SYNERGIC® 500

Imipenem 500mg/vial & Cilastatin 500mg/vial

Powder for injectable preparation Intravenous way (Infusion)

FORM AND PRESENTATION :
Powder for I.V. injectable preparation (infusion).
Box of 1 vial of powder.

COMPOSITION :
Imipenem ……..……..……....500 mg
(under the form of imipenem monohydrate)
Cilastatin ……..……...……500 mg
(under the form of cilastatin sodium)
Excipient : sodium bicarbonate.
Excipient with known effect : Sodium.
This medicine contains sodium. This medicine contains 37,6 mg of sodium (1,6 mEq) per vial.

PHARMACO-THERAPEUTIC CLASS:
Antibacterial for systemic use, carbapenem.

INDICATIONS :
SYNERGIC® is indicated in the treatment of the following infections in the adult and the child of 1 year and more (see paragraph Special care and precautions for use and Pharmaco-therapeutic class):
- complicated intra-abdominal infections,
- severe pneumonia, including the pneumonia acquired at hospital and under mechanic ventilation,
- intra-partum and post-partum infections,
- complicated urinary infections,
- complicated infections of the skin and of the soft tissues.

SYNERGIC can be used in neutropenic patients presenting fever in which bacterial origin is suspected.
Treatment in patients presenting a bacteriemia associated or suspected to be associated with one of the infections mentioned above.
It fits to take into account the official recommendations relative to the appropriate use of antibacterial agents.

CONTRA-INDICATIONS:
- Hypersensitivity to the drug substances or to one of the excipients.
- Hypersensitivity to another antibiotic from the carbapenem class.
- Severe hypersensitivity (for example anaphylactic reaction, severe cutaneous reaction) to any other antibiotic from the family of beta-lactamines (for example penicillin or cephalosporin).

WARNINGS AND PRECAUTIONS OF USE:
Warnings:
- The upcoming of an allergic reaction imposes stopping the treatment.
- Before taking this medicine, inform your doctor if, at the occasion of an anterior antibiotic treatment, you have presented urticaria, itching, Quincke œdema or other cutaneous eruptions.
- The prescription of this medicine necessitates a questioning beforehand.

In case of therapeutic failure, it is necessary to think of the possibility of the emergence of strains resistant to the Pseudomonas aeruginosa, in order to if necessary, modify the antibiotherapy.

Precautions of use:
Use this medicine with precaution in case of :
- colitis or any other gastro-intestinal disease,
- renal or urinary problems, comprising diminution of the renal function (increase in the rates of SYNERGIC® in the blood with a diminished renal function. The side effects affecting the central nervous system can occur if the dose is not adapted to the renal function).
- disorders of the central nervous system such as localized tremor or epilepsia crisis (convulsions),
- liver problems.

You can get a positive test (Coombs test) which indicates the presence of antibodies capable of destroying your red globules. Your doctor will discuss it with you.
Inform your doctor if you are taking medicines named valproic acid or sodium valproate (see MEDICINAL INTERACTIONS).

Children
SYNERGIC® is not recommended in children of less than 1 year or in children presenting kidney problems.
This medicine contains sodium. This medicine contains 37,6 mg of sodium (1,6 mEq) per vial. To take into account in persons following a strict low salt diet.

MEDICINAL INTERACTIONS:
If you take or have recently taken other medicines, comprising a medicine obtained without prescription, tell your doctor or pharmacist.
Inform your doctor if you are taking ganciclovir, which is used to treat certain viral infections.
Similarly, inform your doctor if you are taking the valproic acid or the sodium valproate (used to treat epilepsia, bipolar disorders, the migraine or the schizophrenia) or some blood attenuants such as the warfarine or probenecid.
IT FITS TO SIGNAL ANY OTHER ONGOING TREATMENT TO YOUR DOCTOR.

PREGNANCY AND BREAST FEEDING:
Pregnancy:
SYNERGIC® should not be used in pregnancy only if the doctor considers that the potential benefit for the mother justifies the potential risk for the development of the baby.
Breast feeding :
Weak quantities of this medicine can pass into the mother's milk and have nocuous effects on the child. Consequently, your doctor will decide if you should receive SYNERGIC® when you are breast feeding.

IN ALL CASES, ASK YOUR DOCTOR FOR ADVICE.

SIDE EFFECTS:
The following side effects occur rarely, yet in case they happen during or after the administration of SYNERGIC®, the medicine should be stopped and contact your doctor immediately.
- Allergic reactions including cutaneous eruption, swelling of the face, the lips, the tongue and/or of the throat (with difficulties to breath or swallow) and/or low arterial pressure,
- Skin detachment (toxic epidermal necrolysis, or Lyell syndrome),
- Severe cutaneous reactions (Stevens-Johnson syndrome and erythema multiforme),
- Severe cutaneous eruption with fall of the skin and of the hair (exfoliative dermatitis).

