Urbason® solubile forte

Active ingredient:
Methylprednisolone-21-hydrogen succinate, sodium salt

Urbason® solubile forte 1000

Active ingredient:
Methylprednisolone-21-hydrogen succinate, sodium salt

Composition

Urbason solubile forte: Each ampoule of dry substance contains 331.48 mg methylprednisolone-21-hydrogen succinate, sodium salt (equivalent to 250 mg methylprednisolone), as active ingredient.

Urbason solubile forte 1000: Each vial of dry substance contains 1325.92 mg methylprednisolone-21-hydrogen succinate, sodium salt (equivalent to 1000 mg methylprednisolone), as active ingredient.

Indications

Acute life-threatening conditions such as anaphylactic shock, shock due to burns or injuries, cardiogenic shock; brain oedema; shock lung; status asthmaticus; Addisonian crisis; Waterhouse-Friderichsen syndrome; for control of an immunological crisis after organ transplantation.

Contraindications and precautions

Hypersensitivity to methylprednisolone. There is otherwise no contraindication to the life-saving short-term use of high corticoid doses; any systemic corticoid treatment exceeding replacement therapy or short-term emergency treatment is contraindicated in the following conditions: Gastroduodenal ulcers, severe osteoporosis, history of psychiatric disorders, herpes simplex, herpes zoster (viraemic phase), chickenpox. It is also contraindicated from about 8 weeks before until 2 weeks after vaccinations, in amoebiasis, systemic mycoses, poliomyelitis (except the bulboencephalitic form), lymphoma following a BCG vaccination, narrow and open-angle glaucoma. In the presence of severe infections, use only in conjunction with an antibacterial therapy.

Pregnancy and lactation: During pregnancy or in circumstances where there is any possibility of pregnancy, treatment should be restricted to cases where it is absolutely essential. If systemic treatment with Urbason is necessary during the last few weeks of pregnancy or during lactation, it should be remembered that methylprednisolone crosses the placenta and passes into the breast milk. If higher doses are required on clinical grounds, it is advisable to cease breast-feeding.

Children: Do not administer to children unless there are compelling reasons.

Adverse reactions

If used repeatedly, glucocorticoids may give rise to the following adverse reactions, depending on the dosage and duration of treatment: Moon face, trunk obesity, muscular weakness, hypertension, osteoporosis, reduced glucose tolerance, diabetes mellitus, disorders of sex hormone secretion (amenorrhoea, hirsutism, impotence), red striae, petechiae, ecchymoses, steroid acne, sodium retention with oedema formation, increased potassium excretion, inactivity or atrophy of the adrenal cortex, vasculitis, epigastric discomfort, gastric ulcer, duodenal ulcer, increased risk of infections, impairment of antibody response, delayed wound healing, retarded growth in children, aseptic bone necroses (head of the femur and humerus), glaucoma, cataract, psychic disorders, increased risk of thrombosis, pancreatitis.

Very rarely, hypersensitivity reactions which may even amount to shock (especially in patients with bronchial asthma, and after kidney transplantation).

Interactions

In case of concurrent administration of cardiac glycosides, it should be noted that

potassium depletion may potentiate the glycoside effect. Simultaneous use of saluretics may give rise to increased potassium depletion. The hypoglycaemic effect of antidiabetic agents and the anticoagulant effect of coumarin derivatives may be reduced by glucocorticoids. If administered concomitantly with rifampicin, phenytoin or barbiturates, the corticosteroid effect may be reduced. Concomitant use of non-steroidal anti-inflammatory or antirheumatic agents may increase the risk of gastrointestinal haemorrhage.

Dosage and administration

Unless otherwise prescribed, generally once to several times daily 250–1000 mg methylprednisolone, or more, in adults; in children 4–20 mg per kg of body weight. Intervals between injections: 30 minutes to 24 hours, depending on the severity of the condition.

In anaphylactic shock, brain oedema, status asthmaticus and the early stages of hypovolaemic shock, 250–500 mg methylprednisolone (i.e. 1–2 ampoules of Urbason solubile forte).

In cases of shock lung, cardiogenic shock, burn shock and complicated hypovolaemic shock as well as in rejection crises, it is advisable to inject in one dose up to 30 mg methylprednisolone per kg body weight (for an adult weighing 60–70 kg, this is equivalent to 1–2 vials of Urbason solubile forte 1000).

In brain oedema, status asthmaticus and immunological crises, it is advisable, after initial i.v. treatment with Urbason solubile forte, to continue therapy with tablets of Urbason® in doses that are gradually decreased (please see relevant "Instructions for use").

In burn shock, the initial treatment with Urbason solubile forte is followed by infusions of hydrocortisone.

Urbason solubile forte and Urbason solubile forte 1000 are employed in addition to basic therapy (replacement of circulating fluid volume, treatment of heart and circulation, administration of antibiotics, analgesia, etc.). In Addisonian crises and Waterhouse-Friderichsen syndrome, simultaneous administration of mineralocorticoids is indicated.

The contents of one ampoule of Urbason solubile forte are dissolved in 5 ml water for injections, the contents of 1 vial of Urbason solubile forte 1000 in 10 ml.

The solution prepared from the dry substance should be used up as soon as possible.

The intravenous injection is given slowly. Depending on the clinical condition and response of the patient, the injection may be repeated within the first few hours of treatment.

Urbason solubile forte and Urbason solubile forte 1000 must not be mixed with other drugs in the syringe, because precipitation may occur. For the same reason, they are not to be added to infusion solutions (other than glucose infusion solutions) or injected into the infusion tube.

Special notes

Caution is recommended in patients with severe hypertension and heart failure.

Diabetic patients must be examined for adequate control and, if necessary, antidiabetic medication adjusted.

In long-term glucocorticoid treatment, medical and ophthalmological controls should be carried out regularly.

Expiry date

Do not use later than the date of expiry.

Keep medicines out of the reach of children.

Presentation

Urbason solubile forte: 1 and 5 ampoules of dry substance, with the corresponding number of ampoules of 5 ml water for injections; hospital packs

Urbason solubile forte 1000: 1 vial of dry substance, with 1 ampoule of 10 ml water for injections; hospital packs

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