PATIENT INFORMATION LEAFLET

CYTAGIL IV

SCHEDULING STATUS:

S4

CYTAGIL IV powder for solution for infusion

Tigecycline

Sugar and sodium free

Read all of this leaflet carefully before you are given CYTAGIL IV

- 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

1. What CYTAGIL IV is and what it is used for
2. What you need to know before you are given CYTAGIL IV
3. How to receive CYTAGIL IV
4. Possible side effects
5. How to store CYTAGIL IV
6. Contents of the pack and other information

1. What CYTAGIL IV is and what it is used for

CYTAGIL IV contains tigecycline, one of a group of antibiotics of the glycylcycline group that works by stopping the growth of bacteria that cause infections.

CYTAGIL IV is an antibiotic used to treat the following severe life-threatening infections in adults:

- complicated infections of the skin and soft tissues (the tissue below the skin)
- complicated infections of the abdomen.

2. What you need to know before you are given CYTAGIL IV

CYTAGIL IV should not be administered to you:

- if you are hypersensitive (allergic) to tigecycline or any of the other ingredients of CYTAGIL IV (listed in section 6)
- if you are pregnant or breastfeeding your baby.

Warnings and precautions

Tell your doctor or healthcare professional before receiving CYTAGIL IV:

- if you have, or have previously had liver problems, signs include yellowing of the skin and whites of the eyes (jaundice), fatigue, itching and loss of appetite. Depending on the condition of your liver, your doctor may reduce the dose to avoid potential side effects
- if you previously had any side effects to antibiotics, including sensitivity of skin to the sun, headaches or vision problems caused by an increase of pressure in the brain, changes in blood test results indicating nitrogen, acid or phosphate levels
- if you have, or have previously had problems with blood clotting or are taking medicines to thin your blood. Inform your doctor or healthcare professional if you experience changes of certain blood test values aimed at measuring how well your blood clots
- if you have blockage of the bile ducts (cholestasis), abnormal blood sugar levels, HIV-positive infection and any underlying disease
- if you are suffering from diarrhoea before you are given CYTAGIL IV. If you develop diarrhoea during or after your treatment, tell your doctor or healthcare provider immediately, and do not take any diarrhoea medicine without first consulting with your healthcare provider

- if you have an infection in your abdomen, as it could result in complications when being administered with CYTAGIL IV.

During treatment with CYTAGIL IV:

- although CYTAGIL IV fights certain bacteria, other bacteria and fungi may continue to grow; known as ‘overgrowth’. Your doctor or healthcare provider will monitor you closely for any potential infections and treat you if necessary
- tell your doctor or healthcare provider immediately if you develop symptoms of an allergic reaction, including swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- tell your doctor or healthcare provider immediately if you develop severe abdominal pain, nausea, and vomiting; these may be symptoms of acute pancreatitis (inflamed pancreas)
- staining may occur of developing teeth.

Children and adolescents

Safety and effectiveness in patients under 18 years of age have not been established. Therefore, use of CYTAGIL IV in patients under 18 years of age is not recommended.

Other medicines and CYTAGIL IV

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

It is important to tell your doctor or healthcare provider if you are taking any of the following:

- CYTAGIL IV may increase the effect of medicines used to suppress the immune system (such as tacrolimus or cyclosporin). It is important that you tell your doctor if you are taking these medicines so you can be closely monitored
- medicines which prevent or reduce coagulation of the blood (commonly known as blood thinners), such as warfarin, since CYTAGIL IV may increase the effect of these medicines
- oral contraceptive (birth control) pill, since CYTAGIL IV may cause the pill to be less effective. Talk to your doctor or healthcare provider about using additional contraception while receiving CYTAGIL IV
- certain medicines could affect how CYTAGIL IV works, e.g. ketoconazole (to treat fungal infections), rifampicin (TB treatment) and ciclosporin (uses include to prevent organ transplant rejection, treatment for psoriasis and rheumatoid arthritis).

Pregnancy, breastfeeding and fertility

CYTAGIL IV should not be used if you are pregnant or breastfeeding your baby (see Do not take CYTAGIL IV).

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare professional for advice before receiving CYTAGIL IV.

CYTAGIL IV may make the contraceptive “pill” less effective.

This means you should use a different type of contraception while taking this medicine. Use of a reliable barrier method of contraception such as condoms or the “coil” is recommended while taking CYTAGIL IV and for some time after your treatment has stopped. If you are unsure, please consult your doctor, pharmacist or other healthcare provider for advice.

