

Package leaflet: Information for the user

Dexliq 4 mg/ml Oral Solution

Dexamethasone

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

1. What Dexliq is and what it is used for

Dexliq contains 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.

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

2. What you need to know before you take Dexliq

Do not take Dexliq

- if you are allergic (hypersensitive) to dexamethasone or any of the other ingredients of Dexliq (listed in section 6) or you have ever had an unusual reaction to these substances
- if you have an infection that affects the whole body (unless you are receiving treatment)
- if you have a fungal infection that affects the whole body
- if you have a stomach or duodenal ulcer
- if you have an infection with worms after travelling to a tropical area

Warnings and precautions

Talk to your doctor or pharmacist before taking Dexliq 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.
- **any of your close family** has had these illnesses.

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 kidney or liver problems (liver cirrhosis or chronic liver failure),
- you have a tumour of the adrenal gland (pheochromocytoma),
- 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 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, 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 or a stomach (peptic) ulcer,
- you have psychiatric problems or you have had a psychiatric illness which was made worse by this type of medicine,
- you have epilepsy (condition where you have repeated fits or convulsions),
- you have migraine,
- you have an underactive thyroid gland,
- you have a parasitic infection,
- you have tuberculosis, septicaemia or a fungal infection in the eye,
- 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 are treated for a blockage of blood vessels by blood clots (thromboembolism),
- you have corneal ulcerations and corneal injuries.

Treatment with corticosteroid may reduce your body's ability to fight infection. This can sometimes lead to infections caused by germs that rarely cause infection under normal circumstances (called opportunistic infections). If you get an infection of any kind during treatment with this medicine, contact your doctor immediately. This is particularly important if you notice signs of pneumonia: cough, fever, shortness of breath and chest pain. You may also feel confused, particularly if you are elderly. You should also tell your doctor if you have had tuberculosis or if you have stayed in regions where roundworm infections are common.

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 of any vaccinations.

Treatment with this medicine may cause central serous chorioretinopathy, an eye disease that leads to blurred or distorted vision. This happens usually in one of the eyes. If you notice blurring or distorted vision that lasts for several days, please contact your doctor.

Treatment with this medicine may cause tendon inflammation. In extremely rare cases, a tendon may rupture. This risk is increased by treatment with certain antibiotics and by kidney problems. Contact your doctor if you notice painful, stiff or swollen joints or tendons.

Treatment with dexamethasone can cause a condition called adrenocortical insufficiency. This can cause change in effectiveness of the medicine following stress and trauma, surgery, childbirth or illness and your body may not be able to respond in the usual way to severe stress such as accidents, surgery, childbirth or illness.

If you have an accident, are ill, have other specific physical stress conditions, or require any surgery (even at the dentists) 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 suppression tests (test for the amount of hormone in the body), skin test for allergy or test for bacterial infection you should inform the person performing the test that you are taking dexamethasone as it may interfere with the results.

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 are elderly, some of the side effects of this medicine may be more serious, especially thinning of the bones (osteoporosis), high blood pressure, low potassium levels, diabetes, susceptibility to infection and thinning of the skin. Your doctor will monitor you more closely.

Other medicines and Dexliq

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

If you are taking any of the following medicines, you should consult your doctor before taking dexamethasone:

- anticoagulant medicines which thin the blood (e.g. warfarin, coumarin)
- aspirin or similar (non-steroidal anti-inflammatory drugs) e.g. indometacin
- medicines used to treat diabetes
- medicines used to treat high blood pressure
- diuretics (water tablets)
- amphotericin B injection
- phenytoin, carbamazepine, primidone (epilepsy medication)
- rifabutin, rifampicin, isoniazid (antibiotics used to treat tuberculosis)
- antacids – particularly those containing magnesium trisilicate – or charcoal
- barbiturates (medication used to aid sleep and relieve anxiety)
- aminoglutethimide (anti-cancer treatment)
- carbenoxolone (used in the treatment of stomach ulcers)
- ephedrine (nasal decongestant)
- acetazolamide (used for glaucoma and epilepsy)
- hydrocortisone, cortisone and other corticosteroids
- ketoconazole, itraconazole (for fungal infections)
- ritonavir (for HIV)
- antibiotics including erythromycin, fluoroquinolones
- medicines that help muscle movement in myasthenia gravis (e.g. neostigmine)
- colestyramine (for high cholesterol levels)
- estrogen hormones including the contraceptive pill
- tetracosactide (used in the test for adrenocortical function)
- sultopride (used to calm emotions)
- ciclosporin (used to prevent rejection after transplants)
- thalidomide
- praziquantel (given for certain worm infections)
- vaccination with live vaccines
- chloroquine, hydroxychloroquine and mefloquine (for malaria)
- somatotropin
- protirelin

You may be at an increased risk of serious side effects if you take dexamethasone together with these medicines:

- acetylsalicylic acid or similar (Non-Steroidal Anti-Inflammatory drugs) e.g. indometacin
- medicines used to treat diabetes
- medicines used to treat cardiac diseases
- diuretics (water tablets)
- amphotericin B injection
- acetazolamide (used for glaucoma and epilepsy)
- tetracosactide used in the test for adrenocortical function
- carbenoxolone (used in the treatment of stomach ulcers)
- chloroquine, hydroxychloroquine and mefloquine (for malaria)
- medicines used to treat high blood pressure
- thalidomide used for e.g. multiple myeloma
- vaccination with live vaccines
- medicines that help muscle movement in myasthenia gravis (e.g. neostigmine)
- antibiotics including fluoroquinolones

You must read the package leaflets 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 requirements is needed.

