

# HYDROCORTISONE LEURQUIN 100 mg Lyophilisate (vial) and solution for parenteral use

## QUALITATIVE AND QUANTITATIVE COMPOSITION

HYDROCORTISONE HEMISUCCINATE

quantity corresponding to hydrocortisone ..... 100 mg

Excipients: sodium bicarbonate, disodium hydrogenophosphate dodecahydrate, concentrated phosphoric acid.  
for a vial

Composition of solvent: water for injectable preparations ..... 2 ml  
for an ampoule

**PHARMACEUTICAL FORM:** lyophilisate and solution for parenteral use

**PHARMACO-THERAPEUTIC CATEGORY:** GLUCOCORTICOID HORMONE

**NAME AND ADDRESS OF DISTRIBUTOR:**

**Laboratoires LEURQUIN MEDIOLANUM**  
68-88, rue Ampère - Z.I des Chanoux  
93330 NEUILLY SUR MARNE - FRANCE

## WHEN TO USE THIS MEDICATION

### (THERAPEUTIC INDICATIONS)

This medication is indicated in cases of adrenal insufficiency (reduction or cessation of hormone secretion by the adrenal glands).

### CAUTION:

### WHEN NOT TO USE THIS MEDICATION

*IF IN DOUBT, ASK YOUR DOCTOR OR YOUR PHARMACIST FOR ADVICE*

### SPECIAL WARNINGS

In very rare cases, injectable or oral cortocoids might lead to tendinopathias, including exceptional cases of tendinous rupture.

Inform your doctor in case of tendinous pain.

Diet: it is important to maintain a diet containing normal amounts of salt in case of adrenal insufficiency.

### PRECAUTIONS FOR USE

Quickly inform your doctor of any aggressive factors (fever, infection, illness, surgical intervention, trauma) because the dosage may have to be increased.

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

### DRUG INTERACTIONS AND OTHER INTERACTIONS

*TO AVOID POTENTIAL INTERACTIONS BETWEEN SEVERAL DRUGS, YOU MUST SYSTEMATICALLY INFORM YOUR DOCTOR OR PHARMACIST IF YOU ARE RECEIVING ANY OTHER TREATMENT*

### PREGNANCY AND BREASTFEEDING

If necessary, this medication may be taken during pregnancy. During breastfeeding, this medication should be avoided.

### SPORTS

Caution, this medication contains an active substance which may cause a positive reaction in anti-doping tests.

### HOW TO USE THIS MEDICATION

#### DOSAGE

The dosage and duration of the treatment vary according to the affection involved.

In all cases, comply strictly with your doctor's prescription.

#### METHOD AND ROUTE OF ADMINISTRATION

Intravenous route, intramuscular possible.

The lyophilisate contained in the vial must be dissolved by adding the contents of the solvent ampoule. If necessary, the solution

obtained may be diluted with a sterile isotonic solution.

The solutions prepared in this way must be used within 24 hours. This speciality is used intravenously by slow injection or perfusion.

It can be used intramuscularly at the same dosage.

**FREQUENCY AND TIMING OF DOSES:** Comply with your doctor's prescription.

**DURATION OF TREATMENT:** As specified by your doctor.

#### SIDE EFFECTS

*LIKE ANY DRUG, THIS PRODUCT MAY CAUSE SIDE EFFECTS OF VARYING SEVERITY IN SOME PEOPLE.*

A few rare cases of tendinous ruptures have been reported exceptionally, especially when given with fluoroquinolones.

Rare cases of systemic allergic reactions.

*DO NOT HESITATE TO ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE AND TO REPORT ANY SIDE-EFFECTS NOT MENTIONED IN THIS LEAFLET.*

**STORAGE: DO NOT USE AFTER THE DATE INDICATED ON THE EXTERNAL PACKAGING**

#### SPECIFIC STORAGE PRECAUTIONS

Before reconstitution: Store at a temperature below 30°C

After reconstitution: The solution must be used within 24 hours

**LEAFLET REVISION DATE:** June 2007