

MP® 120 mg Methylprednisolone

1. WHAT IS MP120® ?

Pharmaceutical form

MP 120: DCI: Methylprednisolone Hemisuccinate - Box of 01 vial of lyophilisate + 01 ampoule of W.F.I

Composition :

Vial of lyophilisate :	
Methylprednisolone	120 mg
Excipients :	q. s
Solvent ampoule :	
EPPI	q.s.p. 2 ml

2. IN WHICH CASE IS MP 120® USED?

Those of systemic oral corticosteroid therapy, when the parenteral administration is necessary if the oral administration is not possible (vomiting, gastric aspiration, consciousness disturbances).

Conditions requiring a rapid therapeutic effect:

- Allergic: severe angioedema in addition to antihistamines; anaphylactic shock in addition to adrenaline.
- Infectious: severe typhoid fever, especially with mental confusion, shock, coma; Stridular laryngitis (subglottic laryngitis) in children.
- Neurological: cerebral edema (tumors, toxoplasma abscess...).
- ENT : laryngeal dyspnea.

3. WHAT YOU NEED TO KNOW BEFORE YOU TAKE MP 120®?

Contraindications

Absolutes :

- Any infectious condition.
- Certain evolving viroses (hepatitis, herpes, chickenpox, shingles).
- Psychotic states not yet controlled by treatment.
- Live vaccines.
- Hypersensitivity to one of the constituents.

However, there is no absolute contraindication for a vital indication corticosteroid therapy.

Relative :

- Non-antiarrhythmic medicines giving torsades de pointes.

Warnings and precautions for use

Warnings :

- Since Rare cases of pseudo-anaphylactic-type reactions occurred in patients treated with parenteral corticosteroid therapy; special care should be taken before any administration in subjects with an atopic tendency.
- In the event of peptic ulcer, corticosteroid therapy is not contraindicated if anti-ulcer therapy is combined.

In case of history of peptic disease, corticosteroid therapy may be prescribed, with clinical monitoring and if necessary, after fibroscopy.

•Head trauma, regardless of severity, is not an indication for the administration of methylprednisolone hemisuccinate. Results from a multicenter, randomized, placebo-controlled study showed an increase in early (at two weeks) and late (at six months) mortality after head injury in patients receiving methylprednisolone hemisuccinate, compared to placebo group. Causes of increased mortality in the methylprednisolone group have not been established.

•Corticosteroid therapy can lead to the occurrence of various infectious complications due to bacteria, yeasts, and parasites. The occurrence of malignant anguillulosis is a significant risk. All subjects coming from an endemic area (tropical, subtropical, southern Europe) must have a parasitological examination of the stool and a systematic eradication treatment before corticosteroid therapy.

Progressive signs of infection may be masked by corticosteroid therapy.

It is important, before starting treatment, to rule out any possibility of visceral affection, in particular tuberculosis, and to monitor, during treatment, the onset of infectious pathologies.

In case of old tuberculosis, prophylactic anti-tuberculosis treatment is necessary, if there are significant radiological sequelae and if it is not possible to ensure that a well-managed 6-month treatment with rifampicin has been given.

•The use of corticosteroids requires a particular appropriate monitoring, especially in the elderly and in case of ulcerative colitis (risk of perforation), diverticulitis, recent intestinal anastomosis, renal failure, hepatic failure, osteoporosis, myasthenia gravis.

•Oral or injectable corticosteroids can lead to the occurrence of tendinopathy, or even tendon rupture (exceptional). This risk is increased when co-prescribed with fluoroquinolones and in dialysis patients with secondary hyperparathyroidism or who have undergone kidney transplantation.

•The attention of athletes is drawn to the fact that this specialty contains methylprednisolone; this active ingredient is included in the list of doping substances.

