PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

GEMCITABINE 200 mg PHARMA-Q powder for solution for infusion

GEMCITABINE 1 g PHARMA-Q powder for solution for infusion

Gemcitabine hydrochloride

Contains mannitol

Read all of this leaflet carefully before you are given GEMCITABINE PHARMA-Q

- 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.
- GEMCITABINE PHARMA-Q has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What GEMCITABINE PHARMA-Q is and what it is used for

GEMCITABINE PHARMA-Q belongs to a group of medicines called cytotoxics. These medicines kill dividing cells, including cancer cells.

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

GEMCITABINE PHARMA-Q is used in the treatment of the following types of cancer:

- non-small cell lung cancer (NSCLC), alone or together with cisplatin
- pancreatic cancer, as a single medicine
- bladder cancer, alone or together with cisplatin
- breast cancer, together with paclitaxel
- ovarian cancer, alone or together with carboplatin

2. What you need to know before you receive GEMCITABINE PHARMA-Q

GEMCITABINE PHARMA-Q should not be administered to you:

- If you are hypersensitive (allergic) to gemcitabine or any of the other ingredients of GEMCITABINE PHARMA-Q (listed in section 6).
- If you are pregnant or breastfeeding your baby.

Warnings and precautions

Special care should be taken with GEMCITABINE PHARMA-Q:

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 GEMCITABINE PHARMA-Q.

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.

If you experience any serious skin reactions, often together with flu-like symptoms after you start taking GEMCITABINE PHARMA-Q, consult your doctor. The skin reactions such as swelling, itching, red severe rash especially those covering the whole body (appearing as

allergic wheals) may progress to widespread blistering or peeling of the skin and can be a serious reaction to GEMCITABINE PHARMA-Q, called severe cutaneous adverse reactions (SCARs) (see section 4, Possible side effects).

Please tell your doctor if:

- you have, or have previously had liver disease, heart disease or vascular disease.
- you have recently had, or are going to have radiotherapy.
- you have been vaccinated recently.
- you develop breathing difficulties or feel very weak and are very pale (may be a sign of kidney failure).
- you develop generalised swelling, shortness of breath or weight gain, as this may be a sign of fluid leaking from your small blood vessels into the tissue, and symptoms of a serious condition called Capillary Leak Syndrome (CLS).
- you during treatment with this medicine get symptoms such as headache with confusion, seizures (fits) or changes in vision. You should contact your doctor right away, as this could be a very rare nervous system side effect named posterior reversible encephalopathy syndrome (PRES).

Children and adolescents

GEMCITABINE PHARMA-Q should **not** be given to children.

Other medicines and GEMCITABINE PHARMA-Q

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

GEMCITABINE PHARMA-Q:

- May cause severe toxicity when given together with radiotherapy to the chest;
- May cause a risk of systemic, possible fatal disease, particularly in

immunocompromised patients, when given together with Yellow fever and other live attenuated vaccines.

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 taking this medicine.

Pregnancy

If you are pregnant, or thinking about becoming pregnant, tell your doctor. GEMCITABINE PHARMA-Q should not be administered to you during pregnancy (see **GEMCITABINE PHARMA-Q should not be administered to you** above).

Breastfeeding

If you are breastfeeding, tell your doctor. You must discontinue breastfeeding during GEMCITABINE PHARMA-Q treatment.

Fertility

Men are advised not to father a child during and up to 6 months following treatment with GEMCITABINE PHARMA-Q. You may want to seek counselling on sperm storage before starting your therapy.

Driving and using machines

GEMCITABINE PHARMA-Q may make you feel sleepy, particularly if you have consumed any alcohol. Do not drive a car or use machinery until you are sure that GEMCITABINE PHARMA-Q treatment has not made you feel sleepy.

GEMCITABINE PHARMA-Q contains mannitol

GEMCITABINE PHARMA-Q contains mannitol and may have a laxative effect.

3. How to use GEMCITABINE PHARMA-Q

Do not share medicines prescribed for you with any other person.

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

GEMCITABINE PHARMA-Q is given as an infusion into a vein over 30 to 60 minutes.

It may be used as single therapy or in combination with other anti-cancer medicines.

The usual dose of GEMCITABINE PHARMA-Q is 800-1 250 mg for every square meter 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.

Your doctor will tell you how long your treatment with GEMCITABINE PHARMA-Q will last.

If you have the impression that the effect of GEMCITABINE PHARMA-Q is too strong or too weak, tell your doctor or pharmacist.

If you receive more GEMCITABINE PHARMA-Q than you should

Since a health care provider will administer GEMCITABINE PHARMA-Q, he/ she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you missed a dose of GEMCITABINE PHARMA-Q

Since a health care provider will administer GEMCITABINE PHARMA-Q, it is unlikely that the dose will be missed.

4. Possible side effects

GEMCITABINE PHARMA-Q can have side effects.

Not all side effects reported for GEMCITABINE PHARMA-Q are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving GEMCITABINE PHARMA-Q, please consult your health care provider for advice.

If any of the following happens, stop receiving GEMCITABINE PHARMA-Q 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.

