Patient information leaflet

(For All Products not subject to Medical Prescription)

GEMTERO 200 MG (Gemcitabine for Injection USP 200 mg)

PACKAGE LEAFLET: INFORMATION FOR THE USER

Read all of this leaflet carefully before you start taking this medicine.

Keep this leaflet. You may need to read it again.

If you have any further questions, please ask your doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

If any of the side effects get serious, or you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist

In this leaflet:

1. What Gemcitabine powder for solution for infusion is and what it is used for
2. Before you are given Gemcitabine powder for solution for infusion
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1. WHAT GEMCITABINE POWDER FOR SOLUTION FOR INFUSION IS AND WHAT IT IS USED FOR

Gemcitabine powder for solution for infusion belongs to a group of medicines called “cytotoxics”. These medicines kill dividing cells, including cancer cells.

Gemcitabine powder for solution for infusion may be given alone or in combination with other anti-cancer medicines, depending on the type of cancer.

Gemcitabine powder for solution for infusion is used in the treatment of the following types of cancer:

- non-small cell lung cancer (NSCLC), alone or together with cisplatin
- pancreatic cancer.
- breast cancer, together with paclitaxel.
- ovarian cancer, together with carboplatin.
- bladder cancer, together with cisplatin.

2. BEFORE YOU ARE GIVEN GEMCITABINE POWDER FOR SOLUTION FOR INFUSION

You should not be given Gemcitabine powder for solution for infusion:

- if you are allergic (hypersensitive) to gemcitabine or any of the other ingredients of Gemcitabine powder for solution for infusion.
- if you are breast-feeding

Take special care with Gemcitabine powder for solution for infusion:

Before the first infusion you will have samples of your blood taken to evaluate if you have sufficient kidney and liver function. Before each infusion you will have samples of your blood taken to evaluate if you have enough blood cells to receive Gemcitabine powder for solution for infusion. 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 evaluate your kidney and liver function.

Please tell your doctor if:

- you have, or have previously had liver disease, heart disease or vascular disease.
- you have recently had, or are going to have radiotherapy,
- you have been vaccinated recently
- you develop breathing difficulties or feel very weak and are very pale (may be a sign of kidney failure).

Men are advised not to father a child during and up to 6 months following treatment with Gemcitabine powder for solution for infusion. 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 counseling on sperm storage before starting your therapy.

Taking other medicines

Please tell your doctor or hospital pharmacist if you are taking or have recently taken any other medicines, including vaccinations and medicines obtained without a prescription.

Pregnancy and breast-feeding

If you are pregnant, or thinking about becoming pregnant, tell your doctor. The use of Gemcitabine powder for solution for infusion should be avoided during pregnancy. Your doctor will discuss with you the potential risk of taking Gemcitabine powder for solution for infusion during pregnancy.

If you are breast-feeding, tell your doctor.

You must discontinue breast-feeding during Gemcitabine powder for solution for infusion treatment.

Driving and using machines

Gemcitabine powder for solution for infusion 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 powder for solution for infusion treatment has not made you feel sleepy.

Important information about some of the ingredients of Gemcitabine powder for solution for infusion

Gemcitabine powder for solution for infusion contains 3.5 mg (< 1 mmol) of sodium in each 200 mg vial, 17.5 mg (< 1 mmol) sodium in each 1000 mg vial and 35 mg (1.52 mmol) sodium in each 2000 mg vial. This should be taken into consideration by patients on a controlled sodium diet.

3. HOW GEMCITABINE POWDER FOR SOLUTION FOR INFUSION IS GIVEN

The usual dose of Gemcitabine is 1000-1250 mg for every square meter 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 dosage may be adjusted, or treatment may be delayed depending on your blood cell counts and on your general condition.

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

A hospital pharmacist or doctor will have dissolved the Gemcitabine powder before it is given to you.

You will always receive Gemcitabine by infusion into one of your veins. The infusion will last approximately 30 minutes.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Gemcitabine powder for solution for infusion can cause side effects, although not everybody gets them.

