

PACKAGE INFORMATION LEAFLET

Dilacort 2.5mg and 5mg Gastro-Resistant Tablets (prednisolone)

Dilacort Gastro-Resistant Tablets Leaflet - Headlines

- **Dilacort Gastro-Resistant Tablets 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.
- **Dilacort Gastro-Resistant Tablets can cause side effects in some people** (Read Section 4). 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 tablets, **but see your doctor straight away**.
- **Some side effects only happen after weeks or months**. These include weakness of arms and legs, developing a rounder face (Read Section 4).
- **If you take it for more than 3 weeks, 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 this 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 revised in **April 2021**.

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 Dilacort Gastro-Resistant Tablets is and what it is used for
2. What you need to know before you take Dilacort Gastro-Resistant Tablets
3. How to take Dilacort Gastro-Resistant Tablets
4. Possible side effects
5. How to store Dilacort Gastro-Resistant Tablets
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1. What Dilacort Gastro-Resistant Tablets is and what it is used for

Dilacort Gastro-Resistant Tablets belongs to a group of medicines called steroids. Their full name is **corticosteroids**. These corticosteroids occur naturally in the body, and help to maintain health and well-being. Boosting your body with extra corticosteroid (such as Dilacort Gastro-Resistant Tablets) is an effective way to treat various illnesses involving inflammation in the body. Dilacort Gastro-Resistant Tablets reduces this inflammation, which could otherwise go on making your condition worse. You must take this medicine regularly to get maximum benefit from it.

Dilacort Gastro-Resistant Tablets is used in a wide range of inflammatory and auto-immune conditions including:

- allergies, including severe allergic reactions
- inflammation affecting the:
 - lungs, including asthma
 - blood vessels and heart
 - bowel or kidneys
 - muscles and joints, including rheumatoid arthritis
 - eye or nervous system
- skin conditions
- some infections
- some cancers, including leukaemia, lymphoma and myeloma
- to prevent organ rejection after a transplant.

Also:

- to boost steroid levels when the body is not making enough natural steroid on its own
- to treat high calcium levels.

2. What you need to know before you take Dilacort Gastro-Resistant Tablets

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 Dilacort Gastro-Resistant Tablets.
- **If any of your close family** has had these illnesses.

If either of these applies to you, **talk to a doctor before taking Dilacort Gastro-Resistant Tablets.**

Do not take Dilacort Gastro-Resistant Tablets if you:

- are allergic to prednisolone or any of the other ingredients in this medicine (listed in section 6)
- are suffering from a serious infection which is not being treated
- are suffering from a herpes infection of the eye.

Warnings and precautions

Before you take Dilacort Gastro-Resistant Tablets tell your doctor if you:

- suffer from or have ever been treated for tuberculosis (TB)
- have high blood pressure
- have a heart condition
- have liver or kidney problems
- suffer from diabetes or diabetes runs in your family
- have osteoporosis (thinning of the bone), particularly if you are past the menopause (the change of life)
- are going through, or are past the menopause
- suffer from epilepsy (fits)
- suffer from stomach ulcers
- have taken Dilacort Gastro-Resistant Tablets (or other steroids) before and had muscular problems (steroid myopathy)
- are receiving treatment for a condition called myasthenia gravis (a rare muscle weakness disorder)
- have ever had blood clots (for example, deep vein thrombosis [DVT], or thromboembolism)
- are planning to have a vaccination

- have Cushing's disease (A hormone disorder which can cause symptoms including gaining weight very quickly, especially on the trunk and face, thinning of the skin and sweating)
- suffer from hypothyroidism (an underactive thyroid gland which can cause tiredness or weight gain)
- have Duchenne's muscular dystrophy
- have inflammatory bowel disease such as Crohn's disease
- have an eye disease caused by fluid built-up at the back of the eye that causes visual impairment
- suffer or have suffered from any mental illness
- are undergoing immunosuppression therapy, for example in the treatment of cancer
- have scleroderma (also known as systemic sclerosis, an autoimmune disorder) because daily doses of 15 mg or more may increase the risk of a serious complication called scleroderma renal crisis. Signs of scleroderma renal crisis include increased blood pressure and decreased urine production. The doctor may advise that you have your blood pressure and urine regularly checked.