Precautions for use :

- Oral treatment will be instituted as a relay as soon as possible.
- Water retention is usual, partly responsible for a possible increase in blood pressure. The sodium intake will be reduced.
- Potassium supplementation is only justified for high-dose treatments, prescribed for a long time, or in case of a risk of arrhythmias or associations with hypokalaemic treatment.
- When corticosteroid therapy is essential, diabetes and arterial hypertension are not contraindications, but the treatment can cause their imbalance. Their management should be reassessed.
- Patients should avoid contact with people with chickenpox or measles.

Use during pregnancy and breastfeeding

Pregnancy

In animals, experimentation shows a teratogenic effect that varies according to the species.

In humans, there is a placental transfer. However, epidemiological studies have detected no risk of malformation associated with taking corticosteroids during the first trimester.

In chronic conditions requiring treatment throughout pregnancy, slight intrauterine growth retardation is possible. Neonatal adrenal insufficiency has been observed exceptionally after high dose corticosteroid therapy.

It is justified to follow a period of clinical (weight, diuresis) and biological monitoring of the newborn.

Accordingly, corticosteroids may be prescribed during pregnancy, if needed.

breastfeeding

In case of treatment in large doses and chronically, breastfeeding is not recommended.

Interactions with other medicines

Not recommended:

Medicines giving torsades de pointes: astemizole, bepridil, IV erythromycin, halofantrine, pentamidine, sparflaxacin, sultopride, terfenadine, vincamine, (hypokalemia is a contributing factor as well as bradycardia and a pre-existing prolongation of QT interval). Use of substances which do not have the disadvantage of causing torsades de pointes in case of hypokalemia.

Requiring precautions for use :

•Systemic acetylsalicylic acid (and, by extrapolation, other salicylates): decreased salicyluria during treatment with corticosteroids and risk of salicylic overdose after stopping it (increased elimination of salicylates by corticosteroids). Adjust the doses of salicylates during the combination and after stopping treatment with corticosteroids.

•Antiarrhythmic medicines giving torsades de pointes : amiodarone, disopyramide, quinidines, sotalol, (hypokalemia is a contributing factor as bradycardia and a pre-existing long QT interval). Prevention of hypokalemia and, if necessary, correction; monitoring of QT interval. In case of torsades, do not prescribe an antiarrhythmic (electrosystolic training).

•Oral anticoagulants: possible impact of corticosteroid therapy on the metabolism of the oral anticoagulant and on the metabolism of coagulation factors. Hemorrhagic risk specific to corticosteroid therapy (digestive mucosa, vascular fragility) at high doses or in prolonged treatment (in case of oral relay) for more than 10 days. When the combination is justified, reinforce monitoring: biological control on the 8th day, then every 15 days during corticosteroid therapy and after stopping it.

Other hypokalaemic medicines: hypokalaemic diuretics (alone or in combination), stimulant laxatives, amphotericin B (IV administration): increased risk of hypokalemia (additive effect). Monitoring of serum potassium with, if necessary, correction, to be particularly considered in the case of cardiac glycoside treatment.

Digitalis: hypokalemia favoring the toxic effects of digitalis. Monitoring of serum potassium and, if applicable, ECG.

Heparin (parenteral administration): worsening of the hemorrhagic risk, by heparin, which is specific to corticosteroid therapy (digestive mucosa, vascular fragility) at high doses or in prolonged treatment for more than 10 days. The association must be justified, enhance monitoring.

•Enzyme inducers: anticonvulsants (carbamazepine, phenobarbital, phenytoin, primidone), rifampicin: decrease in plasma concentrations and the efficacy of corticosteroids by increasing their hepatic metabolism. The consequences are particularly important in Addisonians and in case of transplantation. Clinical and biological monitoring, adjustment of the dosage of corticosteroids during the combination and after stopping the enzyme inducer.

•Insulin, metformin, sulfonylureas: increased blood sugar with sometimes ketosis (decreased tolerance to carbohydrates by corticosteroids). Warn the patient and reinforce blood and urine self-monitoring, especially at the start of treatment. If necessary, adjust the dosage of the antidiabetic medication during treatment with corticosteroids and after stopping it.