Driving and using machines

CYTAGIL IV may cause dizziness, which may impair your ability to drive or operate machinery.
It is not always possible to predict to what extent CYTAGIL IV may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which CYTAGIL IV affects them.

3. How to receive CYTAGIL IV

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

CYTAGIL IV will be administered to you by intravenous infusion (injected into a vein). The usual dose is 100 mg, followed by 50 mg every 12 hours. Each infusion will last between 30 and 60 minutes.

Your doctor will tell you how long your treatment with CYTAGIL IV will last, however usual treatment is between 5 to 14 days.
If you have the impression that the effect of CYTAGIL IV is too strong or too weak, tell your doctor or pharmacist.

If you receive more CYTAGIL IV than you should:

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

If you forget a dose of CYTAGIL IV:

Since a healthcare professional will administer CYTAGIL IV, it is unlikely that the dose will be missed.

4. Possible side effects

CYTAGIL IV can have side effects.

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

If any of the following happens, stop using CYTAGIL IV and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching.

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

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- sepsis or septic shock (severe infection in the body and blood stream) which can lead to multiple organ failure and death. Symptoms include fever, chills, confusion, anxiety, difficulty breathing, feeling extremely tired, feeling sick or being sick
- unusual or increased bleeding
- inflammation of a vein in the legs or arms, including pain, swelling, redness or tenderness (signs of a possible blood clot)
- severe, persistent or bloody diarrhoea associated with abdominal pain or fever, which can be a sign of serious bowel inflammation

- severe abdominal pain, nausea, and vomiting; these may be symptoms of acute pancreatitis (inflamed pancreas)
- yellowing of the skin and whites of the eyes (jaundice), fatigue, itching, loss of appetite, dark urine, blood tests indicate an increase in liver enzymes; signs of liver problems or liver failure
- Stevens-Johnson syndrome or other serious skin disorder (begins with flu-like symptoms, followed by a painful red or purplish rash that spreads and blisters).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- abscess (collection of pus), infections
- infection of the lungs (pneumonia), with symptoms such as cough with phlegm or pus, fever, chills, and difficulty breathing
- blood tests indicating low blood sugar, low level of blood protein (which could indicate liver, kidney or digestive disorders), high bilirubin (symptoms include abdominal pain or swelling, chills, fever, chest pain, weakness, fatigue and nausea)
- dizziness
- nausea, vomiting, diarrhoea, loss of appetite, stomach pain or indigestion
- itchy skin, skin rash
- headache, irritation at the injection site, slow wound healing
- blood tests indicating high blood urea nitrogen (BUN, which could indicate kidney problems), or a high level of amylase (which could indicate a swollen pancreas, salivary glands, or another medical condition).

Less frequent side effects:

- blood tests indicate a low level of fibrinogen (a protein involved in blood clotting)
- injection site inflammation, pain or swelling.

The following side effects have been reported but the frequency for them to occur is not known:

- discolouration of developing teeth.

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 any side effects to SAHPRA via the online service for adverse drug reaction reporting by following the link: https://www.sahpra.org.za/Publications/Index/8.

By reporting side effects, you can help provide more information on the safety of CYTAGIL IV. You can also send an email directly to the company, pharmacovigilance@pharmadynamics.co.za to ensure safety of the product.

5. How to store CYTAGIL IV

Store all medicines out of reach of children.

Store at or below 25 ºC prior to reconstitution. The product should be used immediately after reconstitution. The reconstituted product can be stored up to 1 hour at 25 ºC in the vial,IV bag or IV bottle if required.

Keep vial in the carton until required for use.

Do not use after the expiry date stated on the carton.

Return all unused medicine to your pharmacist.

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

6. Contents of the pack and other information

What CYTAGIL IV contains

The active substance is tigecycline.

Each 10 ml vial of CYTAGIL IV contains 50 mg tigecycline.

The other ingredients are arginine and hydrochloric acid (for pH-adjustment).

What CYTAGIL IV looks like and contents of the pack

CYTAGIL IV is an orange lyophilised powder.

After reconstitution with an applicable solvent, the solution is orange in colour.

CYTAGIL IV is packed into a 10 ml glass vial, fitted with a grey rubber stopper and white aluminium flip-off cap. 10 vials are supplied in an outer carton.

Holder of Certificate of Registration

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