are living in the UK, you should always carry a 'Steroid treatment' 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.

This medicine can cause children to grow more slowly since glucocorticoids may affect growth. Because of this, they should take the lowest possible dose for the shortest possible time. Children who use this medicine for any length of time should be carefully monitored by the doctor.

The common side effects of Dexamethasone may be associated with more serious consequences in old age especially thinning of the bones (osteoporosis), high blood pressure, low potassium levels in the blood (hypokalaemia), diabetes, susceptibility to infection and thinning of the skin. Extra supervision by your doctor is necessary.

Do not use Dexsol for the treatment of Acute Respiratory Distress Syndrome (ARDS; a serious lung disease) if you have been diagnosed with this condition for over 2 weeks.

Dexsol and viral infections:
While you are taking this kind of medicine, you should not come into contact with anyone who has chickenpox, shingles or measles. This is because you may need specialist treatment if you get these diseases. If you think you may have had exposure to any of these diseases, you should talk to your doctor **immediately**. You should also tell your doctor if you have ever had infectious diseases such as measles or chickenpox and if you have had any vaccinations for these conditions in the past.

Please tell a doctor or anyone giving you treatment, such as at a hospital, if:
- you have an accident
- you are ill
- you need any surgery. This includes any surgery you may have at your dentist's
- you need to have a vaccination, particularly with 'live virus' vaccines such as MMR, tuberculosis, yellow fever or oral typhoid.

If any of the above applies to you, you should tell your doctor or the person treating you even if you have stopped taking this medicine.
If you have suppression tests or tests for infection, you should tell the person giving you the test that you are taking this medicine as it may interfere with the results of the test.
If a child is taking this medicine, it is important that the doctor monitors their growth and development regularly since glucocorticoids may affect growth. Dexamethasone should not be routinely given to premature babies with respiratory problems.

Other medicines and Dexsol
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 Dexsol can affect the way some other medicines work. Also, some medicines can affect the way Dexsol works.
Some medicines may increase the effects of Dexsol 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:
- medicines to treat heart and blood problems, such as warfarin, high blood pressure medicines, 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 to treat epilepsy, such as phenytoin, carbamazepine, primidone, phenobarbital and acetazolamide, also used for glaucoma
- medicines to treat stomach problems, such as antacids, charcoal and carbenoxolone. You should leave at least two hours between taking these medicines and Dexsol
- medicines that calm emotions or for sleeping, such as barbiturates or sulpiride

- medicines that control pain or lower inflammation, such as aspirin or similar non-steroidal anti-inflammatories (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 Dexsol 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 lower potassium levels
- medicines that help muscle movement in myasthenia gravis, such as neostigmine
- ritonavir, used to treat HIV
- oestrogen tablets including the contraceptive pill
- ciclosporin used to stop the rejection of organs after transplants
- anti-cancer treatments, such as aminoglutethimide and thalidomide, also used for leprosy
- ephedrine which helps to tighten blood vessels
- tetracosactide
- methotrexate
- medicines to treat viral infections such as indinavir and saquinavir
- live vaccines such as MMR, tuberculosis, yellow fever or oral typhoid.

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

Pregnancy and breast-feeding
Talk to your doctor before taking this medicine if you are pregnant, planning to become pregnant or are breast-feeding.

Driving and using machines
You may experience dizziness when taking this medicine (see section 4: possible side effects). Glucocorticoids may cause mood changes or visual disturbances. This may affect your ability to drive. If this happens, do not drive or use tools or machinery.

Dexsol contains sorbitol, liquid maltitol, propylene glycol and benzoic acid
Dexsol contains:

- Sorbitol (E420). This medicine contains 490mg sorbitol in each 5ml dose. Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine.
- Liquid maltitol (E965). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
- Propylene glycol (E1520). This medicine contains 450.6mg propylene glycol in each 5ml dose. If your child is less than 5 years old, talk to your doctor or pharmacist before giving them this medicine, in particular if they use other medicines that contain propylene glycol or alcohol.

- Benzoic acid (E210). This medicine contains 5mg in each 5ml dose. Benzoic acid may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).
- This medicine contains less than 1mmol sodium (23mg) per 5ml dose, that is to say essentially 'sodium-free'.

3. How to take Dexsol

Take Dexsol 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.

Taking this medicine

- this medicine contains 2mg of dexamethasone in each 5ml
- take this medicine by mouth. Some people may be given a dexamethasone injection at the same time
- you may also find that your doctor will tell you to lower the amount of salt in your diet
- you may also need to take potassium supplements whilst taking this medicine. Your prescriber will advise you if this is necessary since patients should not routinely be taking potassium without medical supervision
- if your daily dose is very small, ask your pharmacist for a device to help you measure these amounts, such as an oral syringe.

Administration using NG or PEG tubes:

- This medicine can also be administered via nasogastric (NG) or percutaneous endoscopic gastrostomy (PEG) tubes. Ask your doctor, pharmacist or nurse for further information.
- For use with silicone, PVC and polyurethane NG or PEG tubes **only**.
- Instructions for use via NG or PEG tube:
    1. ensure the tube is clear before taking the medicine
    2. flush the enteral tube with water. A minimum volume of 5 ml is required.
    3. administer the medicine into the tube with a suitable measuring device, which will be provided by your doctor, pharmacist or nurse.
    4. flush the tube with water again, using a minimum volume of 5 ml.

Adults and older people:
The usual dose for adults and older people is:

- take 0.5mg to 9mg each day as a single dose preferably in the morning
- if you are going to take the medicine for a long time your doctor will give you a 'maintenance dose' of 1.5mg each day.

