

Cortancyl 20 mg

prednisone

Hoechst Marion Roussel

COMPOSITION

Prednisone 20 mg

Excipients : maize starch, lactose, talc, magnesium stearate q.s. 1 tablet.

PHARMACEUTICAL FORM AND CONTENTS

Scored tablets, box containing 20 tablets.

PHARMACOTHERAPEUTIC GROUP

GLUCOCORTICOSTEROIDS - SYSTEMIC USE (H: non sexual hormones)

MARKETING AUTHORIZATION HOLDER

Laboratoires Roussel Diamant

1, Terrasse Bellini 92910 Paris La Défense Cedex - France

MANUFACTURER

Usiphar 60200 Compiègne - France

WHEN THIS MEDICINE SHOULD BE USED

This medicine is a corticosteroid.

It is indicated in certain diseases for its anti-inflammatory effect.

WARNING !

WHEN SHOULD YOU NOT USE THIS MEDICINE

You SHOULD NOT USE this medicine :

- for most infections,
- for certain active viral diseases (viral hepatitis, herpes, chickenpox, herpes zoster),
- for certain untreated mental disorders,
- if you are being vaccinated with a live vaccine,
- if you are allergic to one of its ingredients.

Unless otherwise directed by your physician, you SHOULD GENERALLY NOT TAKE THIS MEDICINE along with medication which may cause certain types of heart rhythm disorders (see drug interactions and other interactions).

IF IN DOUBT, DO NOT HESITATE TO ASK YOUR PHYSICIAN OR PHARMACIST.

SPECIAL WARNINGS

Only take this medicine under medical supervision.

BEFORE TREATMENT :

Tell your physician if you were recently vaccinated, suffer from a gastrointestinal ulcer, disease of the colon, if you have recently undergone intestinal surgery, suffer from diabetes, systemic hypertension, an infection (in particular if you have had tuberculosis in the past), impaired liver function, impaired renal function, osteoporosis and myasthenia gravis (muscle disease with muscle weakness).

Inform your physician if you plan to travel to tropical or subtropical countries, or southern Europe, because there is a risk of parasitic disease.

DURING TREATMENT :

Avoid contact with anyone who has chickenpox or the measles.

If you have been receiving this medicine for some time, never stop it abruptly, but decrease the doses as indicated by your physician.

During treatment, and for one year following the end of treatment, tell your physician that you are or were receiving corticosteroid treatment if you must undergo surgery or if a stressful situation develops (fever, disease).

PRECAUTIONS FOR USE

Your physician may advise you to go on a diet, especially a salt-free diet, during treatment.

IF IN DOUBT, DO NOT HESITATE TO ASK YOUR PHYSICIAN OR PHARMACIST.

DRUG INTERACTIONS AND OTHER INTERACTIONS

TO AVOID POTENTIAL INTERACTIONS BETWEEN SEVERAL MEDICINES, ALWAYS TELL YOUR PHYSICIAN OR PHARMACIST IF YOU ARE TAKING ANY TREATMENT, in particular any medication likely to cause certain heart rhythm disturbances : astemizole, bepridil, intravenous erythromycin, halofantrine, pentamidine, sparfloxacin, sultopride, terfenadine, vincamine.

PREGNANCY - BREASTFEEDING

Pregnancy :

If you are pregnant, you should only take this medicine if it is absolutely necessary. If you find out that you are pregnant during treatment, see your physician, who alone can advise you as to whether or not you should continue treatment.

Breastfeeding :

Breastfeeding should be avoided during treatment because cortancyl is secreted in maternal milk.

IF YOU ARE PREGNANT OR BREASTFEEDING, ALWAYS CONSULT YOUR PHYSICIAN OR PHARMACIST BEFORE TAKING ANY MEDICATION.

ATHLETES

This medicinal preparation contains an active ingredient which may yield a positive dope test. **LIST OF EXCIPIENTS TO BE TAKEN INTO ACCOUNT FOR SAFE USE OF THE MEDICINE IN CERTAIN PATIENTS.**

Lactose : 104 mg per tablet.

HOW SHOULD YOU USE THIS MEDICINE

DOSAGE

RESERVED FOR USE IN ADULTS AND CHILDREN OVER 20 KG.

Cortancyl 20 mg is adapted to initial or short-lived treatments for which middle or high doses are required in adults and children over 20 kg.

There are suitable strength for maintenance treatment and for dosage below 20 mg per day. In children below the age of 6 years, more suitable pharmaceutical forms are available.

Your physician will determine the dose you should take, on the basis of your body weight and the disease to be treated.

The dose is calculated individually for each person.

It is essential that you take treatment as prescribed, and that you neither change it nor stop it abruptly without first consulting your physician.

ROUTE OF ADMINISTRATION

ORAL ROUTE

Swallow the tablets in a single dose with a glass of water in the morning with breakfast.

Take as prescribed by your physician.

DURATION OF TREATMENT

Your physician will determine the duration of treatment.

If you have been taking treatment for a prolonged period, do not stop abruptly, but decrease the doses as recommended by your physician.

WHAT TO DO IF YOU FORGET TO TAKE ONE OR MORE DOSES

To be effective, this medication should be taken regularly. However, if you forget one dose, you should continue your treatment as usual.

ADVERSE AND UNPLEASANT EFFECTS

LIKE ANY ACTIVE PRODUCT, THIS MEDICINE MAY, IN CERTAIN PEOPLE, GIVE RISE TO VARYING DEGREES OF UNPLEASANT EFFECTS.

This medicine is essential and is generally well-tolerated when the appropriate recommendations are followed, notably the dietary recommendations (see Precautions). Nevertheless, this medicine may cause more or less unpleasant side effects, depending on the dose and duration of treatment.

The most common side effects are :

- swelling and redness of the face, weight gain,
- bruises,
- raised blood pressure,
- agitation and sleep disturbances,
- bone fragility,
- changes in certain laboratory parameters (sodium, sugar, potassium), which may require a specific diet or additional treatment.

Other much more uncommon adverse effects have been observed :

- risk of impaired adrenal function, disturbances of growth in children,
- menstrual disturbances, muscle weakness,
- ulcers and other gastrointestinal disturbances,
- cutaneous disturbances,
- certain forms of glaucoma (increased pressure inside the eyeball) and cataracts (clouding of the lens).

DO NOT HESITATE TO ASK YOUR PHYSICIAN OR PHARMACIST FOR ADVICE AND TELL YOUR PHYSICIAN OR PHARMACIST OF ANY ADVERSE AND UNPLEASANT EFFECT NOT MENTIONED IN THIS LEAFLET.

STORAGE

DO NOT TAKE AFTER THE EXPIRY DATE INDICATED ON THE OUTSIDE PACKAGING.

DATE OF LEAFLET REVISION February 1998

Hoechst

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The Pharmaceutical Company of Hoechst

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