PATIENT INFORMATION LEAFLET

MRSACİN 50 mg Vial Containing Lyophilized Powder for IV Infusion

For I.V. administration.
Sterile
• Active ingredient: Tigecycline……50 mg
• Excipients: Maltose, Hydrochloric acid, Sodium hydroxide

Read all of this PATIENT INFORMATION LEAFLET carefully before you start using this medicine, because it contains important information for you.
• Keep this patient information leaflet. You may need to read it again later.
• If you have any further questions, consult your doctor or pharmacist.
• This medicine is prescribed for you individually, do not pass it on to others.
• During usage of this medicine, when you go to a doctor or a hospital tell your doctor that you are using this medicine.
*• Follow these instructions exactly. Do not use **higher or lower dosages** of this medicine except for recommended dosages.*

In this patient information leaflet:

1. What is MRSACİN and what is it used for
• MRSACİN is presented in 10 vial packages. It is in the form of orange, lyophilized (freeze dried) cake or powder. The dilute solution for intravenous administration is yellow-orange. Each vial contains 50 mg Tigecycline powder.
• MRSACİN is a glycylcycline group antibiotic that stops the development of bacteria which cause infections.
• MRSACIN should only be used in cases where other alternatives are known or suspected to be inappropriate.
• Your doctor must have prescribed MRSACİN to you because of one of the serious infections specified below:
- Complicated skin and skin structure infections
- Complicated intra-abdominal infections
- Community-acquired bacterial pneumonia (lung infection that is got outside of hospital)
MRSACİN is not indicated for diabetic foot infection.

2. What you need to know before using MRSACİN

DO NOT USE MRSACİN in following situations:

If;
• You are hyper-sensitive (allergic) to tigecycline or other substances contained in MRSACİN. If you are allergic to tetracycline class antibiotics like minocycline, doxycycline, you might be allergic to tigecycline too.

USE MRSACİN CAREFULLY in following situations:
If;
• If you have no healing or slow healing wound
• Symptoms of allergic reactions develop, immediately inform your doctor.
• Severe stomach ache, nausea and vomit symptoms occur, immediately inform your doctor. These might be the symptoms of acute pancreas inflammation.
• You had diarrhea before you start using MRSACİN, inform your doctor. If diarrhea occurs during or after MRSACİN treatment inform your doctor immediately. Do not take any medicine for diarrhea before you talk to your doctor.
• Tell your doctor if you have had side effects (skin sensitization to sunlight, staining of teeth during dental development, pancreatic inflammation and detection of changes in blood clotting values in laboratory tests) due to the use of tetracycline class antibiotics before or during treatment.
• In some serious infections, your doctor may suggest MRSACİN with other antibiotics.
• Your doctor will follow you closely about the occurrence of other bacterial infections. If another bacterial infection develops, your doctor may prescribe another antibiotic based on the type of infection.
• You had or have liver disease, inform your doctor. According to your liver condition, your doctor may reduce the dose in order to reduce possible side effects.
• Inform your doctor if there is a blockage of the bile duct (cholestasis).
• While antibiotics including MRSACİN fight with specific bacteria, other bacteria and fungi continue to reproduce. Your doctor will monitor you in case of possible infections and treat you if necessary.
MRSACİN must not be used in children and young people (under age 18). Tigecycline should not be used in children under 8 years of age as it may cause permanent tooth damage such as spotting in developing teeth

Clinical studies have shown an increase in all-cause mortality rates.

If these precautions are valid for you even in the past, please consult your doctor.

Using MRSACİN with food and drinks:
With regard to administration route, there is no data for interaction with food and drinks.

Pregnancy
Before using this medicine, consult your doctor or pharmacist.
MRSACIN may cause harm to the baby in the case of pregnancy. If you are pregnant or are planning to become pregnant, consult your doctor before using MRSACIN.
Your doctor will recommend contraceptive measures due to your MRSACIN treatment.
If you notice that you are pregnant during treatment, immediately consult your doctor.

Breastfeeding
Before using this medicine, please consult your doctor or pharmacist.
It is not known whether MRSACİN is transferred to breast milk or not. Consult your doctor before you breastfeed your baby.

Driving and machinery usage
Tigecycline can cause dizziness. This situation might affect your driving or machinery usage abilities.

