PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

GEMBICEN 200 mg concentrate for solution for infusion

GEMBICEN 1 000 mg concentrate for solution for infusion

GEMBICEN 2 000 mg concentrate for solution for infusion

Gemcitabine hydrochloride

Sugar free.

Read all of this leaflet carefully before you are given GEMBICEN

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.

What is in this leaflet

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

1. What GEMBICEN is and what it is used for

The active substance is gemcitabine (as gemcitabine hydrochloride).

GEMBICEN belongs to a group of medicines called cytotoxics. These medicines kill dividing cells, including cancer cells.

GEMBICEN may be given alone or in combination with other anti-cancer medicines, depending on the type of cancer.

GEMBICEN is used in the treatment of the following types of cancer:

- Locally advanced or metastatic non-small cell lung cancer (NSCLC).
- Locally advanced or metastatic pancreatic cancer.
- Locally recurrent or metastatic breast cancer.
- Recurrent ovarian cancer.
- Bladder cancer.

2. What you need to know before GEMBICEN is administered

GEMBICEN should not be administered to you

If you are hypersensitive (allergic) to gemcitabine or any of the other ingredients of GEMBICEN (listed in section 6).

If you are pregnant or breastfeeding.

If you are younger than 18 years of age.

Warnings and precautions

Tell your doctor or health care provider before being given the injection:

- If you have decreased counts of platelets, red or white blood cells.
- If you have or have had problems with alcoholism or diseases which causes damage to the liver.
- If you have kidney disease.
- If you have recently had or are going to have radiotherapy.
- If you have been vaccinated recently.
- If you have experience seizures (fits) or high blood pressure.
- If you have or have previously had heart disease or vascular disease.
- If you have symptoms such as fluid retention, weight gain or low blood pressure.
- If you develop breathing difficulties.
- If you feel very weak and you look very pale (may be a sign of kidney failure).

Take special care with GEMBICEN:

Before the first infusion you will have samples of your blood taken to evaluate if you have sufficient kidney and liver function. Before each infusion you will have samples of your blood taken to evaluate if you have enough blood cells to receive GEMBICEN. Your doctor may decide to change the dose or delay treating you depending on your general condition and if your blood cell counts are too low. Periodically you will have samples of your blood taken to evaluate your kidney and liver function.

Children and adolescents

Safety and effectiveness in children have not been established.

Other medicines and GEMBICEN

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

Tell your doctor or pharmacist if you are being treated with radiotherapy or if you have received or are planning to receive any vaccinations.

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 health care provider for advice before receiving GEMBICEN.

The use of GEMBICEN should be avoided during pregnancy. Your doctor will discuss with you the potential risk of receiving GEMBICEN during pregnancy. If you are breastfeeding, tell your doctor. You must discontinue breastfeeding during GEMBICEN treatment.

Men are advised not to father a child during and up to 6 months following treatment with GEMBICEN. If you would like to father a child during the treatment or in the 6 months following treatment with

GEMBICEN, seek advice from your doctor or pharmacist. You may want to seek counselling on sperm storage before starting your therapy.

Driving and using machines

GEMBICEN can cause side effects, such as sleepiness, particularly if you have consumed any alcohol.

Do not drive a car, operate machinery or do anything else that requires your attention until you know how GEMBICEN affects you.

GEMBICEN contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per unit volume, that is to say it is essentially sodium free.

3. How GEMBICEN is administered

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

The usual dose of GEMBICEN is 1 000 – 1 250 mg for every square metre of your body's surface area. Your height and weight are measured to work out the surface area of your body. Your doctor will use this body surface area to work out the right dose for you. This dosage may be adjusted, or treatment may be delayed depending on your blood cell counts and on your general condition.

How frequently you receive GEMBICEN depends on the type of cancer that you are being treated for.

Your doctor will tell you how long your treatment with GEMBICEN will last. If you have the impression that the effect of GEMBICEN is too strong or too weak, tell your doctor or pharmacist.

If you receive more GEMBICEN than you should

Since a health care provider will administer GEMBICEN, he / she will control the dosage. However, in

the event of overdosage your doctor will manage the overdosage.

If you forget to use GEMBICEN

Since a health care provider will administer GEMBICEN, it is unlikely that the dose will be missed.

4. Possible side effects

GEMBICEN can have side effects.

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

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

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to GEMBICEN. 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:

- Fever or infection: if you have a temperature of 38 ºC or greater, sweating or other signs of infection (since you might have less white blood cells than normal).
- Sepsis: when bacteria and their toxins circulate in the blood and starts to damage the organs.
- Frequent infections such as fever, severe chills, sore throat or mouth ulcers (leucopenia, neutropenia).
- Low red blood cells (bone-marrow suppression) and bleeding or bruising more easily than normal

(thrombocytopenia).