Children:
The usual dose for children is:

- take a single dose on alternate days (every other day).

Croup in babies and children:
Your doctor will work out the right dose in millilitres (mls) based on your child's weight. This is normally taken once, however sometimes your doctor will recommend that a second dose is also taken after 12 hours. Make sure you follow the doctors instructions.

Take Dexsol 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 take 6 mg (15ml) once a day for up to 10 days.

Use in adolescents

Paediatric patients (adolescents of 12 years of age or older with body weight at least 40kg) are recommended take 6 mg (15ml) once a day for up to 10 days.

If you are taking this medicine as part of hospital tests:
- take 500 micrograms to 2mg for each dose
- you will have this medicine for a short period of time.

If you take more Dexsol than you should
If you take more of this medicine than you should, talk to a doctor or go to a hospital straight away. Take the medicine pack with you so the doctor knows what you have taken.

If you forget to take Dexsol
- If you forget a dose, take it as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose
- Do not take a double dose (two doses at the same time) to make up for a forgotten dose.

If you stop taking Dexsol
- It can be dangerous to stop taking this medicine suddenly. If you need to stop this treatment, follow your doctor's advice. He or she may tell you to lower the amount of medicine you are taking gradually until you stop taking it altogether.
- If you stop taking this medicine too quickly, you may have low blood pressure and, in some cases, your illness could come back.
- You may also feel a 'withdrawal symptom'. This may include fever, pain in your muscles and joints, swelling in the inside of your nose, weight loss, itchy skin and conjunctivitis.

Effects when treatment with Dexamethasone is stopped:
After therapy with Dexamethasone for a longer period, the dose should be gradually decreased in order to prevent a relapse of your disease and to allow your adrenal gland to recover its normal function. The doctor will give you advice on how to do this.

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

Steroids including dexamethasone can cause serious mental health problems.
These are common in both adults and children. They can affect about 5 in every 100 people taking medicines like dexamethasone. These 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 becoming worse.

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

If you have an allergic reaction to Dexsol stop taking and seek medical help immediately.

An allergic reaction may include:

- any kind of skin rash, flaking skin, boils or sore lips and mouth
- sudden wheezing, fluttering or tightness of the chest or collapse
- swelling of the face, lips, tongue and/or throat with difficulty in swallowing or breathing (angioedema).

If you get any of the following side effects, stop taking Dexsol and see your doctor as soon as possible:

- **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
- **Problems with salts in your blood** such as too much sodium or low potassium or calcium. You may have water retention
- **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), problems with the muscles in your heart after a recent heart attack. There could also be a large rise in the number of white cells in your body. Some types of blood tests will show this affecting you
- **Bone problems:** thinning of the bones with more of a risk of fractures, also hip, arm and leg bone problems, ruptured tendons, muscle wasting and muscle weakness

- **Recurring infections or mild infections** getting worse e.g. chickenpox; being less protected after inoculation; having a decreased response to skin test; recurrence of dormant tuberculosis (TB). 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
- **Eye problems:** cataracts, increased pressure in the eye including glaucoma swelling inside the eye, blurred vision, thinning of the covering of the eyeball, eye infections that you may already have can become worse, bulging of the eyeballs. Frequency rare: blurred vision. Frequency not known: visual disturbances, loss of vision.
- **Hormone problems:** growth of extra body hair (particularly in women), weight gain, irregular or missing periods, changes in the levels of protein and calcium in your body (which would be detected by a blood test), stunted growth in children and teenagers and swelling and weight gain of the body and face (called 'Cushingoid state')
  Dexsol may affect your diabetes and you may notice you start needing higher doses of the medicine you take for diabetes. While taking dexamethasone your body may not be able to respond normally to severe stress such as accidents, surgery or illness
- **Nervous system problems:** fits or epilepsy may become worse, feeling dizzy, headache, severe unusual headache with visual problems usually in children (normally after treatment has been stopped), a feeling that you are addicted to the medicine, being unable to sleep, feeling depressed, extreme mood swings
- **Other side effects:** 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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard
or search for MHRA Yellow Card in the Google Play or Apple App Store

5. How to store Dexsol

- Keep this medicine out of the sight and reach of children
- Do not use after the expiry date which is stated on the label and carton (Exp: month, year)
- The expiry date refers to the last day of that month
- Do not store above 25°C. Store in the original package in order to protect from light.

- Use within 3 months of opening
- Do not use Dexsol if you notice a change in the appearance or smell of the medicine. Talk to your pharmacist
- 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 to protect the environment.

6. Contents of the pack and other information

What Dexsol contains

- The active substance is Dexamethasone Sodium Phosphate. Each 5ml contains 2mg dexamethasone (as dexamethasone sodium phosphate).
- The other ingredients are benzoic acid (E210), propylene glycol (E1520), citric acid monohydrate (E330), liquid maltitol (E965), garden mint flavour (containing isopropanol and propylene glycol), sorbitol, liquid (non-crystallising) (E420), sodium citrate (E331) and purified water.

What Dexsol looks like and contents of the pack

A colourless to faint yellow liquid with an odour of mint.
It comes in a brown glass bottle holding 75ml or 150ml of solution.

Marketing Authorisation Holder and Manufacturer

Rosemont Pharmaceuticals Ltd, Yorkdale Industrial Park, Braithwaite Street, Leeds, LS11 9XE, UK.

This leaflet was last revised in August 2025