•Isoniazid (described for prednisolone): Decreased plasma concentrations of isoniazid. Mechanism invoked: increased hepatic metabolism of isoniazid and decrease in that of glucocorticoids. Clinical and biological monitoring.

To consider :

•Antihypertensive medicines: decrease in the antihypertensive effect (water and sodium retention of corticosteroids).

•Ciclosporin: Possible increase in plasma concentrations of ciclosporin and serum creatinine. Mechanism invoked: decreased hepatic elimination of ciclosporin.

•Fluoroquinolones: possible increased risk of tendinopathy, or even tendon rupture (exceptional), particularly in patients receiving prolonged corticosteroid therapy.

•Interferon alpha: risk of inhibiting the action of interferon.

•Live attenuated vaccines: risk of generalized disease, possibly fatal. This risk is increased in subjects already immunocompromised by the underlying disease. Use an inactivated vaccine when it exists (poliomyelitis).

4. HOW TO TAKE MP 120® ?

Dosage and method of administration

Adults only.

After mixing, the resulting solution can be administered by IV route either:

- directly by slow injection, minimum duration of 20 to 30 minutes.
- by IV infusion after dilution in isotonic sodium chloride or glucose solution.

When the IV route cannot be used, administration can be performed by deep IM route under strict asepsis.

The dosage is 120 mg per day. In very exceptional situations, this dosage may be repeated.

5. POSSIBLE SIDE EFFECTS ?

Related to parenteral administration :

- Rare cases of anaphylactic reactions have been reported in patients treated with parenteral corticosteroids.
- Cases of cardiac arrhythmia and / or cardiovascular collapse and / or cardiac arrest following fast intravenous administration of large doses have been reported.
- Tachycardia has sometimes been observed after injection of the product; it is quickly reversible.
- Episodes of bradycardia occurring during or following large dose infusion have been described regardless of the duration or rate of infusion.

Other effects:

•Hydroelectrolyte disorders: hypokalemia, metabolic alkalosis, water retention, arterial hypertension, congestive heart failure.

•Endocrine and metabolic disorders: iatrogenic Cushing's syndrome, inertia of ACTH secretion, adrenal cortical atrophy sometimes definitive, decrease in glucose tolerance, revelation of latent diabetes, stunted growth in children, menstrual irregularities.

•Musculoskeletal disorders: muscle atrophy preceded by muscle weakness (increased protein catabolism), osteoporosis, pathological fractures, in particular vertebral compression, aseptic osteonecrosis of the femoral heads.

•A few cases of tendon ruptures have been described exceptionally, especially in co-prescription with fluoroquinolones.

•Digestive disorders: hiccups, peptic ulcers, ulceration of the small intestine, gastrointestinal perforations, and hemorrhages; acute pancreatitis has been reported, especially in children.

•Skin disorders: acne, purpura, ecchymosis, hypertrichosis, delayed healing.

•Neuropsychic disorders:

- commonly: euphoria, insomnia, excitement;
- rarely: manic-like fit; confusional or dreamlike states, convulsions;
- depressive state on discontinuation of treatment.

•Eye disorders: some forms of glaucoma and cataracts.

6. HOW TO STORE MP 120® ?

Store at a temperature below 25 ° C.

After reconstitution: the solution must be used immediately.

7. WHAT ARE THE SUPPLY CONDITIONS?

List I ; under medical prescription.

8. PRESENTATION AND M.A NUMBER:

Speciality	Presentation	M.A N°
MP 120	Box of 01 vial + 01 ampoule of WFI	923 323 5

DATE OF THE LAST REVIEW: February 2014

This is a medicine

- A medicine is a product but not like any other product.
- A medicine is a product that affects your health. If it's not used properly : it can be health threatening.
- Strictly adhere to the prescription of you Doctor and the use instructions prescribed, follow your pharmacist advice.
- Your doctor and you pharmacist know the medicine, its use and side effect.
- Don't stop the use of the treatment on your own during the prescribed time.
- Don't retake, Don't increase the doses without doctor's advice.

Keep the medicines out of reach of children

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