- Posterior reversible encephalopathy syndrome (PRES) (headache, nausea [feeling sick], vomiting [being sick], altered mental status, unresponsiveness, confusion, seizures [fits] and loss of vision).
- Irregular heartbeat, heart failure (pain in the chest, back, jaw and other areas of your upper body that lasts more than a few minutes or that goes away and comes back, shortness of breath) or heart attack (shortness of breath, fatigue and weakness, swelling of the legs, ankles and feet, rapid or irregular heartbeat, persistent cough with white or pink phlegm).
- Difficulty breathing (it is very common to have mild breathing difficulty soon after the GEMBICEN infusion, which soon passes).
- Serious liver damage, including liver failure (stomach pain, clay coloured stool, dark urine, unpleasant breath odour, unusual tiredness, nausea [feeling sick], vomiting [being sick] of blood, yellowing of skin or eyes).
- Severe skin reaction, skin pain, followed by a red or purple skin rash that spreads (especially in the face or upper body) and causes blistering and peeling.
- Kidney failure (drowsiness, shortness of breath, fatigue, confusion, nausea, fits, passing less urine than is normal for you).
- Haemolytic uraemic syndrome (vomiting [being sick], bloody diarrhoea, stomach pain, fever, chills and headache).

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

Tell your doctor if you notice any of the following:

Side effects that occur frequently:

- Fatigue, loss of energy, pale skin, cramps in your legs, difficulty with concentration) (anaemia).
- Weight loss (anorexia).
- Headache, sleeplessness (insomnia), sleepiness.
- Cough.
- Runny nose.
- Diarrhoea or constipation, vomiting (being sick), nausea (feeling sick).

- Pain, redness, swelling or sores in the mouth.
- Liver problems: found through abnormal blood test results
- Itching, hair loss, sweating.
- Muscle pain, back pain.
- Blood in urine.
- Abnormal urine tests showing protein in urine.
- Flu-like symptoms including fever, chills, weakness and headache.

Side effects that occur less frequently:

- Increased platelet count (thrombocytosis).
- Low blood pressure.
- Reduced blood flow to the fingers or toes.
- Interstitial pneumonitis (scarring of the air sacs of the lung).
- Ischaemic colitis (inflammation of the lining of the large bowel, caused by reduced blood supply).
- Skin scaling, ulceration or blister formation.
- Injection site reaction including redness, pain or a skin reaction.
- Radiation recall (a skin rash like severe sunburn) which can occur on skin that has previously been exposed to radiotherapy.
- Radiation toxicity: scarring of the air sacs of the lung associated with radiation therapy.

Side effect with unknown frequency:

- Skin redness with swelling (pseudocellulitis).

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 or pharmacist. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (whoumc.org) found on

SAHPRA website. By reporting side effects, you can help provide more information on the safety of GEMBICEN.

5. How to store GEMBICEN

- Store at 2 º C – 8 ºC (in a refrigerator).
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use after the expiry date printed on the carton or vial.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What GEMBICEN contains

The active ingredient is gemcitabine (as gemcitabine hydrochloride).

The other ingredients are sodium hydroxide (for pH adjustment), hydrochloric acid (for pH adjustment), water for injection.

What GEMBICEN looks like and contents of the pack

A clear and colourless to light straw coloured solution.

Contents of the pack:

GEMBICEN 200 mg:

A 10 ml, USP type-I glass vial, stoppered with a grey bromo butyl rubber stopper and sealed with a red coloured aluminium flip-off top.

Each vial contains 5,26 ml concentrate.

GEMBICEN 1 000 mg:

A 30 ml, USP type-I glass vial, stoppered with a grey bromo butyl rubber stopper and sealed with a red coloured aluminium flip-off top.

Each vial contains 26,3 ml concentrate.

GEMBICEN 2 000 mg:

A 100 ml, USP type-I glass vial, stoppered with a grey bromo butyl rubber stopper and sealed with a red coloured aluminium flip-off top.

Each vial contains 52,6 ml concentrate.

Pack size:

1 vial placed in outer carton.

Holder of certificate of registration

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To follow

Registration numbers

GEMBICEN 200 mg: 57/26/0299

GEMBICEN 1 000 mg: 57/26/0300

GEMBICEN 2 000 mg: 57/26/0301

Access to the corresponding Professional Information

https://www.pharmaq.co.za