

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

**GEMTAZ[®] READY TO USE range 10 mg/mL in 0,9 % sodium chloride, solution for infusion
bag**

(Gemcitabine hydrochloride)

GEMTAZ[®] 1200 mg/120 mL READY TO USE solution for infusion
GEMTAZ[®] 1300 mg /130 mL READY TO USE solution for infusion
GEMTAZ[®] 1400 mg /140 mL READY TO USE solution for infusion
GEMTAZ[®] 1500 mg/150 mL READY TO USE solution for infusion
GEMTAZ[®] 1600 mg/160 mL READY TO USE solution for infusion
GEMTAZ[®] 1700 mg/170 mL READY TO USE solution for infusion
GEMTAZ[®] 1800 mg/180 mL READY TO USE solution for infusion
GEMTAZ[®] 1900 mg/190 mL READY TO USE solution for infusion
GEMTAZ[®] 2000 mg/200 mL READY TO USE solution for infusion
GEMTAZ[®] 2200 mg/220 mL READY TO USE solution for infusion

Sugar free.

Each mL of **GEMTAZ[®] READY TO USE** infusion contains 4,575 mg of sodium.

GEMTAZ[®] 1200 mg/120 mL READY TO USE solution for infusion: Each infusion bag of 120 mL contains 549 mg of Sodium.

GEMTAZ[®] 1300 mg /130 mL READY TO USE solution for infusion: Each infusion bag of 130 mL contains 594,75 mg of Sodium.

GEMTAZ[®] 1400 mg /140 mL READY TO USE solution for infusion: Each infusion bag of 140 mL contains 640,5 mg of Sodium.

GEMTAZ[®] 1500 mg/150 mL READY TO USE solution for infusion: Each infusion bag of 150 mL contains 686,25 mg of Sodium.

GEMTAZ[®] 1600 mg/160 mL READY TO USE solution for infusion: Each infusion bag of 160 mL contains 732 mg of Sodium.

GEMTAZ[®] 1700 mg/170 mL READY TO USE solution for infusion: Each infusion bag of 170 mL contains 777,75 mg of Sodium.

GEMTAZ[®] 1800 mg/180 mL READY TO USE solution for infusion: Each infusion bag of 180 mL contains 823,5 mg of Sodium.

GEMTAZ[®] 1900 mg/190 mL READY TO USE solution for infusion: Each infusion bag of 190 mL contains 869,25 mg of Sodium.

GEMTAZ[®] 2000 mg/200 mL READY TO USE solution for infusion: Each infusion bag of 200 mL contains 915 mg of Sodium.

GEMTAZ[®] 2200 mg/220 mL READY TO USE solution for infusion: Each infusion bag of 220 mL contains 1006,5 mg of Sodium.

Read all of this leaflet carefully before you start taking GEMTAZ[®] READY TO USE.

- 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 **GEMTAZ[®] READY TO USE** is and what it is used for
2. What you need to know before you use **GEMTAZ[®] READY TO USE**
3. How to use **GEMTAZ[®] READY TO USE**
4. Possible side effects **GEMTAZ[®] READY TO USE**
5. How to store **GEMTAZ[®] READY TO USE**
6. Contents of the pack and other information

1. What GEMTAZ[®] READY TO USE is and what it is used for

GEMTAZ[®] READY TO USE belongs to a group of medicines called antineoplastic or cytotoxic

medicines. You may also hear of these being called chemotherapy medicines.

GEMTAZ[®] READY TO USE works by killing cancer cells and stopping cancer cells from growing and multiplying.

GEMTAZ[®] READY TO USE is used to treat the following types of cancer:

- lung cancer
- pancreatic cancer
- bladder cancer
- breast cancer
- ovarian cancer.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

GEMTAZ[®] READY TO USE may be used alone or in combination with other medicines to treat cancer.

This medicine is available only with a doctor's prescription.

2. What you need to know before you use **GEMTAZ[®] READY TO USE**

Do not use **GEMTAZ[®] READY TO USE**:

- If you are hypersensitive (allergic) to gemcitabine or any of the other ingredients of **GEMTAZ[®] READY TO USE** (listed in section 6).
- If you are breastfeeding
- If you are pregnant.
- Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching, or hives on the skin.
- If any of these apply to you, tell your doctor before using **GEMTAZ[®] READY TO USE**.

Warnings and precautions

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

- If you have, or have previously had liver disease, vascular disease, lung problem, bone marrow problem or problems with your kidneys as you may not be able to receive **GEMTAZ[®] READY TO USE**
- If you have recently had, or are going to have radiotherapy, as there may be an early or late radiation reaction
- If you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after using **GEMTAZ[®] READY TO USE**

Serious skin reactions including Stevens-Johnson syndrome, toxic epidermal necrolysis and acute generalised exanthematous pustulosis (AGEP) have been reported in association with **GEMTAZ[®] READY TO USE** treatment. Seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section.