Children and adolescents

The use of steroids can slow down normal growth of children and adolescents. Your doctor may need to stop treatment or adjust the dose for your child accordingly.

If above applies to you, or if you are not sure, speak to your doctor or pharmacist before you take Dilacort Gastro-Resistant Tablets.

Other medicines and Dilacort Gastro-Resistant Tablets

Tell your doctor or pharmacist if you are taking or have recently taken or might take any of the following medicines as they may affect, or be affected by Dilacort Gastro-Resistant Tablets:

- antivirals such as ritonavir, which can be used to treat HIV infections
- antifungals such as ketoconazole and amphotericin which are used to treat fungal infections
- antibiotics such as erythromycin and rifamycin which are used to treat bacterial infections
- antiepileptic drugs such as carbamazepine, phenobarbital, phenytoin and primidone which are used to treat epilepsy
- oestrogens, for example, in the contraceptive pill or HRT
- thiazide diuretics ("water tablets") for example bendroflumethiazide used for water retention or high blood pressure
- drugs for diabetes including insulin
- ciclosporin which is used to treat rheumatic disease, skin complaints or after a transplant
- cardiac glycosides, for example digoxin, which is used to help strengthen a weak heart
- non-steroidal anti-inflammatory drugs (NSAIDs) for example aspirin, ibuprofen and indometacin used for pain relief or to treat rheumatic disease
- mifepristone, used to induce labour or abortion
- cytotoxic drugs for example methotrexate which is used to treat cancer
- medicines to treat high blood pressure
- vaccinations: You must tell your doctor or nurse that you are taking a steroid before you are given any vaccinations. Steroids affect your immune response and you must not be given any live vaccines
- anticoagulants for example warfarin which is used to thin the blood
- carbenoxolone which is used for ulcers
- salbutamol, formoterol, bambuterol, fenoterol, ritodrine, salmeterol and terbutaline used to treat asthma
- somatropin which is a growth hormone
- acetazolamide which is used in the treatment of glaucoma and epilepsy
- loop diuretics for example furosemide which is used to treat heart failure
- antimuscarinics/anticholinergics

- theophylline which is used for asthma and chronic obstructive pulmonary disease (COPD)
- immunosuppressants which dampen down the activity of the body's immune system
- antacids such as magnesium trisilicate or aluminium hydroxide, used to treat the symptoms of heartburn and indigestion
- antithyroids such as carbimazole
- isoniazid which is used to treat tuberculosis

Dilacort Gastro-Resistant Tablets with food and drink

Dilacort Gastro-Resistant Tablets should be swallowed with water. You can take the Dilacort Gastro-Resistant Tablets before or after a meal.

Avoid eating liquorice whilst taking Dilacort Gastro-Resistant Tablets.

Pregnancy and breast feeding

If you are pregnant or trying to become pregnant, you must tell your doctor before you start the treatment.

If you are breast-feeding you must tell your doctor before you start the treatment. Your doctor will want to examine your baby during your time of treatment. Small amounts of steroids are present in breast milk.

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

Driving and using machines

If you feel dizzy or tired after taking Dilacort Gastro-Resistant Tablets do not drive or operate machinery until these effects have worn off.

Dilacort Gastro-Resistant Tablets contain lactose, E110 and E124

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product as the tablets contain lactose.

Dilacort 5 mg Gastro-Resistant Tablets contains sunset yellow FCF (E110) and ponceau 4R red (E124). These may cause allergic reactions.

Important information on sodium content

This medicine contains less than 1 mmol sodium (23 mg) per dosage unit, that is to say essentially 'sodium-free'.

