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## **Hydrocortisone Upjohn**

### **Parenteral preparation**

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#### **1. IDENTIFICATION OF THE MEDICINAL PRODUCT**

##### **NAME**

HYDROCORTISONE UPJOHN 100 mg, parenteral preparation  
HYDROCORTISONE UPJOHN 500 mg, parenteral preparation

##### **QUALITATIVE AND QUANTITATIVE COMPOSITION**

###### **? HYDROCORTISONE UPJOHN 100 mg:**

- for one vial of powder: hydrocortisone succinate (sodium salt), amount expressed in hydrocortisone: 100 mg.

Excipients: sodium biphosphate, sodium phosphate

- for one ampoule of solvent: water for injection: 2 ml

###### **? HYDROCORTISONE UPJOHN 500 mg:**

- for one vial of powder: hydrocortisone succinate (sodium salt), amount expressed in hydrocortisone: 500 mg.

Excipients: sodium biphosphate, sodium phosphate

- for one ampoule of solvent: water for injection: 5 ml

##### **PHARMACEUTICAL FORM**

Parenteral preparation (powder and solvent for solution for injection)

HYDROCORTISONE UPJOHN 100 mg: pack containing 1 vial of powder and one ampoule of solvent.

HYDROCORTISONE UPJOHN 500 mg: pack containing 10 vials of powder and 10 ampoules of solvent.

##### **PHARMACO-THERAPEUTIC GROUP**

GLUCOCORTICOIDE HORMONE

##### **HOLDER / EXPLOITANT**

Laboratoires SERB

53, rue Villiers de l'Isle-Adam

75020 PARIS

FRANCE

##### **MANUFACTURER**

VAL DE PHARM

Parc industriel d'Incarville

27100 Val de Reuil

FRANCE

#### **2. WHEN TO USE THIS MEDICINE**

This medicine is indicated for the treatment of adrenal insufficiency (reduction or complete failure of the secretion of the hormones produced by the adrenal glands).

### **3. BE CAREFUL!**

#### **WHEN YOU SHOULD NOT USE THIS MEDICINE**

*IN CASE YOU ARE NOT SURE, YOU MUST TAKE YOUR DOCTOR OR YOUR PHARMACIST'S ADVICE.*

#### **SPECIAL WARNING**

Diet: it is mandatory to keep a normal sodium diet in case of adrenal insufficiency.

Oral or injectable corticoids can conduct to tendinopathies, indeed tendon's breaks, exceptionally. Warn your doctor in case of appearance of pain from tendon.

#### **PRECAUTIONS FOR USE**

Quickly contact your doctor in case of any aggressive intercurrent event (fever, infection, illness, surgical operation, trauma) since an increase in the posology might be required.

*IN CASE YOU ARE NOT SURE, YOU MUST TAKE YOUR DOCTOR OR YOUR PHARMACIST'S ADVICE.*

#### **INTERACTIONS WITH MEDICINAL PRODUCTS AND OTHER INTERACTIONS**

*IN ORDER TO AVOID POSSIBLE INTERACTIONS BETWEEN SEVERAL MEDICINES, YOU MUST SYSTEMATICALLY TELL ALL TREATMENTS YOU ARE CURRENTLY TAKING TO YOUR DOCTOR OR YOUR PHARMACIST.*

#### **PREGNANCY, BREAST-FEEDING**

If necessary, this medicine can be administered during pregnancy.

The administration of this medicine must be avoided during breast-feeding.

#### **SPORTSMEN**

Sportsmen, be careful: this medicine contains a substance that may show a positive reaction in tests performed for anti-doping controls.

### **4. HOW TO USE THIS MEDICINAL PRODUCT**

#### **POSOLOGY**

The posology and the duration of treatment vary according to the medical condition that is treated.

In any case, comply exactly with the prescription of your doctor.

#### **MODE AND ROUTE OF ADMINISTRATION**

*Intravenous route, Intramusclar route is possible.*

The lyophilised powder of the vial must absolutely be dissolved before use, adding the content of the vial of solvent. If necessary, the solution can be further diluted with a sterile isotonic aqueous solution. Once prepared, the solutions must be administered within 24 hours.

This medicine must be administered using a slow bolus injection or an intravenous infusion. It can be administered by intramuscular route at the same posology.

#### **FREQUENCY AND TIME OF ADMINISTRATION OF THE MEDICINAL PRODUCT**

Comply with the prescription of your treating doctor.

#### **DURATION OF TREATMENT**

It is determined by the treating doctor.

#### **5. UNWANTED AND DISTURBING EFFECTS**

*AS ANY MEDICINE, THIS ONE MAY, IN SOME INDIVIDUALS, INDUCE MORE OR LESS DISTURBING EFFECTS.*

Some ruptures of tendons have been exceptionally reported, particularly in case of co-prescription with fluoroquinolones.

Rare cases of general allergic reactions.

*DO NOT HESITATE TO TAKE YOUR DOCTOR OR YOUR PHARMACIST'S ADVICE AND TO REPORT ANY UNWANTED OR DISTURBING EFFECT TO THEM.*

#### **6. STORAGE**

DO NOT USE THE MEDICINE AFTER THE EXPIRY DATE INDICATED ON THE EXTERNAL CONTAINER.

#### **7. DATE OF REVISION OF THE LEAFLET**

July 2007