DEXAMEDIS® - DEXAMEDIS Fort® Dexamethasone Phosphate

FORM AND PRESENTATIONS:

DexamédiS - 4 mg / 1 ml injectable solution.

DexamédiS Fort - 8 mg/ 2ml injectable solution.

COMPOSITION:

| | DexamédiS | DexamédiS Fort |
|--------------------------------|---|---------------------|
| Dexamethasone Sodium phosphate | 4,37 mg | 8,74 mg |
| methyl P-hydroxybenzoate | 1,5 mg | 3 mg |
| propyl P-hydroxybenzoate | 0,2 mg | 0,4 mg |
| Excipients Disodium | edetate, Sodium citrate tribasique dihydr | ate, creatinine q.s |
| W.F.I. q.s.f | 1 ml | 2 ml |

PHARMACOLOGICAL PROPERTIES:

Synthesis steroïdal used for its anti-inflammatory action.

THERAPEUTIC INDICATIONS:

Those of the corticotherapy by systemic or local route when an intense and fast corticotherapy is required.

CONTRAINDICATIONS:

Hypersensitivity to one of the components of this drug, administration of live virus vaccine, mycosic or infectious states not controlled with a treatment, drop, evolutive peptic ulcer, psychotic states, cirrhosis, alcoholic, acute virus A, B, C hepatitis, thrombopenic purpura (I.M route).

No absolute contraindication when glucocorticoïd is considered life-theatening to the patient.

CAUTION AND PRECAUTIONS OF USE:

- It's advised to diminish the salt in a diet which should be essencially rich in proteine and calcium, and weak in glucose.
- Use with care in children , menopansel wemen, ulcer or psychiatric antecedents, hypertension, diabete, osteoporosis, epilepsy.
- Patients receiving glucocorticoids should be monitored closely for the apparence of secondary bacterial or viral infectios.
- The chronic use of glucocorticoide abolish the hypothalamicpituitary axis. Than an adrenocortical insufficiency is frequently observed when the drug is suddenly stopped.

Pregnancy: With human species, the retrospective studies have not detected any malformative risk linked to the taking of corticoids during the first trimester. A neonatal surrenalian insufficiency has been observed after a high-dose corticotherapy.

it is preferable to keep off nursing on treatment because the corticoids pass in the maternal milk.

MEDICINAL INTERACTIONS:

You should inform your doctor about the drugs that you take and especially: cardiologic drugs, drugs decreasing the blood potassium, aspirin, anticoagulant, anti diabetic, Phenobarbital, phenitoïn, primidone or rifamycin.

Let know your doctor if you are in period of de vaccination.

ADVERSE EFFECTS:

Those of the corticotherapy, included water and sodium retention, hypertension, congestive cardiac insufficiency, osteoporosis, peptic ulcer, delay of cicatrization, aggravation of diabetic. Menstrual irregularities, decrease of the resistance of infection, increase of weight and glaucoma.

Let know your doctor about any unusual sensation.

DOSAGE AND MODE OF ADMINISTRATION:

Mode of administration: intravenous or intramuscular route, local injection (intra-articular, soft tissue).

Dosage: To conform to the medical prescription

DELIVERY CONDITIONS:

List I, table A, delivered strictly on medical prescription

CONSERVATION:

Keep away from light, heat and cold.

PRESERVATION:

DexamédiS Box of 10 ampoules of 1 ml 923 313 1

DexamédiS Fort Box of 1 ampoule of 2 ml 923 313 3

Marketing Authorisation Holder and Manufacturer:

LES LABORATOIRES MEDIS

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This is a drug

- A drug is a specific product agent.
- A drug is a product acting on your health and its use, contrary to prescriptions may be dangerous for you.
 Strictly respect the doctor's prescription and the instructions of use he has prescribed.
- Follow your pharmacist's kmow this drug : its indiations and contra-indications.
- Do not discontinue the drug intake by yourself during the prescription period.
- Do not repeat the prescription or increase the dosage without consulting your doctor.

KEEP ANY DRUG OUT OF THE REACH OF CHILDREN.

