

PATIENT INFORMATION LEAFLET SCHEDULING STATUS: SA

MEROZIN™ 500

MEROZIN™ 1000

Powder for solution for injection or infusion
Meropenem anhydrous (as trihydrate)

Sugar free

MEROZIN 500: Contains 45 mg sodium per vial.
MEROZIN 1 000: Contains 90 mg of sodium per vial.

Read all of this leaflet carefully before you give MEROZIN

Keep this leaflet. You may need to read it again.

If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.

What is in this leaflet:

- What MEROZIN is and what it is used for
- What you need to know before MEROZIN is given
- How MEROZIN is given
- Possible side effects
- How to store MEROZIN
- Contents of the pack and other information

1. What MEROZIN is and what it is used for

MEROZIN contains the active ingredient meropenem. Meropenem belongs to a group of medicines called carbapenem antibiotics. It works by killing bacteria, which can cause serious infections.

MEROZIN is prescribed by doctors for bacterial infections in adults and children. These infections may occur in the lungs, bladder and kidney, abdomen, skin, brain or female reproductive organs.

For certain infections your doctor may also prescribe an aminoglycoside type of antibiotic (for example, gentamycin, tobramycin, streptomycin).

2. What you need to know before MEROZIN is given

MEROZIN should not be administered to you:

- if you are allergic (hypersensitive) to meropenem or any of the other ingredients of MEROZIN (listed in section 6).
- if you are allergic (hypersensitive) to other antibiotics such as penicillins, cephalosporins, or carbapenems, as you may also be allergic to MEROZIN.
- if you are pregnant or breastfeeding (see Pregnancy, breastfeeding and fertility).

Warnings and precautions

Take special care with MEROZIN:

- if you have ever had an allergic reaction to any other antibiotics;
- if severe diarrhoea develops during treatment, consult your doctor immediately as this may be a symptom of a condition called pseudomembranous colitis that could be life-threatening. Do not take any medication to stop the diarrhoea, (see POSSIBLE SIDE EFFECTS);
- if you have kidney problems or receive dialysis for kidney failure, as your doctor may want to adjust your dose;
- if you have liver problems as your doctor will need to closely monitor your condition;
- if you have epilepsy and are taking valproic acid) as MEROZIN should not be administered at the same time (see Other medicines and MEROZIN).

You may develop signs and symptoms of severe skin reactions (see POSSIBLE SIDE EFFECTS). If this happens, talk to your doctor or nurse immediately so that they can treat the symptoms.

You may develop a positive blood test ("Coombs test") which indicates the presence of antibodies that may destroy red blood cells.

Your doctor will discuss this with you.

If you are not sure if any of the above apply to you, talk to your doctor or nurse before MEROZIN is administered to you.

Children and adolescents:

Safety and efficacy have not been established in children less than 3 months old and MEROZIN is not recommended for children younger than 3 months.

Other medicines and MEROZIN

Always tell your healthcare provider if you are taking any other medicine. This includes complementary or traditional medicines.

MEROZIN may interact with the following medicines:

- Probenecid (used to treat gout) should not be used while being treated with MEROZIN because it increases the concentration of MEROZIN in your body.
- Valproic acid/sodium valproate (used to treat epilepsy). MEROZIN should not be used with these medicines because it decreases the effect of sodium valproate, impacting the control of seizures.
- Warfarin (used to treat or prevent blood clots), as MEROZIN may increase the effects of warfarin and your doctor may want to monitor your blood clotting time.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before using MEROZIN.

The safety of MEROZIN during pregnancy has not been established. MEROZIN should therefore not be used during pregnancy.

It is important that you tell your doctor if you are breastfeeding or if you intend to breastfeed before receiving MEROZIN. Small amounts of meropenem may pass into the breastmilk and it may affect the baby. You should therefore not breastfeed your baby if you have to be treated with MEROZIN, or your doctor may decide on another treatment if you continue breastfeeding.

There is no data on fertility and the use of MEROZIN.

Driving and using machines

Headache and tingling or pricking skin (paraesthesia) are possible side effects of MEROZIN. MEROZIN may cause involuntary muscle movements which may cause the person's body to shake rapidly and uncontrollably (convulsions).

Any of these side effects could affect your ability to drive or operate machines. It is not always possible to predict to what extent MEROZIN may interfere with your daily activities. You should not drive or use machines until you are aware of the measure to which MEROZIN affects you.

MEROZIN contains sodium

MEROZIN 500 mg contains 45 mg sodium (main component of cooking/table salt) in each vial. This is equivalent to 2.3 % of the recommended maximum daily dietary intake of sodium for an adult.

