PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

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

(Gemcitabine hydrohloride)

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 minitulipe 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

14 Lautre Road, Stormill, Ext.1,

Roodepoort, 1724

South Africa

This leaflet was last revised in

Registration date: 30 January 2024

Registration numbers

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

PASIËNTINLIGTINGSTUK

SKEDULERINGSTATUS

S4

GEMTAZ® READY TO USE reeks 10 mg/mL in 0,9 % natriumchloried, oplossing vir infusie sakkie

(Gemsitabienhidrohloried)

GEMTAZ® 1200 mg/120 mL READY TO USE oplossing vir infusie

GEMTAZ® 1300 mg /130 mL READY TO USE oplossing vir infusie

GEMTAZ® 1400 mg /140 mL READY TO USE oplossing vir infusie

GEMTAZ® 1500 mg/150 mL READY TO USE oplossing vir infusie

GEMTAZ® 1600 mg/160 mL READY TO USE oplossing vir infusie

GEMTAZ® 1700 mg/170 mL READY TO USE oplossing vir infusie

GEMTAZ® 1800 mg/180 mL READY TO USE oplossing vir infusie

GEMTAZ® 1900 mg/190 mL READY TO USE oplossing vir infusie

GEMTAZ® 2000 mg/200 mL READY TO USE oplossing vir infusie

GEMTAZ® 2200 mg/220 mL READY TO USE oplossing vir infusie

Suikervry.

Elke mL **GEMTAZ® READY TO USE** infusie bevat 4,575 mg natrium.

GEMTAZ® 1200 mg/120 mL READY TO USE oplossing vir infusie: Elke 120 mL infusie-sakkie bevat 549 mg natrium.

GEMTAZ® 1300 mg /130 mL READY TO USE oplossing vir infusie: Elke 130 mL infusie-sakkie bevat 594,75 mg natrium.

GEMTAZ® 1400 mg /140 mL READY TO USE oplossing vir infusie: Elke 140 mL infusie-sakkie bevat 640,5 mg natrium.

GEMTAZ® 1500 mg/150 mL READY TO USE oplossing vir infusie: Elke 150 mL infusie-sakkie bevat 686,25 mg natrium.

GEMTAZ® 1600 mg/160 mL READY TO USE oplossing vir infusie: Elke 160 mL infusie-sakkie bevat 732 mg natrium.

GEMTAZ® 1700 mg/170 mL READY TO USE oplossing vir infusie: Elke 170 mL infusie-sakkie bevat 777,75 mg natrium.

GEMTAZ® 1800 mg/180 mL READY TO USE oplossing vir infusie: Elke 180 mL infusie-sakkie bevat 823,5 mg natrium.

GEMTAZ® 1900 mg/190 mL READY TO USE oplossing vir infusie: Elke 190 mL infusie-sakkie bevat 869,25 mg natrium.

GEMTAZ® 2000 mg/200 mL READY TO USE oplossing vir infusie: Elke 200 mL infusie-sakkie bevat 915 mg natrium.

GEMTAZ® 2200 mg/220 mL READY TO USE oplossing vir infusie: Each 220 mL infusie-sakkie bevat 1006,5 mg natrium.

Lees die hele inligtingsblad noukeurig deur voordat GEMTAZ® READY TO USE aan jou toegedien word.

- Hou hierdie inligtingsblad. Dit mag vir jou nodig wees om dit weer te lees.
- Vra asseblief jou dokter, apteker, verpleegkundige of ander gesondheidsorgverskaffer as jy verdere vra het.

Wat is in hierdie inligtingsblad

1. Wat **GEMTAZ® READY TO USE** is en waarvoor dit gebruik word
2. Wat jy moet weet voordat **GEMTAZ® READY TO USE** aan jou toegedien word
3. Hoe **GEMTAZ® READY TO USE** gebruik word
4. Moontlike newe-effekte van **GEMTAZ® READY TO USE**
5. Hoe om **GEMTAZ® READY TO USE** te bewaar
6. Inhoud van die verpakking en ander inligting

1. Wat GEMTAZ® READY TO USE is en waarvoor dit gebruik word

GEMTAZ® READY TO USE behoort aan ‘n groep medisyne wat anti-neoplastiese of sitotoksiese medisyne genoem word. Hierdie medisyne word ook chemoterapie-middels genoem.

GEMTAZ® READY TO USE se werking is om kankerselle dood te maak en te verhoed dat kankerselle groei en vermeerder.