Special care should be taken with **GEMTAZ[®] READY TO USE**.

Before the first infusion you will have samples of your blood taken to check if you have sufficient kidney and liver function. Before each infusion you will have samples of your blood taken to check if you have enough blood cells to receive gemcitabine. 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 check your kidney and liver function.

Children and adolescents

This medicine is not recommended for use in children under 18 years of age because safety and efficacy has not been established.

Other medicines and **GEMTAZ[®] READY TO USE**

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

These medicines may be affected by **GEMTAZ® READY TO USE**, or may affect how well it works.

You may need different amounts of your medicine, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while you are being treated with this medicine.

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.

Like most cytotoxic medicines, **GEMTAZ® READY TO USE** is not recommended for use during pregnancy. If there is any need to consider **GEMTAZ® READY TO USE**, during your pregnancy, your doctor or pharmacist will discuss with you the benefits and risks of using it. **GEMTAZ® READY TO USE** may cause birth defects if either the male or female is using it at the time of conception. It is recommended that you use birth control and/or contraceptive barrier such as a condom while you are being treated with gemcitabine.

Gemcitabine may pass into breast milk and there is a possibility that your baby may be affected. Do not breastfeed during treatment with gemcitabine and for at least one week after the last dose. Gemcitabine may cause reduced fertility in males of reproductive potential.

Driving and using machines

Gemcitabine 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 treatment has not made you feel sleepy.

GEMTAZ[®] READY TO USE contains sodium.

This must be taken into consideration by patients on a controlled sodium diet.

3. How to use **GEMTAZ[®] READY TO USE**

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

Always use **GEMTAZ[®] READY TO USE** exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Gemcitabine may be given alone or in combination with other drugs.

Several courses of gemcitabine therapy may be needed depending on your response to treatment.

Additional treatment may not be repeated until your blood cell numbers return to acceptable levels and any uncontrolled effects have been controlled.

The usual dose of gemcitabine is 800-1250 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 dose may be adjusted, or treatment may be delayed depending on your blood cell counts, your general condition other factors, such as your weight, liver function, kidney function and other chemotherapy medicines you are being given.

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

You will always receive gemcitabine by infusion (a drip) into one of your veins. The infusion will last approximately 30 minutes.

Your doctor will tell you how long your treatment with **GEMTAZ[®] READY TO USE** will last. If you

have the impression that the effect of **GEMTAZ[®] READY TO USE** is too strong or too weak, tell your doctor or pharmacist.

You will not be expected to give yourself **GEMTAZ[®] READY TO USE**. It will be given to you by a person who is qualified to do so.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

If you use more GEMTAZ[®] READY TO USE than you should

If you think that an overdose has happened and you experience such symptoms, call your doctor.

Since a health care provider will administer **GEMTAZ[®] READY TO USE**, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to use GEMTAZ[®] READY TO USE

Since a health care provider will administer **GEMTAZ[®] READY TO USE**, it is unlikely that the dose will be missed.

It won't do any harm if you miss a dose but some of your symptoms may come back temporarily until you get back on schedule.

Do not receive a double dose to make up for forgotten individual doses.

4. Possible side effects

GEMTAZ[®] READY TO USE can have side effects.

Not all side effects reported for **GEMTAZ[®] READY TO USE** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **GEMTAZ[®] READY TO USE**, please consult your healthcare provider for advice.

You must contact your doctor immediately if you notice any of the following:

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.

If any of the following happens, stop using GEMTAZ[®] READY TO USE and tell your doctor immediately or go to the casualty department of your nearest hospital:

Less frequent

- severe hypersensitivity/allergic reaction with severe skin rash including red itchy skin, swelling of the hands, feet, ankles, face, lips, mouth or throat (which may cause difficulty in swallowing or breathing), wheezing, fast beating heart and you may feel you are going to faint (anaphylactic reaction)
- severe rash with itching, blistering or peeling of the skin (Stevens-Johnson syndrome, toxic epidermal necrolysis).

These are all very serious side effects. If you have them, you may have had a serious reaction to **GEMTAZ[®] READY TO USE**. 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:

Frequent

- tiredness, feeling faint, becoming easily breathless or if you look pale (you might have less haemoglobin than normal)
- bleeding from the gums, nose or mouth or any bleeding that would not stop, reddish or pinkish urine, unexpected bruising (you might have less platelets than normal)
- temperature of 38 °C or greater, sweating or other signs of infection (you might have less white blood cells than normal accompanied by fever also known as febrile neutropenia)
- pain, redness, swelling or sores in your mouth (stomatitis)
- allergic reactions:
if you develop mild to moderate skin rash or fever, if you develop itching

mild breathing difficulty (it is common to have mild breathing difficulty soon after the **GEMTAZ®** **READY TO USE** infusion which soon passes).

