

PATIENT INFORMATION LEAFLET

Deltacortril® Enteric 2.5mg Gastro-Resistant Tablets **Deltacortril® Enteric 5mg Gastro-Resistant Tablets**

Active Ingredient: Prednisolone

- **Deltacortril Enteric 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 Enteric 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 tablets, but **see your doctor straight away**.
- **Some side effects only happen after weeks or months**. These include weakness of the arms and legs, or 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 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.

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.

In this leaflet:

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

1. What Deltacortril Enteric is and what it is taken for

Deltacortril Enteric 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 Enteric) is an effective way to treat various illnesses involving inflammation in the body. Deltacortril Enteric **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 Enteric is used in the treatment of allergic and inflammatory diseases and immune reactions. The treatment provides relief for inflamed areas of the body and lessens swelling, redness, itching and allergic reactions. Deltacortril Enteric is included as part of the overall treatment of certain cancers which include: leukaemia (acute and lymphatic) malignant lymphoma and multiple myeloma. Deltacortril Enteric is also used to make up the difference when the body's production of cortisone is too low to maintain good health.

2. Before you take Deltacortril Enteric

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

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

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.

Do not take Deltacortril Enteric if you:

- **are suffering from an untreated widespread (systemic) infection.**
- **are allergic to prednisolone or any of the other ingredients of Deltacortril Enteric**
- **are suffering from herpes infection of the eye.**

Take special care with Deltacortril Enteric

Before you take Deltacortril Enteric tell your doctor if any of the following applies to you:

- Have you taken Deltacortril Enteric (or similar medicine) before and had muscular problems (steroid myopathy)?
- Do you suffer from any heart condition or high blood pressure?
- Do you suffer from kidney problems?
- Do you suffer from liver problems?
- Do you suffer from stomach ulcers?
- Do you suffer from glaucoma or does glaucoma run in your family?
- Do you suffer from diabetes or does diabetes run in your family?
- Do you suffer from thyroid problems?
- Do you suffer from epilepsy (fits)?
- Are you suffering from, or have you been treated for tuberculosis (TB)?
- Are you past the menopause (the change of life) and suffering from osteoporosis (thinning of the bones)?
- Have you suffered from severe affective disorders (mania or depression)?
- Have you taken Deltacortril Enteric coated tablets (or similar medicine) before and suffered from serious mental illness (psychoses)?
- Do you need to receive a vaccination? It is important that if you are to receive a vaccination that you tell your doctor or nurse that you are taking a steroid.
- Are you receiving treatment for a condition called myasthenia gravis?

- Do you have a disease which affects blood clotting, so that the blood clots too easily, (for example, thrombophlebitis, thromboembolism)?
- Do you have Cushing's disease?

If the answer to any of these questions is yes, tell your doctor before you start treatment. Your doctor may still want you to take the tablets.

Taking other medicines

If you are taking any other medicines it is important to tell your doctor before you start the treatment. Certain medicines may interfere with Deltacortril Enteric, so tell your doctor if you are taking or have recently taken any of the following medicines: antibiotics

(e.g. erythromycin), antifungal drugs

(e.g. amphotericin, ketoconazole),

antiviral drugs (e.g. ritonavir, cobicistat), antiepileptic drugs, antiarthritis drugs, analgesics (such as aspirin and ibuprofen), oestrogens, cardiac glycosides (e.g. digoxin), medicines to treat high blood pressure, diuretics, drugs used to treat myasthenia gravis and certain cancers, ciclosporin, somatropin (growth hormone), drugs used to treat asthma, anticoagulants and antidiabetic drugs including insulin and vaccines.

Pregnancy and breast-feeding

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

Important information about some of the ingredients (including lactose) in Deltacortril Enteric

This product 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. A complete list of the ingredients is included in Section 6 "Further Information" below.

3. How to take Deltacortril Enteric

The tablets should only be taken by mouth and can be swallowed with water. They can be taken before or after a meal.

Always take Deltacortril Enteric exactly as your doctor has told you. Treatment with Deltacortril Enteric coated tablets is tailored to each individual. It is important to follow your doctor's instructions.

Different illnesses require different dosages of Deltacortril Enteric tablets. Depending on your illness your daily dose may be between 5 and 60mg. In some cases you may be instructed to take it every other day.

When to stop taking your medicine. 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.

Tell your doctor straight away if any of the following occur:

Chickenpox and Shingles: If you or 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 Enteric. You should avoid contact with people who have chicken pox or shingles whilst taking Deltacortril Enteric and for up to 3 months after you have stopped taking Deltacortril Enteric. Do not

stop taking Deltacortril Enteric.

Measles: If you, anyone in your family or regular contacts catches measles. You should avoid contact with people who have measles.