These are all very serious side effects. If you have them, you may have had a serious reaction to GEMCITABINE PHARMA-Q. 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 (frequent): 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 which is frequent),
- irregular heart rate (arrhythmia) (frequency not known),
- pain, redness, swelling or sores in your mouth (frequent),
- allergic reactions: if you develop skin rash (frequent)/ itching (frequent), or fever (frequent),
- tiredness, feeling faint, becoming easily breathless or if you look pale (since you might have less haemoglobin than normal which is frequent),
- bleeding from the gums, nose or mouth or any bleeding that would not stop, reddish or pinkish urine, unexpected bruising (since you might have less platelets than normal which is frequent),
- difficulty breathing (it is frequent to have mild breathing difficulty soon after the GEMCITABINE PHARMA-Q which soon passes, however uncommonly or rarely

there can be more severe lung problems),

- generalised swelling, shortness of breath or weight gain, as you might have fluid leakage from small blood vessels into tissues (capillary leak syndrome) (less frequent),
- headache with changes in vision, confusion, seizures or fits (posterior reversible encephalopathy syndrome) (less frequent),
- extreme tiredness and weakness, purpura or small areas of bleeding in the skin (bruises), acute renal failure (low urine output or no urine output), and signs of infection. These may be features of thrombotic microangiopathy (clots forming in small blood vessels) and haemolytic uraemic syndrome, which may be fatal.

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

Tell your doctor if you notice any of the following:

Frequent

- low haemoglobin level (anaemia),
- low white blood cells,
- low platelet count,
- difficulty breathing,
- vomiting,
- nausea,
- skin rash- allergic skin rash, frequently itchy,
- hair loss,
- liver problems: found through abnormal blood test results,
- blood in urine,
- abnormal urine tests: protein in urine,
- flu like symptoms including fever,
- oedema (swelling of ankles, fingers, feet, face),

- fever accompanied by low white blood cell count (febrile neutropenia),
- anorexia (poor appetite),
- headache,
- insomnia,
- sleepiness,
- cough,
- runny nose,
- constipation,
- diarrhoea,
- pain, redness, swelling or sores in the mouth,
- itching,
- sweating,
- muscle pain,
- back pain,
- fever,
- weakness,
- chills,
- infections.

Less frequent

- interstitial pneumonitis (scarring of the air sacs of the lung),
- spasm of the airways (wheeze),
- abnormal chest X ray/scan (scarring of the lungs),
- heart attack (myocardial infarction),
- low blood pressure,
- skin scaling, ulceration or blister formation,
- injection site reactions,

- increased platelet count,
- anaphylactic reaction (severe hypersensitivity/ allergic reaction),
- sloughing of skin and severe skin blistering,
- thrombotic microangiopathy: clots forming in small blood vessels.

Frequency not known

- irregular heartbeat (arrhythmia),
- Adult Respiratory Distress Syndrome (severe lung inflammation causing respiratory failure),
- radiation recall - (a skin rash like severe sunburn) which can occur on skin that has previously been exposed to radiotherapy,
- fluid in the lungs,
- radiation toxicity - scarring of the air sacs of the lung associated with radiation therapy,
- ischaemic colitis (inflammation of the lining of the large bowel, caused by reduced blood supply),
- heart failure,
- kidney failure,
- gangrene of fingers or toes,
- serious liver damage, including liver failure,
- stroke,
- sepsis: when bacteria and their toxins circulate in the blood and starts to damage the organs,
- pseudocellulitis: skin redness with swelling.
- acute generalised exanthematous pustulosis (AGEP) (a skin reaction accompanied by fever)

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 eReporting platform (who-umc.org) found on SAHPRA website.

By reporting side effects, you can help provide more information on the safety of GEMCITABINE PHARMA-Q

5. How to store GEMCITABINE PHARMA-Q

Store all medicines out of reach of children.

Before reconstitution:

Store at or below 25 °C.

After reconstitution:

Solutions of GEMCITABINE PHARMA-Q reconstituted with 0,9 % sodium chloride injection without preservatives should be stored at or below 25 °C and should be administered within 24 hours.

Discard unused portion.

Do not refrigerate as crystallisation may occur.

Reconstituted GEMCITABINE PHARMA-Q should be inspected visually for particulate. matter and discolouration, prior to administration.

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

Return all unused medicine to your pharmacist.

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

Procedures for proper handling and disposal of anticancer medicines should be considered.

6. Contents of the pack and other information

What GEMCITABINE PHARMA-Q contains

- The active substance is gemcitabine hydrochloride.

GEMCITABINE 200 mg PHARMA-Q

Each vial contains gemcitabine hydrochloride equivalent to 200 mg gemcitabine.

When reconstituted the solution contains 200 mg gemcitabine per 5 ml Contains sugar: mannitol 200 mg/vial

GEMCITABINE 1 g PHARMA-Q

Each vial contains gemcitabine hydrochloride equivalent to 1 g gemcitabine.

When reconstituted the solution contains 1 g gemcitabine per 25 ml

Contains sugar: mannitol 1 000 mg/vial

- The other ingredients are:

Mannitol (E421), sodium acetate trihydrate (E262), sodium hydroxide (for pH adjustment), hydrochloric acid (for pH adjustment), water for injection

What GEMCITABINE PHARMA-Q looks like and contents of the pack

GEMCITABINE 200 mg PHARMA-Q

White to off white lyophilised plug contained in a flint glass vial.

GEMCITABINE 200 mg PHARMA-Q is packed in a 10 ml clear colourless tubular glass vial, Type I, with 20 mm neck with a 20 mm Lyo rubber stopper and 20 mm blue flip off seal stored in an outer unit carton.

GEMCITABINE 1 g PHARMA-Q

White to off white lyophilised plug contained in a flint glass vial.

GEMCITABINE 1 g PHARMA-Q is packed in a 50 ml clear colourless molded glass vial Type I, with 20 mm neck with a 20 mm Lyo rubber stopper and 20 mm blue flip off seal stored in an outer unit carton.

Pack size: 1 vial per pack.

Holder of Certificate of Registration

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48/26/0459: 200 mg

48/26/0460: 1 g

Access to the corresponding Professional Information

https://www.pharmaq.co.za