Important information about excipients of MRSACİN
Each 1 ml of this medical product contains less than 23 mg sodium. There is no side effect expected due to this amount of sodium.

Usage with other medicines
It is important that you tell your doctor if you are taking medicines (anticoagulant) to avoid an excess of blood clotting and changes are detected in laboratory tests about how well your blood clots. Your doctor may monitor you closely.
MRSACİN may cause interaction with contraceptive pill (birth control pill). Talk to your doctor about the need of an additional method of (not hormonal) contraception while receiving MRSACİN.
Please inform your doctor if you are taking a medication that can reduce the effectiveness of an enzyme called p-gp (such as ketaconazole for the treatment of fungal diseases and cyclosporin used for the suppression of the immune system) or can increase it (such as rifampicin used in the treatment of tuberculosis). These drugs can alter the effect of MRSACIN on your body (pharmacokinetics).
If you are currently using or have recently used any prescription or over-the-counter drug, inform your doctor or pharmacist of these drugs.

3. How to use MRSACİN

Instructions for proper usage and dosage/administration frequency:
Your doctor will adjust the dose according to your disease and administrate to you.
Suggested dose is initially 100 mg, then 50 mg every 12 hours. Suggested treatment time is generally 5-14 days for complicated skin and skin structure infections and complicated intra-abdominal infections. Suggested treatment time for community-acquired bacterial pneumonia is 7-14 days. Your doctor will inform you of how long the MRSACİN treatment will last.
If you have any further questions on how to use this drug, consult your doctor or pharmacist.

Administration method and route
MRSACIN is given intravenously (directly into your blood stream) drop by drop over a period of 30 to 60 minutes by your doctor or nurse.

Different age groups
Usage in children
MRSACİN must not be used on children and young people under age 18.

Usage in geriatric patients:
Dosage arrangement is not necessary for geriatrics.

Special usage conditions

Renal failure:
There is no need for a dose adjustment for people who have renal failure or are having hemodialysis treatment.

Liver failure:
There is no need for a dose adjustment for patients with mild or moderate liver failure. If you have severe liver failure, your doctor will control you while using MRSACİN.

If you notice that the effects of MRSACİN are too low or too high, talk to your doctor or pharmacist.

If you have used more than required dosage of MRSACİN
If you worry that you have taken more MRSACİN than you should, immediately talk to your doctor or nurse.

If you have forgotten to take MRSACİN
If you worry that you have missed a dose of MRSACİN, immediately talk to your doctor or nurse.
Do not take double doses to balance the forgotten dose.

Possible effects after end of the MRSACİN treatment
Continue to use your medication until your doctor terminates your treatment.

4. What are possible side effects?
Like all other medicines, side effects can be seen in people who are sensitive to ingredients of MRSACİN.

If you have any of the following, stop using MRSACIN and IMMEDIATELY tell your doctor or contact the emergency department of the hospital nearest you
• Severe skin reactions including skin swelling, redness, skin peeling (Steven-Johnson syndrome).
• Itching, rash, difficulty in breathing, fall in blood pressure, acceleration in pulse.

Other side effects seen with MRSACIN are as follows and side effects are listed in the following categories.
Very common : It can be seen in at least 1 of 10 patients.
Common : Less than one in 10 patients, but more than one in 100 patients.
Uncommon : Less than one in 100 patients, but more than one in 1000 patients.
Rare : Less than one in 1,000 patients, but more than one in 10,000 patients visible.
Very rare : less than one in 10,000 patients.
Unknown : Unable to predict based on available data.