GEMTAZ® READY TO USE word gebruik om die volgende tipes kanker te behandel:

- longkanker
- pankreaskanker
- blaaskanker
- borskanker
- ovariale kanker.

Vra jou dokter as jy enge vrae het oor hoekom hierdie medisyne vir jou voorgeskryf is.

Jou dokter mag dit vir ‘n ander rede voorgeskryf het.

GEMTAZ® READY TO USE kan alleen of in kombinasie met ander medisyne gebruik word om kanker te behandel.

Hierdie medisyne is slegs op ‘n dokter se voorskrif beskikbaar.

2. Wat jy moet weet voordat GEMTAZ® READY TO USE aan jou toegedien word

GEMTAZ® READY TO USE moet nie toegedien word nie:

- As jy hipersensitief (allergies) is vir gemsitabien of vir enige van die ander bestanddele van **GEMTAZ® READY TO USE** (gelys in afdeling 6).
- As jy borsvoed.
- As jy swanger is.
- Sommige van die simptome van ‘n allergiese reaksie kan kortasemigheid, hyging of moeilike asemhaling; swelling van die gesig, lippe, tong of ander dele van die liggaam; uitslag, gejeuk of netelroos op die vel insluit.

- As enige van hierdie op jou van toepassing is, moet jy jou dokter inlig voordat **GEMTAZ® READY TO USE** aan jou toegedien word.

Waarskuwings en voorsorgmaatreëls

Lig jou dokter of gesondheidsorgverskaffer in voordat hierdie infuus aan jou toegedien word:

- As jy lewersiekte, vaskulêre siekte, longprobleme, beenmurgprobleme of probleme met jou nier het of voorheen gehad het, aangesien jy dan nie gereed is om **GEMTAZ® READY TO USE** te ontvang nie
- As jy onlangs bestralingsterapie gehad het, of bestralingsterapie gaan ontvang, aangesien daar ‘n vroeë of laat bestralingsreaksie kan voorkom
- As jy al ooit ‘n ernstige velreaksie of velafskilfering, blasievorming en/of mondsere ontwikkel het nadat **GEMTAZ® READY TO USE** aan jou toegedien is

  Ernstige velreaksies insluitend Stevens-Johnson-sindroom, toksiese epidermale nekrolise en akute gegeneraliseerde ekantemateuse pustulose (AGEP) is aangemeld in verband met **GEMTAZ® READY TO USE**-behandeling. Verkry dadelik mediese versorging as jy enige van die simptome opmerk wat verband hou met ernstige velreaksies soos beskryf in hierdie afdeling.

Spesiale sorg moet toegepas word met GEMTAZ® READY TO USE.

Voordat die eerste infusie aan jou toegedien word, sal bloedmonsters van jou geneem word om na te gaan of jy oor voldoende nier- en lewerfunksie beskik. Voordat elke infusie aan jou toegedien word, sal bloedmonsters van jou geneem word om na te gaan of jy oor voldoende bloedselle beskik om gemsitabien te ontvang. Jou dokter mag besluit om die dosis te verander of om behandeling te vertraag afhangende van jou algemene toestand en of jou bloedseltellings te laag is. Daar sal gereeld bloedmonsters van jou geneem word om jou nier- en lewerfunksie na te gaan.

Kinders en adolessente

Hierdie medisyne word nie aanbeveel vir gebruik by kinders onder die ouderdom van 18 jaar nie omdat veiligheid en doeltreffendheid nie vasgestel is nie.

Ander medisyne en GEMTAZ® READY TO USE

Lig jou gesondheidsorgverskaffer altyd in as jy enige ander medisyne gebruik (dit sluit alle komplementêre of traditionele medisyne in).

Hierdie medisyne kan deur **GEMTAZ® READY TO USE** geaffekteer word, of kan die meganisme van werking affekteer. Jy mag verskillende hoeveelhede van jou medisyne benodig, of dit kan nodig wees om ander medisyne te gebruik.

Jou dokter en apteker beskik oor meer inligting oor medisyne om met versigtigheid of vermyding op te tree voordat jy met hierdie medisyne behandel word.

Swangerskap, borsvoeding en vrugbaarheid

As jy swanger is of borsvoed, dink dat jy swanger mag wees of as jy beplan om ‘n baba te hê, moet jy asseblief jou dokter, apteker of ander gesondheidsorgverskaffer raadpleeg vir advies voordat hierdie medisyne aan jou toegedien word.

