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## PATIENT INFORMATION LEAFLET

**SCHEDULING STATUS:** S4

**GEMTAZ 200 mg injection**

**GEMTAZ 1 g injection**

**Gemcitabine hydrochloride**

Contains sugar alcohol:

GEMTAZ 200 mg contains 200 mg mannitol per vial.

GEMTAZ 1 g contains 1 000 mg mannitol per vial.

**Read all of this leaflet carefully before you are given GEMTAZ.**

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

### **What is in this leaflet:**

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

#### **1. What GEMTAZ is and what it is used for**

GEMTAZ belongs to a general group of medicines known as antimetabolites. It is used to treat cancer of the breasts, pancreas and lung. It may also be used to treat other kinds of cancer, as

determined by your doctor.

Before you begin treatment with GEMTAZ, you and your doctor should talk about the good this medicine will do as well as the risks of using it. GEMTAZ should be administered under direct physician supervision.

## **2. What you need to know before GEMTAZ is administered to you**

### **GEMTAZ should not be administered to you:**

- If you are hypersensitive (allergic) to gemcitabine or any of the other ingredients GEMTAZ listed in section 6.
- If you are pregnant or breast feeding your baby.
- Safety and efficacy in children have not been established.

### **Warnings and precautions:**

Talk to your doctor before using GEMTAZ if:

- You have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after using gemcitabine.

Serious skin reactions including Stevens-Johnson syndrome, toxic epidermal necrolysis and acute generalised exanthematous pustulosis (AGEP) have been reported during treatment with GEMTAZ. Seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4 below.

The use of GEMTAZ in combination with radiotherapy can result in extensive side effects. This combination should be avoided.

It is very important that your doctor check your progress at regular visits to make sure that GEMTAZ is working properly and to check for unwanted effects.

While you are being treated with GEMTAZ, and after you stop treatment with it, do not have any immunizations (vaccinations) without your doctor's approval. Gemcitabine may lower your body's resistance and there is a chance you might get the infection the immunization is meant to prevent.

Check with your doctor immediately if shortness of breath occurs or worsens while you are being treated with GEMTAZ.

Inform your doctor if you are suffering from any of the following:

- Bone marrow depression
- Existing or recent chickenpox
- Shingles

**Children and adolescents:**

GEMTAZ is not intended for use in children younger than 18 years of age.

**Other medicines and GEMTAZ:**

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

Inform your doctor if you are currently being treated with any of the following:

- Bone marrow suppressants or radiotherapy.
- Immunosuppressants (e.g. azathioprine, chlorambucil, corticosteroids, cyclophosphamide, cyclosporine, mercaptopurine, muromonab CD-3 and tacrolimus).

**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 before GEMTAZ is administered.

GEMTAZ is contraindicated in pregnant and breastfeeding women.

If you are a female patient receiving GEMTAZ, your doctor will advise you to use effective contraception during treatment and not to fall pregnant during, and up to 6 months following treatment with GEMTAZ.

Male patients will be advised to use effective contraception during treatment and not to father a child during and up to 3 months following treatment with GEMTAZ. If you would like to father a child during the treatment or in the 3 months following treatment, seek advice from your doctor or pharmacist. You may want to seek counselling on sperm storage before starting your therapy.

**Driving and using machines:**

GEMTAZ can lead to somnolence and caution is advised when driving or using machinery.

**3. How GEMTAZ will be administered**

You will not be expected to give yourself GEMTAZ, it will be given to you by a person who is qualified to do so.

Your doctor will determine the dose that is suitable for your condition.

You will receive the medication through intravenous infusion.

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

**If you receive more GEMTAZ than you should:**

Since a health care provider will administer GEMTAZ, he/she will control the dosage. However, in the event of an overdose, your doctor will manage the overdose.

**If you miss a dose of GEMTAZ:**

GEMTAZ is administered under the supervision of your doctor. If you think that you may have missed a dose, talk to your doctor or health care provider.

**4. Possible side effects**

GEMTAZ can have side effects.

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

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

- Swelling of your hands, feet, ankles, face, 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 GEMTAZ. 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:

- A red, scaly widespread rash with bumps under the swollen skin (including your skin folds, trunk, and upper extremities) and blisters accompanied by fever, known as acute generalised exanthematous pustulosis (AGEP)
- Unusual tiredness or weakness
- Shortness of breath
- Swelling of the fingers, feet or legs
- Less frequent occurrence

- Fast irregular heartbeat
- Fever or chills

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

Tell your doctor if you notice any of the following:

*Frequent occurrence*

- Constipation, diarrhoea, nausea or vomiting

*Less frequent occurrence*

- Irritation, redness of pain at the injection site
- Sores, ulcers, or white spots on lips and in mouth

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 (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of GEMTAZ.

Suspected adverse reactions can also be reported directly to the Holder of certificate of registration via email or telephonically: [pharmacovigilance.alricasme@sunpharma.com](mailto:pharmacovigilance.alricasme@sunpharma.com) or Tel: +27(0) 12 6432000

**5. How to store GEMTAZ**

Store at or below 25 °C.

Reconstituted solution can be stored for 24 hours below 25 °C.

Discard any unused portion.

Do not refrigerate.

KEEP ALL MEDICINES OUT OF REACH OF CHILDREN

Do not use after the expiry date printed on the vial.

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

## **6. Contents of the pack and other information**

### **What GEMTAZ contains:**

The active ingredient is gemcitabine hydrochloride.

GEMTAZ 200 mg: Each vial contains gemcitabine hydrochloride equivalent to 200 mg of gemcitabine (40 mg/mL).

GEMTAZ 1 g: Each vial contains gemcitabine hydrochloride equivalent to 1 g of gemcitabine (40 mg/mL).

The other ingredients are: Mannitol, sodium acetate, sodium hydroxide and hydrochloric acid.

### **What GEMTAZ looks like and contents of the pack:**

White to off-white lyophilized cake.

GEMTAZ 200 mg is packed into 10 mL colourless type-I tubular glass vials with 20 mm crimp, with 20 mm grey bromobutyl rubber stopper and sealed with green flip-off tear-off aluminium seal.

GEMTAZ 1 g is packed into 50 mL colourless type-I moulded glass vial with 20 mm crimp, with 20 mm grey bromobutyl rubber stopper and sealed with green flip-off tear-off aluminium seal.

### **Holder of certificate of registration and manufacturer:**

Ranbaxy Pharmaceuticals (Pty) Ltd

14 Lautre Road

Stormill, Ext. 1

Roodepoort

Johannesburg 1724

**This leaflet was last revised:**

08 April 2024

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GEMTAZ 200 mg: 41/26/0934

GEMTAZ 1 g: 41/26/0933

**Date of registration:**

10 June 2009