Dexamethasone with food, drink and alcohol

Dexamethasone should be taken with or after food to minimise irritation to the gastrointestinal tract. Drinks containing alcohol or caffeine should be avoided. Eating small, frequent meals is recommended, and possibly taking of antacids, if recommended by your doctor.

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.

Dexliq 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. A risk to the newborns/infants cannot be excluded. A decision on whether to continue/discontinue breast feeding or to continue/discontinue therapy with dexamethasone should be made taking into account the benefit of breast feeding to the child and the benefit of dexamethasone therapy to the woman.

Driving and using machines

Do not drive, use any tools or machines or carry out any hazardous tasks if you experience side effects, such as confusion, hallucinations, dizziness, tiredness, sleepiness, fainting or blurred vision.

Dexliq contains liquid maltitol, sorbitol, ethanol and propylene glycol

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

This medicine contains small amounts of ethanol (alcohol), less than 100 mg per 10 mg dexamethasone.

This medicine contains 225 mg propylene glycol per 10 mg dexamethasone.

If your baby is less than 4 weeks old, talk to your doctor or pharmacist before giving them this medicine, in particular if the baby is given other medicines that contain propylene glycol or alcohol.

This medicine contains 245 mg sorbitol per 10 mg dexamethasone.

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.

3. How to take Dexliq

Dexliq is only to be taken by mouth. Your doctor will prescribe the most appropriate dose to treat your condition.

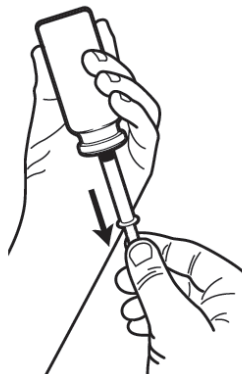
Always take this medicine exactly as your doctor has told you. These instructions will have been added to the dispensing label by your pharmacist. Check with your doctor or pharmacist if you are not sure.

Using the syringe

A 3 ml graduated syringe and a syringe/bottle adaptor is provided with your medicine. Use the syringe to withdraw, from the bottle, the amount of Dexliq that has been prescribed for you by your doctor.

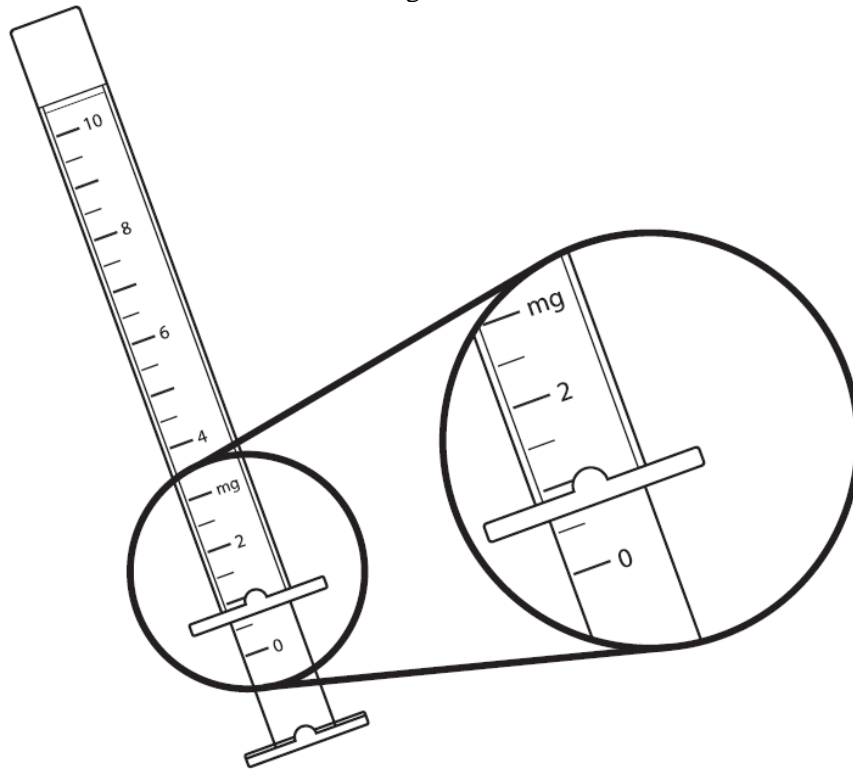
- Insert the bottle adaptor firmly into the neck of the bottle.
- Push the tip of the syringe into the hole in the top of the adaptor and ensure that it is secure.
- Hold the syringe in place and then turn the bottle upside down (refer to Figure 1).
- Still holding the syringe in place, pull the plunger down to the correct mark on the syringe (refer to Figure 1 and Figure 2).
- Turn the bottle the right way up.
- Remove the syringe, from the adaptor, by holding onto the bottle and gently twisting the syringe.
- After use replace the bottle cap and wash the syringe in warm water. Allow to dry.
- Do not remove the adaptor from the bottle.