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 effects can be more serious especially thinning of the bones, diabetes, high blood pressure, infections and thinning of the skin.

Make sure that you have been given a STEROID TREATMENT CARD by your doctor which you should always keep with you.

Mental problems while taking Deltacortril Enteric

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

If you take more Deltacortril Enteric than you should

Too many tablets can make you unwell. Contact your doctor or nearest hospital accident and emergency department.

If you forget to take Deltacortril Enteric

Take that tablet as soon as you realise and take the next dose at the correct time.

If you stop taking Deltacortril Enteric Withdrawal symptoms: Sudden stopping of treatment can cause the following withdrawal symptoms: fever, painful muscles and joints, inflammation of the eyes and nasal passages, painful and itchy skin lumps, loss of weight.

4. Possible side effects

Like all medicines, Deltacortril Enteric can cause side effects, although not everybody gets them.

Although there is a risk that you may experience one or more of the listed side-effects, your doctor will have chosen this treatment bearing in mind these risks and the risks to you from your illness. If you suffer from any of these or other undesirable effects they should be reported to your doctor or pharmacist.

Serious effects: tell a doctor straight away

Steroids including prednisolone can cause serious mental health problems. These are common (affecting about 5 in every 100) in both adults and children taking medicines like prednisolone. If you notice any of these problems, **talk to a doctor straight away.**

- 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 include:

- **Body as a whole:** Allergic reaction, tiredness, increased number of white blood cells, blood clotting, nausea and vomiting.
- **Heart and blood vessels:** High blood pressure, slow heart rate, heart failure in patients who have a risk.
- **Central and Peripheral Nervous system:** Convulsions, dizziness, headache, increased intracranial pressure usually after treatment.
- **Gastro-intestinal:** indigestion, stomach ulcers with bleeding or perforation, bloating, oesophageal (gullet) ulcers, or candidiasis (thrush) abdominal pain, increased appetite which may result in weight gain, diarrhoea, nausea and inflammation of the pancreas.
- **Musculo-skeletal:** muscle wasting of the upper arms and legs, muscle pain, thinning or wasting of the bones, bone fractures and tendon rupture.
- **Metabolic/ Nutritional:** water and salt retention, hypertension (high blood pressure), a change in the mineral balance in the blood.
- **Skin / Appendages:** reduction in healing, thinning of the skin, bruising, stretch marks, patches of reddening, itching, rash, hives and acne. Extra hair growth, impaired wound healing, thin fragile skin, bruising, increased sweating, may suppress reactions to skin tests
- **Hormone system and metabolism:** reduction in the balance between certain hormones, reduction of growth in babies, children and adolescents, absence or irregularity of menstrual periods, moon shaped face, extra hair growth, weight gain, carbohydrate imbalance in diabetes, increased appetite, reduction in protein and calcium in the blood.
- **Nervous disorders:** euphoria (feeling high). feeling of dependency on treatment, depression, sleeplessness, pressure on the nerve to the eye (sometimes in children after stopping treatment), worsening of schizophrenia, worsening of epilepsy.
- **Eyes:** 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), protruding eyes, worsening of viral or fungal infections of the eye, blurred or distorted vision, loss of vision.
- **Effects of infections:** risk of contracting infection is increased, existing infections can worsen, signs of infection can be masked, dormant infections (such as TB) can reappear.
- **Scleroderma:** 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.

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.

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 HPRC Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting

side effects you can help provide more information on the safety of this medicine.

5. How to store Deltacortril Enteric

Do not take this medicine after the expiry date stamped on the label and carton after 'EXP'. The expiry date refers to the last day of that month.

Keep out of the sight and reach of children. Do not store above 25°C.

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 Enteric?

The active ingredient in this medicine is prednisolone. Each Deltacortril Enteric 2.5mg tablet contains 2.5mg prednisolone and each Deltacortril Enteric 5mg tablet contains 5mg 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, lactose monohydrate, methylcellulose (E461), sodium carboxymethyl cellulose, beeswax (E901), carnauba wax (E903), polysorbate 20 (E432) and sorbic acid (E200).

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

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

What Deltacortril Enteric looks like and contents of the pack

Deltacortril Enteric coated tablets come in two strengths.

Deltacortril Enteric 2.5 mg is a brown tablet. Deltacortril Enteric 5 mg is a maroon tablet. They are gastro-resistant tablets.

Deltacortril Enteric tablets come in packs of 30 or 100 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer The Marketing Authorisation is held by Phoenix Labs, Suite 12, Bunkilla Plaza, Bracetown Business Park, Clonee, Co. Meath, Ireland.

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Deltacortril Enteric Manufacturer (EU QP Release Site):

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