APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

Accord Gemcitabine 200 mg (Powder for Injection)

Accord Gemcitabine 1 g (Powder for Injection)

Gemcitabine

Sugar free:

Read all of this leaflet carefully before you start receiving ACCORD GEMCITABINE

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- ACCORD GEMCITABINE 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 ACCORD GEMCITABINE is and what it is used for:

ACCORD GEMCITABINE contains the active substance gemcitabine.

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ACCORD GEMCITABINE is used to treat patients with:

- Lung cancer
- Cancer of the pancreas
- Bladder cancer
- Breast cancer
- Ovarian cancer

ACCORD GEMCITABINE works by killing cancer cells and preventing cancer cells from growing and multiplying.

ACCORD GEMCITABINE belongs to a group of medicines called antineoplastic or cytotoxic medicines. You may also hear of these being called chemotherapy medicines.

ACCORD GEMCITABINE may be used in combination with other cytotoxic medicines to treat cancer.

2. What you need to know before you take ACCORD GEMCITABINE:

Do not receive ACCORD GEMCITABINE if:

- You have had an allergic reaction to ACCORD GEMCITABINE or to any of the ingredients of ACCORD GEMCITABINE (listed in section 6).
- The packaging is torn or shows signs of tampering.
- The expiry date printed on the pack has passed.

Warnings and precautions

Take special care and talk to your doctor before taking ACCORD GEMCITABINE:

- if you have problems with your liver.
- if you have problems with your kidneys.
- If you are at risk of bleeding or have an inherited risk of bleeding.
- if you are on other radiotherapy (given together or < 7 days apart).
- if you have taken a yellow fever or other live vaccine.

- if you have problems with your heart.

Your doctor will regularly monitor your condition to check whether ACCORD GEMCITABINE is having the desired effect. You will also have blood tests regularly before and while you are taking ACCORD GEMCITABINE.

Children and adolescents

The safety and efficacy of ACCORD GEMCITABINE has not been established in children younger than 18 years.

Other medicines and ACCORD GEMCITABINE:

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

Some medicines may be affected by ACCORD GEMCITABINE or may affect how it works. Your doctor and healthcare professional may have more information on medicines to be careful with or avoid while being give ACCORD GEMCITABINE.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare professional for advice before receiving ACCORD GEMCITABINE.

Pregnancy

Like most medicines used to treat cancer, **ACCORD GEMCITABINE** is not recommended to be given during pregnancy. If there is a need to consider **ACCORD GEMCITABINE** during your pregnancy, your doctor will discuss with you the benefits and risks involved.

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Breastfeeding

Tell your doctor if you are breastfeeding or plan to breastfeed.

It is recommended that you do not breastfeed while you are receiving **ACCORD GEMCITABINE**, as it is not known whether **ACCORD GEMCITABINE** passes into breast milk.

Fertility

Men are advised not to father a child during and up to 6 months following treatment with ACCORD GEMCITABINE. If you would like to father a child during the treatment or in the 6 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

- ACCORD GEMCITABINE may influence your ability to drive and use machines.
- Do not drive a car or use machinery until you are certain that you are not drowsy.

3. How ACCORD GEMCITABINE will be administered to you:

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

ACCORD GEMCITABINE will be administered to you through an intravenous injection.

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

If you receive more ACCORD GEMCITABINE than you should:

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Since a healthcare professional will administer ACCORD GEMCITABINE**,** he/she will control the dosage.

However, in the event of overdosage your doctor will manage the overdosage.

4. Possible side effects:

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

ACCORD GEMCITABINE may have unwanted side effects, some of which may be serious. You may need medical treatment if you experience some of the side effects.

Ask your doctor or healthcare professional to answer any questions you may have.

Tell your doctor as soon as possible if you notice any of the following side effects:

- frequent infections such as fever, severe chills, sore throat or ulcers
- sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips or tongue or other parts of the body, shortness of breath, wheezing or trouble breathing
- difficulty in breathing; wheezing or coughing
- shortness of breath
- bruising or bleeding more easily than normal
- tiredness, headaches, being short of breath when exercising, dizziness and looking pale.

Skin reactions such as:

- skin lesions
- small, solid, raised areas of skin
- raised bumps on the skin that contain fluid (blisters)
- open sores on the skin (ulcers)
- peeling of skin.

