Méthotrexate Bellon®

Méthotrexate / Methotrexate

Méthotrexate Bellon®5mg2ml
Méthotrexate Bellon®25mg1ml
Méthotrexate Bellon®50mg2ml
Méthotrexate Bellon®500mg20ml

Aventis

IDENTIFICATION OF THE MEDICINAL PRODUCT

Name of the product

Methotrexate Bellon 5 mg, solution for injection.
Methotrexate Bellon 25 mg, solution for injection.
Methotrexate Bellon 50 mg, solution for injection.
Methotrexate Bellon 500 mg, solution for injection.

Qualitative and quantitative composition

Methotrexate Bellon.....5 mg/2 ml:
methotrexate.....5 mg per vial.
Methotrexate Bellon.....25 mg/1 ml:
methotrexate.....25 mg per vial.
Methotrexate Bellon.....50 mg/2 ml:
methotrexate.....50 mg per vial.
Methotrexate Bellon.....500 mg/20 ml:
Methotrexate.....500 mg per vial.
Excipients : sodium chloride, sodium hydroxide, water for injections.

Pharmaceutical form

Solution for injection of 5 mg/2 ml in vial, box of 1 & 10 vials.
Solution for injection of 25 mg/1 ml in vial, box of 1 & 10 vials.
Solution for injection of 50 mg/2 ml in vial, box of 1 & 10 vials.
Solution for injection of 500 mg/20 ml in vial, box of 10 vials

Pharmaco-therapeutic class: Antimetabolite, folic acid analogue (L: Antineoplastic and immunomodulating agent).

When should this drug be used (Therapeutic indications)

This drug is a cytostatic agent, it inhibits the growth of some cells.

How should this drug be used

Strictly follow the recommended dosage unless directed otherwise by the physician.

Dosage

The dosage varies depending on indication and treatment protocol. It should be adjusted according to clinical response and haematological tolerance.

Method of administration

Parenteral route: depending on the indication, by subcutaneous, intramuscular, intravenous or intra-arterial route. Intrathecal route: solutions for injection of methotrexate 5 mg/2 ml, 25 mg/1 ml and 50 mg/2 ml.

When and how often should this drug be taken

In all cases, strictly follow the physician's prescription.

Duration of treatment

In all cases, strictly follow the physician's prescription.

WHEN SHOULD THIS DRUG NOT BE USED (Contraindications)

This drug MUST NOT BE USED in the following cases:

- In patients with known hypersensitivity to methotrexate or to any of its excipients,
- Severe renal or liver disease,
- Chronic respiratory insufficiency,
- Pregnancy and lactation,
- When administered in combination with yellow fever vaccine, probenecid, trimethoprim with or without sulfamethoxazole, pyrazoles, phenytoin at prophylactic doses and salicylates, when methotrexate is administered at doses above 15 mg per week (see Interactions),

As a general rule, this drug SHOULD NOT BE USED, unless otherwise advised by your physician: in combination with some non-steroidal anti-inflammatory drugs, penicillins and live attenuated vaccines (measles, rubeola, mumps, poliomyelitis, tuberculosis, varicella) (see Interactions).

In case of doubt you must consult your physician or pharmacist.

Warnings and precautions

Treatment should be administered under strict medical supervision.

Usually, before the start of the treatment and before every following course, biological control of blood formula, blood cell count and platelets, as well as assessment of renal and liver functions have to be performed.

When large doses of methotrexate are given, alkaline hyperdiuresis must be performed and folinic acid must be administered.

The attending physician is the only person qualified to decide of the clinical indication of methotrexate, its dosage, route of administration and the necessary measures for monitoring the patient.

In case of aplastic anaemia, the dosage must be adjusted according to the cause ofthis insufficiency.

In case of doubt do not hesitate to consult your physician or pharmacist.

Overdosage

Calcium folinate should be administered, with a frequency and a dosage depending on the renal and liver function and requiring a concomitant intensive hydration-alkalinisation.

In case of overdosage or accidental intoxication, patients should be immediately transferred to a specialized oncology unit.

Interactions

In order to avoid possible interactions with other drugs, inform your physician or pharmacist about any other current treatment.

The coadministration ofmethotrexate with yellow fever vaccine, probenecid, trimethoprim with or without sulfamethoxazole, pyrazoles (phenylbutazone), phenytoin at prophylactic doses and salicylates, when methotrexate is administered at doses above 15 mg/week, is contraindicated (see Contraindications).

The coadministration ofmethotrexate with non-steroidal anti-inflammtory drugs, ciclosporin, tacrolimus, live attenuated vaccines, penicillins and sulphonamides should be carefully monitored.

Pregnancy and lactation

This drug is contraindicated during pregnancy and lactation.

In case of pregnancy or lactation you always have to ask your physician or pharmacist for advice before the beginning ofthe treatment.

UNDESIRABLE EFFECTS

Please tell your physician or pharmacist, ifyou experience any adverse effect with the use of this product.

- Disorders in blood cell count: a regular monitoring ofblood formula and blood cell count is recommended,
- Renal function disorders which may lead to a definitive renal insufficiency,
- Liver function disorders,
- Respiratory disorders,
- Gastrointestinal disorders: nausea, vomiting, diarrhea,
- Neurological disorders: mood and memory disorders. In case ofadministration by Intrathecal route or ofhigh doses, more or less severe neurological disorders, more often reversible, may occur,
- Other adverse reactions: redness ofthe skin, ulceration in the mouth, fever, impotency, azoospermia (disappearance of spermatozoa in the sperm), amenorrhea (disappearance of periods), absence of libido.

STORAGE

Respect the expiry date indicated on the outer packaging.

Keep out ofthe reach ofchildren.

Special storage conditions

Do not store above 25°C and protect from light.

After dilution in the vehicle ofinfusion (0.9% isotonic aqueous solution ofNaCl, 5% glucose solution, 1.4% sodium bicarbonate), the reconstituted solution can be stored for 12 hours at a temperature ≤ 25°C and protected from light.

Recommendations for handling and disposal

Methotrexate is a cytostatic agent and, as with other potentially toxic compounds, careful handling and disposal should be exercised.

Manufacturer

Laboratoires Thissen
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Marketing Authorization Holder

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