MEROZIN 1 000 mg contains 90 mg sodium (main component of cooking/table salt) in each vial. This is equivalent to 4.5 % of the recommended maximum daily dietary intake of sodium for an adult.

Your doctor will take this into account if you are on a sodium-controlled diet. If you have a condition which requires you to monitor your sodium intake, such as hypertension, please inform your doctor or healthcare provider.

3. How MEROZIN will be given to you

You will not be expected to give yourself MEROZIN. It will be given to you by a person who is qualified to do so.

Your doctor will tell you how long your treatment with MEROZIN will last.

Your doctor will determine the dose you require. The dose depends on the type of infection that you have, where the infection is in the body and how serious the infection is. Your doctor will also take into account your kidney function.

MEROZIN will be given to you as an injection or infusion into a large vein.

Your healthcare provider will ensure that the injection is not mixed with, or added to, solutions that contain other medicines.

The injection may take about 5 minutes and the infusion between 15 and 30 minutes. You should normally have your injections at the same times each day.

MEROZIN will be given to you as an injection or infusion into a large vein.

Your healthcare provider will ensure that the injection is not mixed with, or added to, solutions that contain other medicines.

The injection may take about 5 minutes and the infusion between 15 and 30 minutes. You should normally have your injections at the same times each day.

Safety and efficacy in babies under 3 months have not been established and MEROZIN is therefore not recommended in this age group.

If you are given more MEROZIN than you should

Since a healthcare provider will administer MEROZIN, he/she will control the dosage. However, in the event of overdose your doctor will manage the overdose.

If you missed a dose of MEROZIN

Since a healthcare provider will administer MEROZIN, it is unlikely that the dose will be missed.

4. Possible side effects

MEROZIN can have side effects.

Not all side effects reported for MEROZIN are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using MEROZIN, please consult your doctor, pharmacist or other healthcare provider for advice.

If any of the following happens, tell your doctor or nurse immediately, as he/she may decide to stop administering MEROZIN:

Severe allergic reactions:

- Swelling of the face, lips, tongue or other parts of the body.
- Shortness of breath, wheezing or trouble breathing.
- Severe rash, itching or hives on the skin.
- Serious allergic skin reactions which include:
 - Fever, skin rash, and changes in the blood tests that check how the liver is working (increased levels of liver enzymes) and an increase in a type of white blood cell (eosinophilia) and enlarged lymph nodes. These may be signs of a multi-organ sensitivity disorder known as "Drug reaction with eosinophilia and systemic symptoms" (DRESS)- syndrome.
 - Severe red scaly rash, itching, skin bumps that contain pus, blisters or peeling of the skin (erythema multiforme), sometimes also with fever and joint pains.
 - Severe skin rashes that can appear as redish circular patches (often with central blisters on the trunk), skin peeling, ulcers of mouth, throat, nose, genitals and eyes and can be preceded by fever and flu-like symptoms (Stevens-Johnson syndrome) or a more severe form (toxic epidermal necrolysis).

Damage to red blood cells:

- The signs include breathlessness when you do not expect it, red or brown urine, yellowing of skin and eyes, abnormal paleness, fever (haemolytic anaemia).

Apnoea: Breathing stops and starts while sleeping.

Pseudomembranous colitis: Watery diarrhoea, bloody stools, and fever.

These are all very serious side effects. If you have them, you may have had a serious reaction to MEROZIN. You may need urgent medical attention or further hospitalisation.

Tell your doctor if you notice any of the following:

- Frequent side effects**
- Unexplained bruising, bleeding (thrombocythaemia)
 - Headache
 - Diarrhoea
 - Abdominal (stomach) pain
 - Feeling sick (nausea)
 - Being sick (vomiting)
 - Constipation
 - Blood tests show that your liver is not functioning well
 - Skin rash, itchy skin
 - Pain and inflammation
 - Inflammation of a vein that occurs when a blood clot forms (thrombophlebitis) – you may experience pain, swelling or redness at the site.

Less frequent side effects

- Infectors of the mouth (white lesions on the inside of your mouth) or the vagina (itchiness and a thick white discharge) that are caused by a fungus (thrush)
- Sore throat
- Other changes in your blood. Some signs are frequent infections, high temperature and sore throat (agranulocytosis). Your doctor may do blood tests from time-to-time
- Bruising easily (thrombocytopenia)

- Changes in your blood. These include less blood platelets (this may make you bruise more easily), increased numbers of some other white blood cells, decreased numbers of other white cells and increased amounts of a substance called 'bilirubin'. Your doctor may do blood tests from time to time

- Low blood sugar
- Acute disorientation and confusion (delirium)
- A tingling feeling (pins and needles)
- Fits (convulsions)
- Nose bleeding
- Inflammation of the bowel with diarrhoea
- Skin rashes or other skin conditions, such as flushing, hives, itching, dry skin
- Blood tests showing that kidneys are not functioning well
- Pain at the injection site.

