MIOCAMEN®

Miocamycin Tablet 600 mg
Miocamycin Granulate 6 g

COMPOSITION

Miocamen 600 mg tablets
Each tablet contains:
Active ingredients: 600 mg of miocamycin
Excipients: ethylcellulose, hydroxypropylmethyl cellulose, aluminum glycinate, sodium starch glycolate, microcrystalline cellulose, magnesium stearate, polyethylene glycol, talc, titanium dioxide, sunset yellow, erythrosin.

Miocamen granulate
Each 30 g bottle of granulate contains:
Active ingredients: 6 g of miocamycin
Excipients: ethylcellulose, methyl p-hydroxybenzoate, propyl p-hydroxybenzoate, citric acid, anhydrous sodium phosphate, banana flavouring, sodium saccharinate, sunset yellow, hydroxypropylmethyl cellulose, simethicone, sorbitan monopalmitate, glyceril monostearate, saccharose monopalmitate, mannitol.

INDICATIONS

Infections in adults and children sustained by germs that are sensitive to miocamycin:
- Bronchitis, pneumonia, tonsillitis, pharyngitis, rhinopharyngitis, sinusitis, otitis, otitis media, scarlet fever, furunculosis, pyodermatitis, abscesses, phlegmons, etc.
- It is active also in odontostomatological and urogenital infections and in those of the bile ducts from sensitive germs.
- It may also be administered to patients who are allergic to penicillin.

CONTRAINDICATIONS

Known individual hypersensitivity to miocamycin

PRECAUTIONS

Treatment with miocamycin, as with other antibiotics, may give rise to superinfections from resistant bacterial agents and from mycetes, which necessitate interruption of the treatment and the initiation of a suitable therapy.
In pregnant women and in early infancy, the product is to be administered only in cases of effective necessity and always under the direct control of a physician.
In prolonged treatment in patients with hepatobiliary insufficiency, controls of hepatic functionality are advisable.

DRUG AND SUBSTANCE INTERACTIONS

An increase of carbamazepine, cyclosporine, dihydroergotamine plasmatic level is possible in case of concomitant treatment.
On the basis of pharmacokinetic studies, miocamycin does not modify the clearance of theophylline in significant manner. These results do not seem to justify, in the case of association, the need for a modification in the usual dosage of the said theophylline.

WARNINGS

It is best to avoid administration of the preparation to patients with serious hepatobiliary insufficiency.

EFFECT ON ABILITY TO DRIVE AND OPERATE MACHINERY
None

DOSAGE AND ADMINISTRATION
Adults: the daily dosage is between 900 and 1,800 mg, subdivided into 2 to 3 oral administrations.
The average daily dosage is one 600-mg tablet every 12 hours.
In serious infections, the daily dosage may be increased up to 1,800 mg in three administrations: one 600-mg tablet every 8 hours.
Children: the daily dosage is 50 mg/kg/day, subdivided into 2 to 3 administrations according to the physician's judgement.

body weight	quantity of miocamycin
up to 5 kg	250mg/day
from 5 to 10 kg	500mg/day
from 10 to 15 kg	750mg/day
from 15 to 20 kg	1,000mg/day

The dosing measurer is graduated from 1 to 10 ml, corresponding respectively to 50,100 etc. mg of miocamycin.

Instructions for use: for the preparation of the suspension, slowly add water to the bottle, being careful not to shake it.
Once the level is reached, shake the bottle hard for several minutes.
The suspension prepared in this way is ready for use, and should be kept in the refrigerator and used within 14 days.
The bottle must be shaken hard before each dose is administered.

OVERDOSAGE
No taking of an excessive dose has been reported up until now.

SIDE EFFECTS
Up until now no side effects of particular importance have been found in patients treated with miocamycin. In some cases, modest disturbances of a gastrointestinal nature (pain and abdominal bloating, nausea, vomiting, anorexia, diarrhoea) or transitory cutaneous manifestations (itching, skin eruptions) have been reported.
Any undesirable effect not described in this illustrative page should be communicated to the physician in charge or to the pharmacist.

PHARMACEUTICAL FORM AND PACKAGE
12 600-mg tablets and 30 g of granulate for extemporaneous suspension.

Keep out of the reach of children.