Less frequent

- difficulty breathing due to more severe lung problems (interstitial pneumonitis, bronchospasm),
- irregular heart rate (arrhythmia)
- difficulty breathing due to more severe lung problems (pulmonary oedema, adult respiratory distress syndrome)
- severe chest pain (myocardial infarction)
- generalised swelling, shortness of breath or weight gain, as you might have fluid leakage from small blood vessels into the tissues (capillary leak syndrome)
- headache with changes in vision, confusion, seizures or fits (posterior reversible encephalopathy syndrome).

Frequency not known:

A red, scaly widespread rash with bumps under the swollen skin (including your skin folds, trunk, and upper extremities) and blisters accompanied by fever (Acute Generalized Exanthematous Pustulosis (AGEP)).

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

Other side effects

Tell your doctor as soon as possible about any of the following side effects:

Frequent

- low white blood cells
- difficulty breathing
- feeling or being sick

- hair loss
- liver problems: found through abnormal blood test results
- blood in urine
- abnormal urine tests: protein in urine
- flu like symptoms including fever
- swelling of ankles, fingers, feet, face (oedema)
- poor appetite (anorexia)
- headache
- insomnia
- sleepiness
- cough
- runny nose
- constipation
- diarrhoea
- itching
- sweating
- muscle pain
- back pain
- fever
- weakness
- chills
- infections.

Less frequent

- scarring of the air sacs of the lung (interstitial pneumonitis)
- wheeze (spasm of the airways)
- scarring of the lungs (abnormal chest X ray/scan)

- heart failure
- kidney failure
- serious liver damage, including liver failure
- stroke
- low blood pressure
- skin scaling, ulceration or blister formation
- sloughing of skin and severe skin blistering
- injection site reactions
- a skin rash like severe sunburn which can occur on skin that has previously been exposed to radiotherapy (radiation recall)
- fluid in the lungs
- scarring of the air sacs of the lung associated with radiation therapy (radiation toxicity)
- gangrene of fingers or toes
- inflammation of the blood vessels (peripheral vasculitis)
- increased platelet count
- inflammation of the lining of the large bowel, caused by reduced blood supply (ischaemic colitis)
- clots forming in small blood vessels (thrombotic microangiopathy).

Frequency not known

- sepsis: when bacteria and their toxins circulate in the blood and starts to damage the organs
- skin redness with swelling (pseudocellulitis)

Low haemoglobin level (anaemia), low white blood cells and low platelet count will be detected by a blood test.

Other side effects not listed above may occur in some patients. Some of these side effects can only be found when your doctor does tests from time to time to check your progress.

Tell your doctor, nurse or pharmacist if you notice anything that is making you feel unwell.

The benefits and side effects of gemcitabine may take some time to occur. Therefore even after you have finished your **GEMTAZ[®] READY TO USE** treatment you should tell your doctor immediately if you notice any of the side effects listed in this section.

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 “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8> . By reporting side effects, you can help provide more information on the safety of **GEMTAZ[®] READY TO USE**.

5. How to store GEMTAZ[®] READY TO USE

Store at or below 25 °C. Do not freeze as crystallization can occur.

KEEP OUT OF REACH OF CHILDREN.

6. Contents of the pack and other information

What GEMTAZ[®] READY TO USE looks like and contents of the pack

GEMTAZ[®] READY TO USE is filled in printed multilayer M312 infusion bag with M916M polyolefin tube and stoppered with polycarbonate minituliipe M95A spike port with chlorobutyl (latex free) 6321 GS joint.

The filled and stoppered infusion bag is packed in preprinted aluminium pouch in such a way that the port of infusion bag will be towards the sealing side.

Holder of Certificate of Registration

RANBAXY PHARMACEUTICALS (PTY) LTD

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South Africa

This leaflet was last revised in

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GEMTAZ[®] 1200 mg/120 mL READY TO USE: 54/26/0842

GEMTAZ[®] 1300 mg/130 mL READY TO USE: 54/26/0843

GEMTAZ[®] 1400 mg/140 mL READY TO USE: 54/26/0844

GEMTAZ[®] 1500 mg/150 mL READY TO USE: 54/26/0845

GEMTAZ[®] 1600 mg/160 mL READY TO USE: 54/26/0846

GEMTAZ[®] 1700 mg/170 mL READY TO USE: 54/26/0847

GEMTAZ[®] 1800 mg/180 mL READY TO USE: 54/26/0848

GEMTAZ[®] 1900 mg/190 mL READY TO USE: 54/26/0849

GEMTAZ[®] 2000 mg/200 mL READY TO USE: 54/26/0850

GEMTAZ[®] 2200 mg/220 mL READY TO USE: 54/26/0851