Soos die meeste sitotoksiese medisyne, word **GEMTAZ® READY TO USE** nie aanbeveel vir gebruik tydens swangerskap nie. Indien daar enige noodsaaklikheid is om die gebruik van **GEMTAZ® READY TO USE** tydens swangerskap te oorweeg, sal jou dokter of apteker die voordele en risikos vir die gebruik daarvan met jou bespreek. **GEMTAZ® READY TO USE** kan geboortedefekte veroorsaak wanneer dit aan of mans of vroue toegedien word tydens konsepsie. Daar word aanbeveel dat jy geboortebeperking toepas en/of geboorte-versperring gebruik, soos ‘n kondoom, terwyl jy met gemsitabien behandel word.

Gemsitabien kan in borsmelk uitgeskei word en daar is ‘n moontlikheid dat jou baba geaffekteer kan word. Moenie borsvoed tydens behandeling met gemsitabien nie of vir ten miste een week ná die toediening van die laaste dosis.

Gemsitabien kan verlaagde vrugbaarheid by mans tydens vrugbare tydperk veroorsaak

Bestuur en gebruik van masjinerie

Gemsitabien kan jou slaperig laat voel, veral as jy alkohol gebruik het. Moenie ‘n motor bestuur of masjinerie gebruik totdat jy seker is dat behandeling met gemsitabien jou nie slaperig laat voel nie.

GEMTAZ® READY TO USE bevat natrium.

Dit moet in ag geneem word by pasiënte op ‘n gekontroleerde natriumdieet.

3. Hoe om GEMTAZ® READY TO USE te gebruik

Moenie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie.

GEMTAZ® READY TO USE moet altyd presies aan jou toegedien word soos op jou dokter of apteker se voorskrif. Raadpleeg jou dokter of apteker as jy onseker is.

Gemsitabien kan alleen of in kombinasie met ander middels toegedien word.

Verskeie kursusse gemsitabien-terapie mag nodig wees afhangende van jou reaksie op die behandeling.

Addisionele behandeling mag nie herhaal word totdat jou bloedseltelling na aanvaarbare vlakke teruggekeer het nie en enige ongekontroleerde effekte onder beheer is nie.

Die normale dosis van gemsitabien is 800-1250 mg vir elke vierkante meter van jou liggaamsoppervlak. Jou lengte en massa word gebruik om jou liggaamsoppervlak te bepaal. Jou dokter sal hierdie liggaamsoppervlak gebruik om die regte dosis vir jou te bepaal. Hierdie dosis kan aangepas word, of behandeling kan uitgestel word, afhangende van jou bloedseltellings, jou algemene toestand en ander faktore soos jou gewig, lewerfunksie, nierfunksie en ander chemoterapie-medisyne wat jy ontvang.

Hoe dikwels jy die gemsitabien-infusie ontvang, hang af van die tipe kanker waarvoor jy

behandeling ontvang.

Jy sal altyd gemsitabien deur infusie (‘n drip) binne-in jou are ontvang. Die infusie kan ongeveer 30 minute neem om in te loop.

Jou dokter sal jou inlig oor hoe lank jou behandeling met **GEMTAZ® READY TO USE** sal duur. As jy onder die indruk is dat die effek van **GEMTAZ® READY TO USE** te sterk of te swak vir jou is, moet jy dit aan jou dokter of apteker meedeel.
Daar sal nie van jou verwag word om **GEMTAZ® READY TO USE** aan jouself toe te dien nie. Dit sal deur ‘n gekwalifiseerde persoon aan jou toegedien word.
Vra jou dokter of apteker as jy enige verdere vrae oor die gebruik van hierdie medisyne het.

As daar meer GEMTAZ® READY TO USE aan jou toegedien is as wat daar behoort te wees
As jy dink dat ‘n oordosis voorgekom het en jy sulke simptome ervaar, moet jy jou dokter ontbied. Aangesien jou gesondheidsorgverskaffer **GEMTAZ® READY TO USE** sal toedien, sal hy/sy die dosis kontroleer. In die geval van oordoering, sal jou dokter egter die oordosering beheer.

As jy vergeet het om GEMTAZ® READY TO USE te ontvang
Aangesien jou gesondheidsorgverskaffer **GEMTAZ® READY TO USE** toedien, is dit onwaarskynlik dat die dosis oorgeslaan sal word.
Dit sal geen skade veroorsaak as jy ‘n dosis oorgeslaan het nie , alhoewel sommige van jou simptome tydelik kan terugkeer totdat jy teruggaan op die skedule. Moenie ‘n dubbele dosis ontvang om te vergoed vir die individuele dosis wat jy oorgeslaan het nie.