Figure 1



Each graduation on the syringe provided is equivalent to 0.5 mg dexamethasone (refer to Figure 2).

Figure 2



Dexamethasone is given in usual doses of 0.5 to 9 mg, depending on the disease being treated. In more severe disease conditions doses above 9 mg may be required.

The dose you have to take is determined by your doctor, according to your weight and the disease to treat. This dose is strictly personal.

The duration and frequency of treatment is determined by your doctor.

It is very important to follow the instructions given by your doctor and/or pharmacist and not modify your treatment without asking your doctor. It is also very important not to stop suddenly your treatment without asking your doctor first.

Your doctor may change the dose and frequency of administration based on certain parameters including your blood analyses, your general condition, other medicines prescribed to you and your response to the treatment.

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 prescribed dose.

Do not take it more or less often than prescribed.

Use in children

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

If you take more Dexliq than you should

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

If you forget to take Dexliq

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 Dexliq

If your treatment is to be stopped follow your doctor's advice. He may tell you to reduce the amount of medicine you are taking gradually until you stop taking it altogether. 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.

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.

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) or moods that go up and down
 - feeling anxious, 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.
- have an allergic reaction to Dexliq. Talk to your doctor immediately or go to hospital straight away if you experience any of the following side effects:
 - red and lumpy skin rash
 - difficulty in breathing
 - swelling of the face, mouth, lips or eyelids
- 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.

Other side effects may include:

- mental health problems: a feeling of dependence, a severe headache with visual disturbances (linked to withdrawal of treatment), worsening of schizophrenia (where you may sense, see or hear things that do not exist, become withdrawn or have mistaken beliefs or suspicions)
- stomach and bowel problems: nausea, vomiting, hiccups, increased appetite, stomach discomfort, swollen abdomen, 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
- 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, increased need for diabetic medication, increased cholesterol levels
- heart and blood problems: blood clots, congestive heart failure in susceptible people, 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
- muscle, bone and skin problems: thinning of the bones with an increased risk of fractures, bone disease, ruptured tendons, muscle wasting, 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, impaired reaction to skin tests, skin rash, thinning of the hair

- immune system problems: thrush, greater chance of picking up infections, recurrence of tuberculosis 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
- reproductive system problems: irregular or lack of menstruation (periods), impotence
- 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)
- nervous system problems: fits and worsening of epilepsy, dizziness, headache
- other general effect: a change in the effectiveness of the medicine following stress and trauma, surgery or illness, withdrawal effects (fever, muscle and joint pain, inflammation of the eye or nose, itchy skin and weight loss)

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [the national reporting system listed in Appendix V](#).^{*} By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Dexliq

Keep this medicine out of the sight and reach of children.
Do not store above 30°C. Do not refrigerate.
Store in the original package in order to protect from light.

After first opening, use within 3 months.

Do not use this medicine after the expiry date printed on the bottle label 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 Dexliq contains

The active substance is dexamethasone.
Each ml of solution contains 4 mg of dexamethasone (as dexamethasone sodium phosphate).

The other ingredients are: Propylene glycol (E1520), Liquid maltitol (E965), Mint flavour (peppermint, spearmint, menthol, and ethanol), Liquid sorbitol (non-crystallising) (E420), Sodium citrate (E331), Disodium edetate, Sucralose, Sodium hydroxide, Purified water.

What Dexliq looks like and contents of the pack

Dexliq is a colourless to yellowish oral solution with a mint odour. It comes in an amber glass bottle, holding 30 or 50 ml of solution, with child resistant screw-cap. The pack also contains a 3 ml plastic oral dosing syringe and a bottle/syringe adaptor.

Marketing Authorisation Holder and Manufacturer

Marketing authorisation holder

Laboratoires CTRS
16 Rue Montrosier
92200 Neuilly-sur-Seine

France

Manufacturer

Rafarm S.A.

Thesi Pousi-Xatzi, Agiou Louka

Peania, Attiki, TK 19002

Greece

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

Denmark:	Dexliq 4 mg/ml oral opløsning
Finland:	Dexliq 4 mg/ml oraaliliuos
France:	Dexliq 4 mg/ml solution buvable
Iceland:	Dexliq 4 mg/ml mixtúra, lausn
Ireland:	Dexliq 4 mg/ml oral solution
Luxembourg:	Dexliq 4 mg/ml solution buvable
Norway:	Dexliq 4 mg/ml mikstur, oppløsning
Portugal:	Dexametasona Laboratoires CTRS 4 mg/ml solução oral
Slovakia:	Dexliq 4 mg/ml perorálny roztok

This leaflet was last revised in <{MM/YYYY}> <{month YYYY}>.