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These may be serious side effects. You may need medical attention.

Tell your doctor immediately or go to casualty department at your nearest hospital if any of the following happen:

- rapid laboured breathing; extreme shortness of breath; slightly bluish, greyish or dark purple discolouration of the skin; cold extremities
- quick shallow breathing followed by shortness of breath and difficulty in breathing
- tiredness, headaches and bruising or bleeding more easily than normal; yellowing of the skin and/or eyes; passing less urine than is normal
- chest pain, changes in the rhythm or rate of the heart beat
- discolouration or loss of sensation in the extremities.

These are very serious side effects.

You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects:

- infections
- Vomiting, nausea, diarrhoea, stomatitis (inflammation of the cheek, tongue or gums), ulceration of the mouth, constipation
- Allergic skin rash, itching, hair loss, sweating
- Back pain
- Blood in the urine
- Flu-like symptoms with the most common being fever, headache, chills, muscle aches and anorexia.
- Cough, runny or blocked nose, fatigue, perspiration, sleeping difficulties.
- Oedema/peripheral oedema including facial oedema. Oedema is usually reversible after stopping treatment.

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Less frequent side effects:

- Allergic reactions
- Acute hypertension, seizures, headaches, lethargy, confusion, blindness (Posterior reversible encephalopathy syndrome)
- Heart attacks
- Ulceration, vesicle and sore formation, scaling, severe skin reactions, including desquamation and bullous skin eruptions.
- Injection site reactions (usually mild)

Not known (frequency cannot be estimated from the available data):

- Sepsis
- Pseudocellulitis (skin infection characterized by erythema, swelling, warmth and tenderness)
- acute generalised exanthematous pustulosis (AGEP) (superficial pustules).
- radiation toxicity

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist. The benefits and side effects of ACCORD GEMCITABINE may take some time to occur. Therefore, even after you have finished your ACCORD GEMCITABINE treatment, you should tell your doctor or healthcare professional immediately if you notice any of the side effects listed in this section.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the “Adverse drug reaction and quality problem reporting form”, found online under SAHPRA’s publications:

https://www.sahpra.org.za/document/adverse-drug-reactions-and-quality-problem-reporting-form/.

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By reporting side effects, you can help provide more information on the safety of ACCORD GEMCITABINE .

5. How to store ACCORD GEMCITABINE:

Before reconstitution: Store at or below 25°C.

After reconstitution: Solutions of **ACCORD GEMCITABINE** reconstituted with 0,9% sodium chloride injection without preservatives should be stored below 25 °C and should be administered within 24 hours. Discard unused portion. Do not refrigerate as crystallisation may occur. Reconstituted **ACCORD GEMCITABINE** should be inspected visually for particulate matter and discolouration, prior to administration. Procedures for proper handling and disposal of anti-cancer drugs should be considered.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Store in original package.

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

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

6. Contents of the pack and other information:

What ACCORD GEMCITABINE contains

The active substance is gemcitabine.

The other ingredients are mannitol, sodium acetate trihydrate, sodium hydroxide, hydrochloric acid 37 % and water for injection

What ACCORD GEMCITABINE looks like and contents of the pack

ACCORD GEMCITABINE 200 mg: A white to off white lyophilized powder in a clear glass vial. Reconstitution with 0,9% sodium chloride injection without preservatives produces a clear, colourless to light straw coloured solution for injection.

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ACCORD GEMCITABINE 1 g: A white to off white lyophilized powder in a clear glass vial. Reconstitution with 0,9% sodium chloride injection without preservatives produces a clear, colourless to light straw coloured solution for injection.

ACCORD GEMCITABINE 1 g: An outer carton containing one 50 ml USP type 1 clear colourless glass vial with a 20 mm grey bromobutyl rubber stopper and 20 mm aluminium flip off royal blue seal.

ACCORD GEMCITABINE 200 mg: An outer carton containing one 10 ml USP type 1 clear colourless glass vial with a 20 mm grey bromobutyl rubber stopper and 20 mm aluminium flip off royal blue seal.

HOLDER OF CERTIFICATE OF REGISTRATION

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REGISTRATION NUMBER

ACCORD GEMCITABINE 200 mg: 42/26/0088

ACCORD GEMCITABINE 1 g: 42/26/0903