

Méthylprednisolone

MYLAN

methylprednisolone hemisuccinate

40 mg | 120 mg

20 vial
powder for solution for injection

IV **IM** intravenous use
(slow injection or infusion),
intramuscular use

Mylan

Identification of the medicinal product

Qualitative and quantitative composition

Methylprednisolone hemisuccinate50.68.....152.04 mg *For one vial*
Quantity equivalent to Methylprednisolone base40.00.....120.00 mg

Excipients: sodium hydroxide, lactose monohydrate, sodium dihydrogen phosphate dihydrate, disodium phosphate dodecahydrate.

Pharmaceutical Form

Box of 20 vials of Powder for solution for injection (I.M.-I.V.).

Pharmaco-therapeutic class

GLUCOCORTICOID - SYSTEMIC USE

(H. Non sex hormones) (D. Dermatology) (M. Locomotive apparatus) (S. Sensory organs)

Benta S.A.L., Dbayeh - Lebanon



Under license from

Mylan S.A.S. 117 Allée des Parcs
69800 SAINT-PRIEST - FRANCE

When to use this drug?

This medicine is a corticosteroid.

Because of its anti-inflammatory effect, it is indicated in the treatment of certain diseases.

Warning!



In which cases should this medicinal product not be used?

This medicinal product **must not be used** in the following cases:

- most infections,
- certain active viral diseases (viral hepatitis, herpes, chickenpox, herpes zoster),
- certain untreated mental disorders,
- vaccination with live vaccines,
- allergy to one of the constituents,
- coagulation disorders or ongoing anticoagulant treatment, in the case of intramuscular injection.

In general, this medicine must not be used - unless you are advised to the contrary by your doctor - in combination with medicines that may cause certain disturbances of cardiac rhythm (see "Drug interactions and other interactions").

In case of doubt, it is essential to ask your doctor or pharmacist for advice.



Special warnings

This medicine must be taken under strict medical supervision.

Before treatment

Inform your doctor in case of allergy, recent vaccination, gastric ulcer, diseases of the colon, recent surgical operation on the intestine, diabetes, hypertension, infection (especially a history of tuberculosis), liver failure, kidney failure, osteoporosis or myasthenia gravis (muscle disease with muscle fatigue).

Because of the risk of a parasitic disease, inform your doctor of any stay in tropical or subtropical regions or southern Europe.

After treatment

Avoid contact with individuals suffering from chickenpox or measles.

Precautions for use

During intramuscular or intravenous administration, your doctor may advise you to follow a diet, especially a low-salt diet.

In case of doubt, do not hesitate to ask the advice of your doctor or pharmacist.



Drug interactions and other interactions

To prevent possible interactions between several medicines, particularly certain medicines that may cause disturbances of cardiac rhythm: astemizole, bepridil, erythromycin by intravenous injection, halofantrine, pentamidine, sparfloxacin, sultopride, terfenadine, or vincamine, **please systematically inform your doctor or your pharmacist if you are taking or have recently taken any other medicines, even those not prescribed.**



Pregnancy - Lactation

This medicine should only be administered during pregnancy if necessary. If you discover that you are pregnant during treatment, see your doctor since he alone can assess whether you need to continue this treatment.

This medicine is excreted in breast milk and therefore breast-feeding should be avoided during treatment.

Generally speaking, during pregnancy or breast-feeding, you should always ask for your doctor or pharmacist's advice before using a medication.



Sportsmen - Women

This medicinal product contains an active ingredient which might produce a positive reaction in tests carried out during antidoping controls.

List of excipients stated so as to ensure risk-free use in certain patients

Sodium.

How should this medicine be used?



Dosage

The dose to be administered is determined on a strictly individual basis by your doctor, according to your weight and the disease being treated.

Methylprednisolone Mylan 120 mg, Powder for solution for injection (I.M.- I.V.) is for adults only.

In all cases, follow your doctor's prescription exactly.



Method of administration

Intravenous or intramuscular injection.



Duration of treatment

This is determined by your doctor.

Undesirable and bothersome effects

Like all medicines, this medicinal product can have side effects:

This essential medicine is usually well tolerated when your doctor's recommendations are followed (see "Precautions for use").

It may, however, give rise to varying degrees of side effects.

The most frequently encountered are: swelling and redness of the face; weight gain; bruises; rise in blood pressure; excitation and sleep disorders; fragility of bone; alteration in certain laboratory test parameters (salt, sugar, potassium) which may require a diet or additional treatment.

Other effects have been observed far more rarely: risk of failure of secretion by the adrenal gland; growth disorders in children; disturbances in periods; muscle weakness; ulcers and other gastrointestinal disturbances; skin disorders; certain forms of glaucoma (increased pressure inside the eye) and cataract (lens opacification).

Some effect related to the route of administration have been described: allergic reactions, disturbances of cardiac rhythm.

Do not hesitate to ask the advice of your doctor or pharmacist or to inform your doctor or pharmacist of any side effect not mentioned in this leaflet.

Storage

Do not exceed the expiry date for use marked on the outer package.

Do not Store above 25°C.

This leaflet was last approved in: 10/2009

This is a medicament

- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you
- Follow strictly the doctor's prescription, the method of use, and the instructions of the pharmacist who sold the medicament
- The doctor and the pharmacist are experts in medicine, its benefits and risks
- Do not by yourself interrupt the period of treatment prescribed for you
- Do not repeat the same prescription without consulting your doctor
- Medicament: keep out of reach of children