Frequency unknown:

- Reduced sense of touch and sensation (numbness), cold/blue/aching feet when resting, sore legs or feet (symptoms of a blood circulation disorder).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and the eReporting platform (who-umc.org) found on the SAHPRA website. By reporting side effects, you can help provide more information on the safety of MEROZIN.

5. How to store MEROZIN

Storage will be handled by healthcare providers.

Dry powder:

Store all medicines out of reach of children.

Store at or below 25 °C. Do not freeze. Keep the vial in the outer carton in order to protect from light.

Reconstituted solution:

The reconstituted solution should be used immediately.

Do not freeze the reconstituted solution.

Single use only. Discard any unused portion.

Do not use MEROZIN after the expiry date which is stated on the container. The expiry date refers to the last day of that month.

Do not dispose of unused medicine in drains or sewerage systems (e.g., toilets).

6. Contents of the pack and other information

What MEROZIN contains

The active substance is meropenem.

MEROZIN 500: Each vial contains 500 mg meropenem anhydrous (as trihydrate).

MEROZIN 1 000: Each vial contains 1 000 mg meropenem anhydrous (as trihydrate).

The other ingredient is sodium carbonate.

What MEROZIN looks like and contents of the pack

MEROZIN is a white to light yellow, crystalline powder. The reconstituted solution is a clear colourless solution practically free from particulate matter.

MEROZIN 500 is packed in 20 ml Type I colourless glass vials, closed with grey bromobutyl rubber stoppers and plastic-aluminium caps, available in pack sizes of 1 or 10 vials.

MEROZIN 1 000 is packed in 30 ml Type I colourless glass vials closed with grey bromobutyl rubber stoppers and plastic-aluminium caps, available in pack sizes of 1 or 10 vials.

Not all pack sizes may be marketed.

Holder of the Certificates of Registration

Abex Pharmaceutica (Pty) Ltd

Suite C, Rubenstein Ridge

617 Rubenstein Drive

Moreleta Park, 0181

South Africa

Tel: +27 (0)12 997 6974

Marketed by:

AFT Pharmaceuticals SA (Pty) Ltd

Suite A, Rubenstein Ridge

617 Rubenstein Drive

Moreleta Park, 0181

This leaflet was last revised in

August 2025

Registration numbers

MEROZIN 500: 57/2011/0514/512

MEROZIN 1 000: 57/2011/0515/513

PASIENTINLIGTINGSBLAD SKEDULERINGSTATUS: SA

MEROZIN™ 500

MEROZIN™ 1000

Poeier vir oplossing vir inspuiting of infusie
Meropenem anhidries (as trihidraat)

Suikervry

MEROZIN 500: Bevat 45 mg natrium per flesie.

MEROZIN 1 000: Bevat 90 mg natrium per flesie.

Lees die hele inligtingsblad aandagtig deur voordat MEROZIN aan jou gegee word

Hou hierdie inligtingsblad. Dit is moontlik dat jy dit weer sal wil deurlees.

Indien jy verdere vrae het, vra jou dokter, apteker, verpleegster of ander gesondheidsorgerskaffer.

Wat is in hierdie inligtingsblad:

- Wat is MEROZIN en waarvoor word dit gebruik
- Wat jy moet weet voordat MEROZIN aan jou gegee word
- Hoe MEROZIN gegee sal word
- Moontlike newe-effekte
- Hoe om MEROZIN te bewaar
- Inhoud van die pak en ander inligting

1. Wat is MEROZIN en waarvoor word dit gebruik

MEROZIN bevat die aktiewe bestanddeel meropenem. Meropenem behoort tot 'n groep medisyne genaamd karbapenem-antibiotika.

Dit werk deur bakterieë, wat ernstige infeksies kan veroorsaak, te dood.

MEROZIN word vir bakteriële infeksies by volwassenes en kinders deur dokters voorgeskryf. Hierdie infeksies kan in die longe, blaas en niere, buik, vel, brem of vroulike voortplantingsorgane voorkom.

Vir sekere infeksies kan jou dokter ook 'n aminoglikosied-tipe antibiotika (byvoorbeeld gentamisien, tobramisien, streptomisien) voorskryf.

