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**PATIENT INFORMATION LEAFLET**

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**Deltacortril<sup>®</sup> gastro-resistant Tablets**  
prednisolone

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**Deltacortril Leaflet – Headlines**

- **Deltacortril 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.
- **Deltacortril can cause side effects in some people** (read Section 4 Possible Side Effects below). 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 Possible Side Effects for more information)
- **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 updated on 16<sup>th</sup> July 2009.**

**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 pharmacist.
- This medicine has been prescribed 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 the side effects gets serious, or if you notice any side effects not listed in this leaflet please tell your doctor or pharmacist.

The information in this leaflet has been divided into the following sections:

- 1. What Deltacortril is and what it is taken for**
- 2. Check before you take Deltacortril**
- 3. How to take Deltacortril**
- 4. Possible side effects**
- 5. How to store Deltacortril**
- 6. Further information**

## **1. What Deltacortril is and what it is taken for**

Deltacortril 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 Deltacortril) is an effective way to treat various illnesses involving inflammation in the body. Deltacortril reduces this inflammation, which could otherwise go on making your condition worse. You must take this medicine regularly to get maximum benefit from it.

Deltacortril 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. Check before you take Deltacortril

### 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 Deltacortril.
- **If any of your close family** has had these illnesses.

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

### Do not take Deltacortril if you:

- are allergic (hypersensitive) to prednisolone or any of the ingredients of Deltacortril (see Section 6 Further Information)
- are suffering from a serious infection which is not being treated
- are suffering from a herpes infection of the eye.

### Take special care with Deltacortril

Before you take Deltacortril 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)
- suffer from epilepsy (fits)
- suffer from stomach ulcers
- have taken Deltacortril (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.

If any of the above applies to you, or if you are not sure, speak to your doctor or pharmacist before you take Deltacortril.

## Taking other medicines

Tell your doctor or pharmacist if you are taking or have recently taken any of the following medicines as they may interfere with Deltacortril:

- antivirals such as ritonavir which can be used to treat HIV infection
- 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.
- antiarthritis drugs
- anticoagulants for example warfarin which is used to thin the blood
- oestrogens, for example in the contraceptive pill or HRT
- medicines to treat high blood pressure
- thiazide diuretics (“water tablets”) for example bendroflumethiazide used for water retention or high blood pressure
- carboxymethylcellulose sodium which is used for ulcers
- salbutamol, formoterol, bambuterol, fenoterol, ritodrine, salmeterol and terbutaline used to treat asthma
- 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
- 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.
- 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
- theophylline which is used for asthma and chronic obstructive pulmonary disease (COPD)

Please tell your doctor or pharmacist if you are taking or have recently taken/used any other medicines, including medicines obtained without a prescription.

### **Taking with food and drink**

Deltacortril should be swallowed with water. You can take Deltacortril before or after a meal.

### **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 Deltacortril do not drive or operate machinery until these effects have worn off.

### **Important information about some of the ingredients of Deltacortril**

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

## **3. How to take Deltacortril**

**Always take Deltacortril 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 Deltacortril. 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 Deltacortril.

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 Deltacortril:** 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.

**Treatment of children:** 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.

**Treatment of the 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 Deltacortril, 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 Deltacortril. 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 whilst taking Deltacortril. You should avoid contact with people who have chicken pox or shingles whilst taking Deltacortril and for up to 3 months after you have stopped taking Deltacortril. Do not stop taking Deltacortril.
- **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 Deltacortril**

Mental health problems can happen while taking steroids like Deltacortril (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.

### **What to do if you take more Deltacortril than you should**

If you accidentally take too many Deltacortril 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 Deltacortril**

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, Deltacortril can cause side effects, although not everyone gets them.

### **Serious effects: tell a doctor straight away**

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:

- allergic reaction
- tiredness
- increased number of white blood cells
- blood clotting
- nausea and vomiting
- high blood pressure
- heart problems which can cause shortness of breath
- convulsions
- dizziness
- headache
- raised pressure in the brain (which can cause headaches, nausea and vomiting)

- 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
- carbohydrate imbalance in diabetes

- euphoria (feeling high)
- feeling of dependency on treatment
- depression
- pressure on the nerve to the eye (sometimes in children after stopping treatment)
- worsening of schizophrenia
- worsening of epilepsy

- 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
- 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
- feeling sick
- 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

- water and salt retention
- high blood pressure (hypertension)
- a change in the levels of some hormones, mineral balance or protein in blood tests

weight gain

- diarrhoea
- inflammation of the pancreas.

If any of the side effects gets worse, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

## **5. How to store Deltacortril**

Keep out of the reach and sight of children.

Do not take Deltacortril after the expiry date which is stated on the packaging. The expiry date refers to the last day of that month.

Store below 25°C. Keep your medicine in a dry place.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist on how to dispose of medicines no longer required. These measures will help protect the environment.

## **6. Further information**

### **What is in Deltacortril?**

The active ingredient in this medicine is prednisolone.

The other ingredients are: calcium carbonate, lactose, magnesium stearate, maize starch, polyvinyl alcohol, titanium dioxide (E171), purified talc, lecithin, xanthan gum (E415), polyvinyl acetate phthalate, polyethylene glycol, sodium hydrogen carbonate, triethyl citrate, purified stearic acid, sodium alginate (E401), colloidal silicon dioxide, methylcellulose (E461), sodium carboxymethyl cellulose, beeswax (E901), carnauba wax (E903), polysorbate 20 (E432) and sorbic acid (E200).

The Deltacortril 5 mg tablet also contains carmine (E120) and indigo carmine aluminium lake (E132).

The Deltacortril 2.5 mg tablet contains iron oxide (E172).

### **What Deltacortril looks like and contents of the pack**

Deltacortril tablets come in two strengths.

Deltacortril 2.5 mg is a brown tablet.

Deltacortril 5 mg is a maroon tablet.

They are gastro-resistant tablets.

Deltacortril tablets come in packs of 30 or 100 tablets.

**Marketing Authorisation Holder and Manufacturer**

The product licence holder is: Alliance Pharmaceuticals Ltd, Avonbridge House, Chippenham, Wiltshire, SN15 2BB, UK.

Deltacortril is manufactured by: Recipharm Stockholm AB, Lagervägen 7, SE-136 50 Haninge, Sweden.

The information in this leaflet applies only to Deltacortril. If you have any questions or you are not sure about anything, ask your doctor or a pharmacist.

**This leaflet was last approved:** 16th July 2009

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