3. How to take Dilacort Gastro-Resistant Tablets

Always take Dilacort Gastro-Resistant Tablets exactly as your doctor has told you to. You should check with your doctor or pharmacist if you are not sure.

Different illnesses require different doses of Dilacort Gastro-Resistant Tablets. Depending on your illness your daily dose may be between 5 and 60 mg. In some cases you may be instructed to take it every other day. Your doctor will decide when and how to treat you with Dilacort Gastro-Resistant Tablets.

Once your condition starts to get better, your doctor may change your dosage to a lower one. Your doctor may also reduce your dosage before stopping treatment completely. This may depend on your illness, your dosage and how long you have been taking this medicine. In all cases you should be careful to follow any changes.

Stopping taking Dilacort Gastro-Resistant Tablets:

It is important to discuss your treatment with your doctor before stopping treatment. **Sudden stopping of treatment can cause the following symptoms:** fever, painful muscles and joints, inflammation of the eyes and nasal passages, painful and itchy skin lumps, loss of weight.

Use in children and adolescents:

The use of steroids can slow down normal growth of children and adolescents. In order to lessen this effect the tablets are often taken in a single dose every other day.

Elderly:

When steroids are taken by elderly patients some of the unwanted side effects can be more serious especially brittle bone disease, diabetes, high blood pressure, infections and thinning of the skin.

Whilst you are taking Dilacort Gastro-Resistant Tablets, if any of the following occur tell your doctor straight away:

- **Infections:** If you think you might have an infection. You are more likely to develop illnesses due to infection whilst you are taking Dilacort Gastro-Resistant Tablets. Also any existing infections may become worse. This is especially so during periods of stress. Certain infections can be serious if not controlled.
- **Chickenpox and Shingles:** If you, anyone in your family or regular contacts catches chickenpox or shingles. This is because you may become very ill if you get chicken pox or shingles whilst taking Dilacort Gastro-Resistant Tablets. You should avoid contact with people who have chicken pox or shingles whilst taking Dilacort Gastro-Resistant Tablets and for up to 3 months after you have stopped taking it. Do not stop taking Dilacort Gastro-Resistant Tablets.
- **Measles:** If you, anyone in your family or regular contacts catches measles. You should avoid contact with people who have measles.

Your doctor will give you a steroid treatment card. You must carry it with you at all times. You should show your steroid treatment card to anyone who is giving you treatment such as a doctor, nurse or dentist.

Mental problems while taking Dilacort Gastro-Resistant Tablets:

Mental health problems can happen while taking steroids like Dilacort Gastro-Resistant Tablets (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 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.

If you take more Dilacort Gastro-Resistant Tablets than you should:

If you accidentally take too many Dilacort Gastro-Resistant Tablets or someone else takes any of your medicine, you should tell your doctor at once or contact your nearest accident and emergency department. Show any left-over medicines or the empty packet to the doctor.

If you forget to take Dilacort Gastro-Resistant Tablets:

Do not worry. If you forget to take a dose, take it as soon as possible, unless it is almost time to take the next dose. Do not take a double dose. Then go on as before.

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

4. Possible side effects

Do not worry. Like all medicines, Dilacort Gastro-Resistant Tablets can cause side effects, although not everyone gets them.

Stop taking Dilacort Gastro-Resistant Tablets and contact your doctor straight away if the following allergic reaction occurs:

- Puffy, swollen face, tongue or body, which may cause shortness of breath, shock and collapse.

Serious effects: tell a doctor straight away

- inflammation of the pancreas (very severe abdominal pains)
- painful skin ulcers.

Steroids including prednisolone 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 prednisolone.

- 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 which do not exist. Having strange and frightening thoughts, changing how you act or having feelings of being alone.