2. Wat jy moet weet voordat MEROZIN aan jou gegee word

MEROZIN moet nie aan jou toegedien word nie:

- indien jy allergies (hipersensitief) is vir meropenem of enige van die ander bestanddele van MEROZIN (gelys in afdeling 6).
- indien jy allergies (hipersensitief) is vir ander antibiotika soos penisilliene, kefalosporiene of karbapenems, aangesien jy dan ook vir MEROZIN allergies kan wees.
- indien jy swanger is of borsvoed (kyk Swangerskap, borsvoeding en vrugbaarheid).

Waarskuldigings en voorsorgmaatreëls

Wees versigtig met MEROZIN:

- indien jy al ooit 'n allergiese reaksie op enige ander antibiotika gehad het;
- indien erge diarree tydens die behandeling ontwikkel, raadpleeg dadelik jou dokter, aangesien dit 'n simptome kan wees van 'n siektetoestand genaamd pseudomembraneuse kolitis, wat lewensgevaarlik kan wees. Moenie enige medisyne neem om die diarree te stop nie. (Sien MOONTLIKE NEWE-EFFEKTE).
- indien jy nierprobleme het of dialise vir nierversaking ontvang, aangesien jou dokter daik dan jou dosis sal aanpas;
- indien jy leverprobleme het, aangesien jou dokter jou siektetoestand noulettend sal moet dophou;
- indien jy epilepsie het en valproemid (valproiensuur) neem, aangesien MEROZIN nie gelyktydig toegedien moet word nie (kyk Ander medisyne en MEROZIN).

Jy kan tekens en simptome van ernstige vrekreïes ontwikkel (sien MOONTLIKE NEWE-EFFEKTE). Indien dit gebeur, praat dadelik met jou dokter of verpleegster sodat hulle die simptome kan behandel.

Jy kan 'n positiewe bloedtoets ("Coombs-toets") ontwikkel, wat dui op die aanwesigheid van antiliggame wat rooi-bloedselle kan vernietig. Jou dokter sal dit met jou bespreek.

Indien jy twyfel of enige van die bogenoemde op jou van toepassing is, raadpleeg jou dokter of verpleegster voordat MEROZIN aan jou toegedien word.

Kinders en adolessente:

Veiligheid en doeltreffendheid is nie vir kinders onder 3 maande oud bepaal nie. MEROZIN word nie vir kinders onder 3 maande oud aanbeveel nie.

Ander medisyne en MEROZIN

Lig aityd jou gesondheidsorgerskaffer in as jy enige ander medisyne neem. Dit sluit komplementêre of tradisionale medisyne in.

MEROZIN kan 'n interaksie met die volgende medisyne hê:

- Probenesid (gebruik vir die behandeling van jiq) moet nie gebruik word terwyl jy met MEROZIN behandel word nie, want dit verhoog die konsentrasie van MEROZIN in jou liggaam.
- Valproiensuur/natriumvalproaat (gebruik vir die behandeling van epilepsie). MEROZIN moet nie saam met hierdie medisyne gebruik word nie, omdat dit die werking van natriumvalproaat verminder, wat die beheer van aanvalle beïnvloed.
- Warfarien (gebruik vir die behandeling van of voorkoming van bloedklonte), aangesien MEROZIN die uitwerking van warfarien kan verhoog en u dokter moontlik u bloedstollingstyd wil monitor.

Swangerskap, borsvoeding en vrugbaarheid

Indien jy swanger is of jou baba borsvoed, dink jy is dalk swanger, of beplan om 'n baba te hê, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgerskaffer voordat jy MEROZIN gebruik.

Die veiligheid van MEROZIN tydens swangerskap is nie bepaal nie. MEROZIN moet gevolglik nie tydens swangerskap gebruik word nie.

Dit is belangrik dat jy, voordat jy MEROZIN ontvang, jou dokter inlig as jy borsvoed of van plan is om jou baba te borsvoed. Klein hoeveelhede meropenem kan in die borsmelk voorkom en dit kan die baba beïnvloed. Jy moet dus nie jou baba borsvoed as jy met MEROZIN behandel moet word nie, of jou dokter kan op 'n ander behandeling besluit as jy aanhou borsvoed.

Daar is geen data oor vrugbaarheid en die gebruik van MEROZIN nie.

Bestuur en die gebruik van masjinerie

Hoofpyn en tintelende of prikkelige vel (parestesie) is moontlike newe-effekte van MEROZIN. MEROZIN kan onwillekeurige spierbewegings veroorsaak, waardeur die liggaam van die persoon vinnig en onbeheerbaar kan ruk (konvulsies).