4. Moontlike newe-effekte

GEMTAZ® READY TO USE kan newe-effekte hê.
Nie alle newe-effekte wat vir **GEMTAZ® READY TO USE** aangemeld word, is in hierdie inligtingsblad ingesluit nie. Indien jou algemene gesondheid versleg of as jy enige ongewenste

effekte ervaar terwyl jy **GEMTAZ® READY TO USE** ontvang, moet jy asseblief jou gesondheidsorgverskaffer raadpleeg vir advies.

Jy moet jou dokter onmiddellik kontak as jy enige van die volgende opmerk:

Uitermatige moegheid en swakheid, purpura of klein areas van bloeding in die vel (kneusings), akute nierversaking (lae of geen uitset van urine) en tekens van infeksie. Hierdie kan kenmerke wees van trombotiese mikro-angiopatie (klontvorming in klein bloedvate) en hemolitiese uremiese sindroom, wat fataal mag wees.

Indien enige van die volgende gebeur, staak die gebruik van GEMTAZ® READY TO USE en lig jou dokter onmiddellik in of gaan na die noodgevalle afdeling by jou naaste hospitaal:

Minder algemeen

- ernstige hipersensitiwiteits/allergiese reaksie met erge veluitslag insluitend ‘n rooi jeukende vel, swelling van die hande, voete, enkels, gesig, lippe, mond of keel (wat probleme met sluk of asemhaling kan veroorsaak), hyging, vinnige hartklop en dit mag voel asof jy gaan flou word (anafilaktiese reaksie)
- ernstige uitslag met gejeuk, blasievorming of afskilfering van die vel (Stevens-Johnson se sindroom, toksiese epidermale nekrolise).

Hierdie is almal baie ernstige newe-effekte. As jy dit ervaar het, kon jy ‘n ernstige reaksie teen **GEMTAZ® READY TO USE** gehad het. Jy mag dringende mediese aandag of hospitalisasie benodig.

Lig jou dokter onmiddellik in of gaan na die noodgevalle afdeling by jou naaste hospital:

Dikwels

- moegheid, flou gevoel, raak maklik uitasem of as jy bleek lyk (jy kan minder hemoglobien as normaalweg hê)
- bloeding van die tandvleise, neus of mond of enige bloeding wat nie wil stop nie, rooierige of

pienkerige urine, onverwagte kneusing (jy kan minder plaatjies as normaalweg hê)

- liggaamstemperatuur bo 38 °C of hoër, sweet of ander tekens van infeksie (jy kan minder witbloedbelle as normaalweg hê) gepaardgaande met koors (wat ook bekend staan as febriele neutropenie)
- pyn, rooiheid, swelling of sere in jou mond (stomatitis)
- allergiese reaksies:

  as jy ligte tot matige veluitslag of koors ontwikkel, as jy gejeuk ontwikkel

  ligte asemhalingsprobleme (dit is normaal om ligte asemhalingsprobleme wat gou sal verbygaan, ervaar kort nadat **GEMTAZ® READY TO USE** infusie aan jou toegedien is).

Minder dikwels

- asemhalingsprobleme as gevolg van meer ernstige longprobleme (interstisiële pneumonitis, brongospasma),
- onreëlmatige hartklop (aritmie)
- moeilike asemhaling as gevolg van meer ernstige longprobleme (pulmonêre edeem, volwasse respiratoriese noodsindroom)
- ernstige borskaspyn (miokardiale infarksie)
- veralgemeende swelling, kortasemigheid of gewigstoename, aangesien jy vloeistoflekkasie vanuit klein bloedvate in jou weefsel kan hê (kapillêre uitlek-sindroom)
- hoofpyn met veranderinge in visie, verwardheid, toevalle of aanvalle (posterior omkeerbare ensefalopatie-sindroom).

Voorkoms onbekend:

'n Rooi, korsvormige uitgebreide uitslag met knoppe onder die geswelde vel (insluitend jou velvoue, romp en boonste ledemate) en blasievorming gepaardgaande met koors (Akute Gegeneraliseerde Eksantemateuse Pustulose (AGEP).

Hierdie is almal ernstige newe-effekte. Jy mag dringend mediese aandag benodig.

Ander newe-effekte

Lig jou dokter so gou as moontlik in oor die volgende newe-effekte:

Dikwels

- lae witbloedseltelling
- moeilike asemhaling
- voel siek of is siek
- haarverlies
- lewerprobleme: uitgewys deur abnormale uitslae van bloedtoetse
- bloed in urine
- abnormale urine-toetse: proteïen in urine
- griepagtige simptome, insluitend koors
- swelling van enkels, vingers, voete, gesig (edeem)
- swak eetlus (anoreksie)
- hoofpyn
- slapeloosheid
- slaperigheid
- hoes
- loopneus
- hardlywigheid
- diarree
- gejeuk
- sweet
- spierpyn
- rugpyn
- koors

- swakheid
- koue rillings
- infeksies.

Mider algemeen

- letsels op die lugsakke van die long (interstisiële pneumonitis)
- hyging (spasma van die lugweë)
- letsels op die longe (abnormale borskas- X-strale/skanderings)
- hartversaking
- nierversaking
- ernstige lewerskade, insluitend lewerversaking
- beroerte
- lae bloeddruk
- velafskilfering, verswering of blasievorming
- afskotweefsel van vel en ernstige blasievorming
- inspuitplekreaksies
- ‘n veluitslag soos erge sonbrand wat op die vel kan voorkom wat voorheen aan betralingsterapie blootgestel is (bestralings-herinnering)
- vloeistof in die longe
- letsels op die lugsakke van die long wat verband hou met bestralingsterapie (bestralingstoksisiteit)
- gangreen van vingers of tone
- inflammasie van die bloedvate (perifere vaskulitis)
- verhoogde plaatjietelling
- inflammasie van die voering van die dikderm, veroorsaak deur verminderde bloedvoorsiening (iskemiese kolitis)
- klontvorming in die klein bloedvate (trombotiese mikro-angiopatie).

Voorkoms onbekend

- sepsis: wanneer bakterieë en hulle toksiene in die bloed sirkuleer en begin om skade aan organe aan te rig
- velrooiheid met swelling (pseudo-sellulitis)

Lae hemoglobienvlakke (anemie), lae witbloedsel- en lae plaatjietelling wat deur bloedtoetse opgespoor word.

Ander newe-effekte wat nie hierbo gelys is nie, mag by sommige pasiënte voorkom. Sommige van hierdie newe-effekte kan slegs opgespoor word wanneer jou dokter van tyd tot tyd toetse laat doen om jou vordering te bepaal.

Lig jou dokter, verpleegkundige of apteker in as jy enige iets opmerk wat jou sleg laat voel.

Die voordele en newe-effekte van gemsitabien kan ‘n tyd neem om voor te kom. Selfs as jy klaargemaak het met jou **GEMTAZ® READY TO USE** behandeling, moet jy daarom jou dokter onmiddellik inlig as jy enige newe-effekte opmerk wat in hierdie afdeling gelys word.

Lig asseblief jou dokter of apteker in as jy enige newe-effekte opmerk wat nie in hierdie inligtingsblad genoem word nie.

Aanmelding van newe-effekte

Praat met jou dokter, apteker of verpleegkundige as jy newe-effekte ervaar. Jy kan ook newe-effekte by SAHPRA aanmeld *via* die “6.04 Adverse Drug Reaction Reporting Form”, wat aanlyn beskikbaar is onder SAHPRA se publikasies: https://www.sahpra.org.za/Publications/Index/8 .

Deur newe-effekte aan te meld, kan jy help om meer inligting oor die veiligheid van **GEMTAZ® READY TO USE** te verskaf.

5. Hoe om GEMTAZ® READY TO USE te bewaar

Bewaar by of onder 25 °C. Moenie bevries word nie, aangesien kristallisasie kan voorkom.

HOU BUITE DIE BEREIK VAN KINDERS.

6. Inhoud van die verpakking en ander inligting

Hoe GEMTAZ® READY TO USE lyk en inhoud van die verpakking

GEMTAZ® READY TO USE word gevul in ‘n gedrukte veellagige M312 infusie-sakkie met ‘n M916M poli-olefienbuis en verseël met ‘n polikarbonaat-minitulpvormige M95A-skerppuntpoort met ‘n chlorobutiel- (laktosevrye) sluitstuk.

Die gevulde en verseëlde infusie-sakkie word verpak in ‘n voorafgedrukte aluminiumsak op so ‘n wyse dat die poort van die infusie-sakkie na die verseëlde kant toe gerig is.

Houer van die Registrasiesertifikaat

RANBAXY PHARMACEUTICALS (PTY) LTD

Lautreweg 14 Road, Stormill, Uitbreiding1,

Roodepoort, 1724

Suid-Afrika

Hierdie inligtingsblad is laas hersien op

Registrasiedatum: 30 Januarie 2024

Registrasienommers

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