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

Other side effects you may experience:

- tiredness
- increased number of white blood cells
- blood clotting
- nausea and vomiting
- heart problems which can cause shortness of breath
- convulsions
- dizziness
- vertigo
- headache
- raised pressure in the brain (which can cause headaches, nausea and vomiting)
- sleeplessness
- vision problems
- worsening of schizophrenia
- worsening of epilepsy
- risk of stroke is increased in Horton disease
- increased pressure in the eyeball (glaucoma)
- whitening or clouding of the lens (cataracts)
- pressure on the nerve to the eye, thinning of the tissues of the eye (sclera and cornea)
- bulging eyes
- thinning of the skin
- bruising
- stretch marks
- patches of skin reddening
- itching
- rash
- hives
- acne
- extra hair growth

- slow healing of wounds
- increased sweating
- hiding or altering reactions to skin tests such as for tuberculosis
- reduction of growth in babies, children and adolescents
- absence or irregularity of menstrual periods
- face becomes very round
- weight gain
- increased blood sugar
- carbohydrate imbalance in diabetes
- euphoria (feeling high)
- feeling of dependency on treatment
- depression
- general unwell feeling
- scleroderma renal crisis in patients already suffering from scleroderma (an autoimmune disorder). Signs of scleroderma renal crisis include increased blood pressure and decreased urine production.
- worsening of viral or fungal infections of the eye
- risk of contracting infection is increased
- existing infections can worsen
- signs of infection can be masked
- previous infections, such as tuberculosis (TB) may be re-activated (flare up)
- muscle wasting of the upper arms and legs
- muscle pain
- brittle bone disease or wasting of the bones
- bone fractures
- tendon rupture
- indigestion
- stomach ulcers with bleeding or perforation
- bloating
- ulcers in the gullet (oesophagus) which may cause discomfort on swallowing
- candidiasis (thrush)
- abdominal (stomach) pain
- increased appetite which may result in weight gain
- diarrhoea
- water and salt retention
- high blood pressure (hypertension)
- a change in the levels of some hormones, mineral balance or protein in blood tests
- Increased cholesterol or fat levels in blood
- Slow heart rate

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 Dilacort Gastro-Resistant Tablets

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

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

Store below 30 °C.

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

6. Contents of the pack and other information

What Dilacort Gastro-Resistant Tablets contains:

The active substance is prednisolone.

Each Dilacort 2.5 mg gastro-resistant tablet contains 2.5 mg of prednisolone.

Each Dilacort 5 mg gastro-resistant tablet contains 5 mg of prednisolone.

The other ingredients are lactose monohydrate, microcrystalline cellulose, pregelatinised maize starch, magnesium stearate, hypromellose, titanium dioxide (E171), triethyl citrate, sorbic acid, methacrylic acid - ethyl acrylate copolymer, talc, colloidal anhydrous silica, sodium bicarbonate, sodium lauryl sulfate, polyvinyl alcohol and macrogol 3350.

Dilacort 2.5 mg Gastro-Resistant Tablets also contains black iron oxide (E172), red iron oxide (E172) and yellow iron oxide (E172).

Dilacort 5 mg Gastro-Resistant Tablets also contains ponceau 4R red (E124), indigo carmine aluminium lake (E132) and sun set yellow FCF (E110).

What Dilacort Gastro-Resistant Tablets looks like and contents of the pack

Dilacort 2.5 mg Gastro-Resistant Tablets is dark brown, circular, deep biconvex, enteric coated tablets.

Dilacort 5 mg Gastro-Resistant Tablets is red, circular, deep biconvex, enteric coated tablets.

Dilacort Gastro-Resistant Tablets is available in blister packs of 28 tablets.

Marketing Authorisation Holder and Manufacturer:

Marketing Authorisation Holder

<to be completed nationally>

Manufacturer

Crescent Pharma Limited,
3&4 Quidhampton Business Units, Polhampton Lane,
Overton, Hampshire, RG25 3ED, UK

This medicinal product is authorised in the Member States of the European Economic Area (EEA) under the following names:

< {Name of Member State} > < {Name of medicinal product} >

< { Name of Member State} > < { Name of medicinal product} >

This leaflet was last revised in April 2021.

If you would like this leaflet in a different format, please contact the marketing authorisation holder at the above address.