Enige van hierdie newe-effekte kan jou vermoë om te bestuur of masjiene te gebruik, beïnvloed. Dit is nie altyd moontlik om te voorspel tot hoe 'n mate MEROZIN jou daaglikse aktiwiteite kan beïnvloed nie. Jy moet nie bestuur of masjinerie gebruik voordat jy nie weet tot welke mate MEROZIN jou aantens nie.

MEROZIN bevat natrium

MEROZIN 500 mg bevat 45 mg natrium (hoofkomponent van kook/tafelsout) in elke flesie. Dit is gelykstaande aan 2,3 % van die aanbevole maksimum daaglikse dieetinname van natrium vir 'n volwassene.

MEROZIN 1 000 mg bevat 90 mg natrium (hoofkomponent van kook/tafelsout) in elke flesie. Dit is gelykstaande aan 4,5 % van die aanbevole maksimum daaglikse dieetinname van natrium vir 'n volwassene.

Jou dokter sal dit in ag neem as jy op 'n natrium-beheerde dieet is. Indien jy 'n toestand het wat vereis dat jy jou natriumnamme dophou, soos hipertensie, lig asseblief jou dokter of gesondheidsorgerskaffer in.

3. Hoe MEROZIN aan jou gegee sal word

Daar sal nie van jou verwag word om MEROZIN aan jouself toe te dien nie. Dit sal aan jou gegee word deur 'n persoon wat gekwalifiseer is om dit te doen.

Jou dokter sal jou inlig hoe lank jou behandeling met MEROZIN sal aanhou.

Jou dokter sal die regte dosis vir jou bepaal. Die dosis hang af van die tipe infeksie wat jy het, waar die infeksie in die liggaam is en hoe ernstig die infeksie is. Jou dokter sal ook jou nierfunksie in ag neem.

MEROZIN sal aan jou gegee word as 'n inspuiting of infusie in 'n groot aar. Jou gesondheidsorgerskaffer sal verseker dat die inspuiting nie by oplossings wat ander medisyne bevat, gemeng of bygevoeg word nie. Die inspuiting kan ongeveer 5 minute duur en die infusie tussen 15 en 30 minute. Normalweg moet jy jou inspuitings elke dag op dieselfde tyd kry.

Veiligheid en doeltreffendheid by babas jonger as 3 maande is nie vasgestel nie en MEROZIN word dus nie vir hierdie ouderdomsgroep aanbeveel nie.

Indien jy meer MEROZIN ontvang as wat jy moet

Aangesien 'n gesondheidsorgerskaffer MEROZIN sal toedien, sal hy/sy die dosis beheer. In geval van oordosering sal jou dokter egter die oordosering behandel.

Indien jy 'n dosis van MEROZIN oorgeslaan het

Aangesien 'n gesondheidsorgerskaffer MEROZIN sal toedien, is dit onwaarskynlik dat die dosis oorgeslaan sal word.

4. Moontlike newe-effekte

MEROZIN kan newe-effekte hê.

Nie alle newe-effekte wat vir MEROZIN aangemeld is, is by hierdie inligtingsblad ingesluit nie. Indien jou algemene gesondheid agteruitgaan of jy enige ongunstige effekte ervaar terwyl jy MEROZIN ontvang, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgerskaffer.

Indien enige van die volgende gebeur, lig jou dokter of verpleegster dadelik in, want hy/sy kan dalk besluit om toediening van MEROZIN te staak:

Erge allergiese reaksies:

- Opgeswelde gesig, lippe, tong of ander dele van die liggaam.
- Kortasemigheid, hyging of moeilike asemhaling.
- Erge uitslag, jeuk of netelroos op die vel.
- Ernstige allergiese vrekreïes wat insluit:
 - Koors, veluitslag en veranderinge in bloedtoetsme om lewerfunksie te kontroleer (verhoogde lewerensieme), 'n toename in 'n sekere tipe witbloedsel (eosinofie) en vergrote limfknope. Dit kan tekens wees van 'n multi-orgaan sensitiviteitsversteuring bekend as "Drug reaction with eosinophilia and systemic symptoms" (DRESS)-sindroom.
 - Erge rooi, skubberige uitslag, jeuk, etterge vulde knoppe op die vel, blase of afskiferende vel (erythema multiforme), soms met koors en gewrigspyne.
 - Erge veluitslag, wat as rooierige, ronde kolle (dikwels met blase in die middel) op die romp kan voorkom, afskiferende vel, sere in die mond, keel, nes, geslagsdele en oë; dit kan voorafgegaan word deur koors en griepagtige simptome (Stevens-Johnson-sindroom) of 'n ernstiger vorm (toksiese epidermale nekrolise).

Skade aan rooi-bloedselle: