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 leafelt 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 adminstered 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 you 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 overdosage, your doctor will manage the overdosage.

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 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 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

Registration numbers:

GEMTAZ 200 mg: 41/26/0934

GEMTAZ 1 g: 41/26/0933

Date of registration:

10 June 2009

PASIËNTINLIGTINGSTUK

SKEDULERINGSTATUS: S4

GEMTAZ 200 mg inspuiting
GEMTAZ 1 g inspuiting

Gemsitabienhidrohloried

Bevat suikeralkohol:

GEMTAZ 200 mg bevat 200 mg mannitol per flessie

GEMTAZ 1 g bevat 1 000 mg mannitol per flessie

Lees hierdie hele inligtingstuk noukeurig deur voordat GEMTAZ aan jou toegedien word.

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

Wat is in hierdie inligtingstuk:

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

1. Wat GEMTAZ is en waarvoor dit gebruik word

GEMTAZ behoort aan ‘n algemene groep medisyne, bekend as antimetaboliete. Dit word gebruik om kanker van die borste, pankreas en long te behandel. Dit kan ook gebruik word om ander tipes kanker, soos wat deur jou dokter vasgestel is, te behandel.

Voordat jy begin met **GEMTAZ** behandeling, moet jy en jou dokter praat oor die voordelige uitwerking asook die risikos verbonde aan die gebruik daarvan. **GEMTAZ** moet onder die direkte toesig van ‘n dokter toegedien word.

2. Wat jy moet weet voordat GEMTAZ aan jou toegedien word

GEMTAZ moet nie aan jou toegedien word nie:

- As jy hipersensitief (allergies) is vir gemsitabien of vir enige van die ander bestanddele van GEMTAZ soos gelys in afdeling 6.
- As jy swanger is of jou baba borsvoed.
- Veiligheid en doeltreffendheid by kinders is nie vasgestel nie.

Waarskuwings en voorsorgmaatreëls:

Praat met jou dokter voordat GEMTAZ toegedien word, as:

Jy al ooit ‘n ernstige veluitslag of velafskilfering, blasievorming en/of mondsere ontwikkel het nadat gemsitabien aan jou toegedien is

Ernstige velreaksies, insluitend Stevens-Johnson se sindroom, toksiese epidermale nekrolise en akute gegeneraliseerde eksantemateuse pustulose (AGEP) is aangemeld tydens behandeling met GEMTAZ. Verkry dadelik mediese versorging as jy enige van die simptome opmerk wat verband hou met ernstige velreaksies soos beskryf in afdeling 4 hieronder.

Die gebruik van GEMTAZ in kombinasie met bestralingsterapie kan tot uitgebreide newe-effekte lei. Hierdie kombinasie moet vermy word.

Dit is baie belangrik dat jou dokter jou vordering met gereelde besoeke nagaan om seker te maak dat GEMTAZ die gewenste uitwerking het en om vir ongewenste effekte na te gaan.

Terwyl jy met **GEMTAZ** behandel word, en nadat jy met die behandeling daarvan opgehou het, moet jy nie enige immunisasies (inentings) sonder jou dokter se goekeuring ontvang nie. Gemsitabien kan jou liggaam se weerstand verlaag en daar is ‘n moontlikheid dat jy die infeksie kan opdoen wat bedoel was om voorkom te word deur die immunisasie.

Kontroleer dadelik met jou dokter as kortasemighied voorkom of vererger terwyl jy met GEMTAZ behandel word.

Lig jou dokter in as jy aan enige van die volgende ly:

- Beenmurgonderdrukking
- Bestaande of onlangse waterpokkies
- Gordelroos

Kinders en adolessente:

GEMTAZ is nie bedoel vir gebruik by kinders onder die ouderdom van 18 jaar nie.

Ander medisyne en GEMTAZ:

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

Lig jou dokter in as jy tans met enige van die volgende behandel word:

- Beenmurgonderdrukkers of bestralingsterapie.
- Immuunonderdrukkers (bv. asatioprien, chlorambusiel, kortikosteroïede, siklofosfamied, siklosporien, merkaptopurien, muromonab CD-3 en takrolimus).

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 voordat GEMTAZ aan jou toegedien word.

GEMTAZ is teenaangedui vir swanger of borsvoedende vroue.

As jy ‘n vroulike pasiënt is wat GEMTAZ ontvang, sal jou dokter jou aanraai om doeltreffende voorbehoeding te tref tydens behandeling en om nie swanger te raak tydens en vir tot 6 maande ná behandeling met GEMTAZ nie.

Manlike pasiënte word aangeraai om doeltreffende voorbehoeding tydens behandeling te gebruik en om nie ‘n kind te verwek tydens en vir tot 3 maande ná behandeling met GEMTAZ nie. Verkry advies van jou dokter of apteker as jy graag ‘n kind wil verwek tydens behandeling of in die tydeperk van 3 maande ná die behandeling. Jy kan raad verkry oor die bewaring van sperms voordat jou behandeling in aanvang neem.

Bestuur en gebruik van masjinerie:

GEMTAZ kan tot slaperigheid lei en versigtigheid word aanbeveel wanneer jy bestuur of masjinerie gebruik.

3. Hoe GEMTAZ toegedien sal word

Daar sal nie van jou verwag word om GEMTAZ aan jouself toe te dien nie, dit sal deur ‘n gekwalifiseerde persoon aan jou toegedien word.

Jou dokter sal die dosis bepaal wat geskik is vir jou toestand.

Jy sal die medikasie deur ‘n intraveneuse infusie ontvang.

Jou dokter sal jou inlig oor hoe lank jou behandeling met GEMTAZ sal duur As jy onder die indruk is dat die effek van GEMTAZ te sterk of te swak is, moet jy jou dokter of apteker inlig.

As jy meer GEMTAZ ontvang het as wat jy behoort te ontvang:

Aangesien jou gesondheidsorgverskaffer GEMTAZ sal toedien, sal hy/sy die dosis kontroleer. In die geval van oordosering, sal jou dokter egter die oordosering beheer.

As jy ‘n dosis van GEMTAZ oorgeslaan het:

GEMTAZ word onder die toesig van jou dokter toegedien. As jy dink dat jy ‘n dosis oorgeslaan het, praat met jou dokter of gesondheidsorgverskaffer.

4. Moontlike newe-effekte

GEMTAZ kan newe-effekte hê.

Nie alle newe-effekte wat vir GEMTAZ aangemeld word, is in hierdie inligtingsblad ingesluit nie. Indien jou algemene gesondheid versleg of as jy enige ongewenste effekte ervaar terwyl jy GEMTAZ ontvang, moet jy asseblief jou dokter, apteker of ander gesondheidsorgverskaffer raadpleeg vir advies.

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

- Swelling van jou hande, voete, enkels, gesig, mond of keel, wat probleme om te sluk of asem te haal kan veroorsaak
- Uitslag of gejeuk
- Floute

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

Lig jou dokter onmiddellik in of gaan na die noodgevalle-afdeling by jou naaste hospitaal as jy enige van die volgende opmerk:

- ‘n Rooi, korsvormige uitgebreide uitslag met knoppe onder die geswelde vel (insluitend jou velvoue, romp en boonste ledemate) en blasievorming gepaardgaande met koors, bekend as akute gegeneraliseerde eksantemateuse pustulose (AGEP).
- Ongewone moegheid of swakheid
- Kortasemigheid
- Swelling van die vingers, voete of bene
- Minder algemene voorkoms
- Vinnige onreëlmatige hartklop
- Koors of koue rillings

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

Lig jou dokter in as jy enige van die volgende opmerk:

Dikwelse voorkoms

- Hardlywigheid, diaree, naarheid of braking

Minder algemene voorkoms

- Irritatasie, rooiheid of pyn by die inspuitplek
- Sere, ulkusse of wit vlekke op die lippe en in die mond

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 of apteker 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 te verskaf.

5. Hoe om GEMTAZ te bewaar

Bewaar by of onder 25 °C.

Die hersaamgestelde oplossing kan vir 24 uur onder 25 °C bewaar word.

Gooi enige ongebruikte gedeelte weg.

Moenie in die yskas bewaar nie.

HOU ALLE MEDISYNE BUITE DIE BEREIK VAN KINDERS.

Moenie na die vervaldatum, soos op die flessie gedruk, gebruik nie.

Moenie van ongebruikte medisyne in dreinering- en rioleringstelsels (bv. toilette) ontslae raak nie.

6. Inhoud van die verpakking en ander inligting

Wat GEMTAZ bevat:

Die aktiewe bestanddeel is gemsitabienhidrochloried.

GEMTAZ 200 mg: Elke flessie bevat gemsitabienhidrochloried gelykstaande aan 200 mg gemsitabien (40 mg/mL).

GEMTAZ 1 g: Elke flessie bevat gemsitabienhidrochloried gelykstaande aan 1 g gemsitabien (40 mg/mL).

Die ander bestanddele is: Mannitol, natriumasetaat, natriumhidroksied en soutsuur.

Hoe GEMTAZ lyk en inhoud van die verpakking:

Wit tot naaswit gevriesdroogde koekie.

GEMTAZ 200 mg word verpak in 10 mL kleurlose tipe-I buisvormige glasflessies met ‘n 20 mm krimpwydte, met ‘n 20 mm grys bromobutiel-rubberprop en verseël met ‘n groen aftrekbare aluminiumseël.

GEMTAZ 1 g word verpak in ‘n 50 mL kleurlose tipe-I gevormde glasflessie met ‘n 20 mm krimpwydte, met ‘n 20 mm grys bromobutiel-rubberprop en verseël met ‘n groen aftrekbare aluminiumseël.

Houer van die registrasiesertifikaat en vervaardiger:

Ranbaxy Pharmaceuticals (Pty) Ltd

Lautreweg 14

Stormill, Uitbreiding 1

Roodepoort

Johannesburg 1724

Hierdie inligtingstuk was laas hersien op:

08 April 2024

Registrasienommers:

GEMTAZ 200 mg: 41/26/0934

GEMTAZ 1 g: 41/26/0933

Datum van registrasie:

10 Junie 2009