Very Common side effects:
•Nausea, vomiting, diarrhea
Common:
• Abscess (collection of pus), infections
• Laboratory measurements of decreased ability to form blood clots
• Dizziness
• Abdominal pain, dyspepsia (stomach ache and indigestion), anorexia (loss of appetite)
• Increase in liver enzymes, hyperbilirubinemia (increase of bile pigment in the blood)
• Pruritus (itching), rash
• Abnormality in tissue healing. Slow healing or no healing of the wound
• Headache
• Increase in amylase, which is an enzyme found in the salivary glands and pancreas, increased blood urea nitrogen (BUN).
• Pneumonia
• Low blood sugar
•Sepsis (severe infection in the body and blood) / septic shock (a serious disease that can lead to many organ failure and death due to sepsis)
•Application site reactions (pain, redness, inflammation)
•Decrease of protein levels in blood
Uncommon:
•Acute pancreatitis (inflamed pancreas which may result in severe abdominal pain, nausea, and vomiting)
•Jaundice (yellow coloration of the skin), inflammation of the liver
• Reduced blood count in the blood (increased bleeding tendency and bruising / hematoma)
• Irritation due to infection, such as pain at the injection site, swelling and clot formation
Unknown:
• Liver failure
• Low fibrinogen levels in the blood (a protein involved in blood clotting)
Pseudomembranous colitis may occur with most antibiotics including MRSACİN. This consists of severe, persistent or bloody diarrhea associated with abdominal pain or fever, which can be a sign of serious bowel inflammation, which may occur during or after your treatment.
If you notice other side effects which are not described in this patient information leaflet, inform your doctor or pharmacist.
Reporting of side effects
If you feel any side effects listed or not listed in this leaflet, talk to a doctor, pharmacist or nurse. Furthermore report the side effects you feel by clicking "Reporting Medicine Side Effect" at www.titck.gov.tr or by calling 0 800 314 00 08 side effect report line of Turkey Pharmacovigilance Center. By reporting side effects, you can help provide more information on the safety of this medicine

5. How to store MRSACİN
Keep MRSACİN out of the reach and sight of children and store in the package.
MRSACİN must be kept in proper conditions in a hospital.
Store MRSACİN at room temperature below 25°C.

Storage after dilution:
After MRSACİN is prepared for usage, it can be stored for up to 24 hours in room temperature (25°C), up to 48 hours in refrigerator (2°C -8°C).
Do not use MRSACİN after the expiry date written on the package or vial.
Registration holder: Biem İlaç San. ve Tic. A.Ş.
Anıttepe Mah. Turgut Reis Cad. No:21
Tandoğan / Çankaya - Ankara

Manufacturing site: Mefar İlaç Sanayii A.Ş.
Kurtköy-Pendik / İstanbul

This patient information leaflet was approved on 30/11/2018.

THE FOLLOWING INFORMATION IS INTENDED FOR MEDICAL OR HEALTHCARE PROFESSIONALS ONLY:

Instructions for preparation and use
The lyophilised powder should be reconstituted with 5 ml of sodium chloride 9 mg/ml (0.9 %) solution for injection or dextrose 50 mg/ml (5 %) solution for injection to achieve a concentration of 10 mg/ml of tigecycline. The vial should be gently swirled until the active substance is dissolved. Thereafter, 5 ml of the reconstituted solution should be immediately withdrawn from the vial and added to a 100 ml intravenous bag for infusion.

For a 100 mg dose, reconstitute using two vials into a 100 ml intravenous bag. (Note: The vial contains a 6 % overage. Thus, 5 ml of reconstituted solution is equivalent to 50 mg of the active substance.) **The reconstituted solution should be orange or dark orange in color; if not, the solution should be discarded.** Parenteral products should be inspected visually for particulate matter and discoloration (e.g. green or black) prior to administration. When reconstituted in IV bag, tigecycline can be stored up to 24 hours in room temperature (25°C), up to 48 hours in refrigerator (2°C -8°C).

Unused solutions must be discarded

MRSACİN may be administered intravenously through a dedicated line or through a Y-site. If the same intravenous line is used for sequential infusion of several active substances, the line should be flushed before and after administration of MRSACİN with either sodium chloride 9 mg/ml (0.9 %) solution for injection or dextrose 50 mg/ml (5 %) solution for injection. An infusion solution compatible with tigecycline must be used and any other medicinal product(s) administrated via this common line must be compatible with tigecycline.

Drugs and solutions which are compatible with MRSACİN

Compatible intravenous solutions include: sodium chloride 9 mg/ml (0.9 %) solution for injection (USP), dextrose 50 mg/ml (5 %) solution for injection (USP), and Lactated Ringer's solution for injection (USP). When administered together, compatibility of MRSACİN diluted in sodium chloride 0.9 % (USP) or dextrose 5 % solution (USP) may be demonstrated with the following medicinal products or solutions: amikacin, dobutamine, dopamine HCl, gentamicin, haloperidol, Lactated Ringer's solution, lidocaine HCl, metoclopramide, morphine, norepinephrine, piperacillin/tazobactam (EDTA formulation), potassium HCL, propofol, ranitidine HCl, theophylline, and tobramycin.