Other possible side effects:
Frequent (affects from 1 to 10 patients in 100)
Nausea, vomiting, diarrhea. The nausea and vomiting seem to be more frequent in patients with a un weak number of white globules; swelling and redness along a vein which is extremely sensitive when touched; cutaneous eruption; anomaly of the hepatic function detected by the blood tests ; increase in the number of certain white globules in the blood.
Less frequent (affects from 1 to 10 patients in 1 000)
Localized redness of the skin ; localized pain and formation of a firm nodule at the site of injection ; skin itching ; urticaria; fever ; blood disorders affecting certain blood elements sang and detected generally by the blood tests (the symptoms can be : fatigue, pallor of the skin and persistent blue coloration after an injury) ; anomalies of the renal function, hepatic or sanguine detected by the blood tests; tremor and incontrollable muscle contractions; crisis of epilepsia (convulsions) ; psychic disorders (such as mood swings and alteration of judgment) ; sensation of sseing, hearing or feeling things which do not exist (hallucinations) ; confusion ; light headedness, somnolence ; low blood pressure.
Rare (affects from 1 to 10 patients in 10 000)
Fungal infection (candidiasis) ; coloration of the teeth and/or the tongue ; inflammation of the colon with severe diarrhea; taste disorders ; incapacity of the liver to carry the normal functions; inflammation of the liver ; incapacity of the kidneys to carry their normal functions; modification of the volume of urines, modifications of the colour of urines ; brain attack, sensation of tingling, localized tremor; loss of hearing.
Very rare (affects less than 1 patient in 10 000)
major malfunction of the liver due to an inflammation (fulminant hepatitis) ; inflammation of the stomach or of the intestine (gastro-enteritis) ; inflammation of the intestine with bloody diarrhea (hemorrhagic colitis) ; red and inflated tongue, magnification of the tongue buds langue giving to the latter a « hairy » appearance, burning of the stomach, throat pain, increase in the production of saliva ; gastric pain; sensations of dizziness, headache ; whistling or buzz in the ears (tinnitus) ; pain in many articulations, weakness ; irregular cardiac rhythm, with strong or rapid heartbeats ; chest discomfort, difficulties in breathing, abnormally rapid and superficial breathing, neck pain ; hot flushes, bluish coloration of the face and of the lips ; modifications of the skin texture, excessive sweating; itching of the vulva in women ; modifications in the quantities of blood cells ; worsening of a rare disease associated to a muscle weakness (worsening of myasthenia).
Undetermined frequency (cannot be estimated based on the available data): Abnormal movements, agitation.
SIGNAL TO YOUR DOCTOR OR TO YOUR PHARMACIST ANY UNDESIRABLE AND DISTURBING EFFECT NOT MENTIONED IN THIS LEAFLET.

POSOLOGY and METHOD OF ADMINISTRATION:
Posology :
The posology of SYNERGIC® corresponds to the dose of imipenem to administer, associated to the quantity of cilastatin.
SYNERGIC® will be prepared and administered by a doctor or another heath professional. Your doctor will determine the necessary dose of SYNERGIC®.

Adults and adolescents
The habitual dose of SYNERGIC® in the adults and adolescents is of 500mg/500mg all the 6 hours or 1 000 mg/1 000 mg every 6 or 8 hours. Your doctor will be able to diminish this dose if you suffer from renal or if you weigh less than 70 kg.

Childern
The habitual dose in children aged 1 year and more is of 15/15 or 25/25 mg/kg/dose every 6 hours. SYNERGIC® is not recommended in children below 1 year, and in children having kidney problems.

Method of administration :
IV Administration in infusion.
The infusions could be prepared through using the following solvents: sodium chloride at 0,9 %, glucose at 5 or at 10 %, mannitol at 2,5, at 5 and 10 %.
SYNERGIC® is administered by intravenous way (in the vein) in 20 to 30 minutes for a dose ≤ 500 mg/500 mg or in 40 to 60 minutes for a dose > 500 mg/500 mg. the speed infusion can be slowed down if you have nauseas.
The infusions will be prepared by dissolution of the powder for injectable preparation in a un solvent, at the rate of 500 mg of imipenem for 100 ml.

PARTICULAR STORAGE CONDITIONS:
- Store at a temperature inferior to 25° C.
- After reconstitution, the solution should be used immediately.

LIST I
MA : 9093551H

THIS IS A MEDICAMENT

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 the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

COUNCIL OF ARAB HEALTH MINISTERS

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