Frequencies of the observed side effects are defined as:

- very common: affects more than 1 user in 10
- common: affects 1 to 10 users in 100
- uncommon: affects 1 to 10 users in 1,000
- rare: affects 1 to 10 users in 10,000
- very rare: affects less than 1 user in 10,000
- not known: frequency can't be estimated from the available data

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

- Fever or infection (common): if you have a temperature of 38ºC or greater, sweating or other signs of infection (since you might have less white blood cells than normal which is very common).
- Irregular heart rate (arrhythmia) (frequency not known).
- Pain, redness, swelling or sores in your mouth (common).
- Allergic reactions: if you develop skin rash (very common) / itching (common), or fever (very common).
- Tiredness, feeling faint, becoming easily breathless or if you look pale (since you might have less haemoglobin than normal which is very common).

- Bleeding from the gums, nose or mouth or any bleeding that would not stop, reddish or pinkish urine, unexpected bruising (since you might have less platelets than normal which is very common).
- Difficulty breathing (it is very common to have mild breathing difficulty soon after the Gemcitabine infusion which soon passes, however uncommonly or rarely there can be more severe lung problems)

Side effects with Gemcitabine powder for solution for infusion may include:

Very common side effects

Low haemoglobin level (anaemia)

Low white blood cells

Low platelet count

Difficulty breathing

Vomiting

Nausea

Skin rash- allergic skin rash, frequently itchy

Hair loss

Liver problems: found through abnormal blood test results

Blood in urine

Abnormal urine tests: protein in urine

Flu like symptoms including fever

Oedema (swelling of ankles, fingers, feet, face)

Common side effects

Fever accompanied by low white blood cell count (febrile neutropenia)

Anorexia (poor appetite)

Headache

Insomnia

Sleepiness

Cough

Runny nose

Constipation

Diarrhoea

Pain, redness, swelling or sores in the mouth

Itching

Sweating

Muscle pain

Back pain

Fever

Weakness

Chills

Uncommon side effects

Interstitial pneumonitis (scarring of the air sacs of the lung)

Spasm of the airways (wheeze)

Abnormal chest X ray/scan (scarring of the lungs)

Rare side effects

Heart attack (myocardial infarction)

Low blood pressure

Skin scaling, ulceration or blister formation

Injection site reactions

Very rare side effects

Increased platelet count

Anaphylactic reaction (severe hypersensitivity/ allergic reaction)

Sloughing of skin and severe skin blistering

Side effects with frequency not known

Irregular heart beat (arrhythmia)

Adult Respiratory Distress Syndrome (severe lung inflammation causing respiratory failure)

Radiation recall-(a skin rash like severe sunburn) which can occur on skin that has previously been exposed to radiotherapy.

Fluid in the lungs

Radiation toxicity- scarring of the air sacs of the lung associated with radiation therapy

Ischaemic colitis (inflammation of the lining of the large bowel, caused by reduced blood supply)

Heart failure

Kidney failure

Gangrene of fingers or toes

Serious liver damage, including liver failure

Stroke

You might have any of these symptoms and/or conditions. You must tell your doctor as soon as possible when you start experiencing any of these side effects.

If you are concerned about any side effects, talk to your doctor.

If any of the side effects gets serious, or if you notice any side effects not mentioned in this leaflet, please tell your doctor.

5. HOW TO STORE GEMCITABINE POWDER FOR SOLUTION FOR INFUSION

Keep out of the reach and sight of children.

Do not use Gemcitabine powder for solution for infusion after the expiry date, which is stated on the carton and vial. The expiry date refers to the last day of that month.

Unopened vial: This medicinal product does not require any special storage conditions.

Reconstituted solution: The product should be used immediately. When prepared as directed, chemical and physical in-use stability of reconstituted solutions of gemcitabine were demonstrated for 21 days at 25°C. Further dilution by a healthcare provider may be done. Solutions of reconstituted gemcitabine should not be refrigerated, as crystallisation may occur.

This medicine is for single use only; any unused solution should be discarded under the local requirements.

6. FURTHER INFORMATION

What Gemcitabine powder for solution for infusion contains

The active substance is gemcitabine. Each vial contains Gemcitabine Hydrochloride equivalent to Gemcitabine 200 mg.

The other ingredients are Mannitol (Pearlitol PF), USP, Sodium Acetate Trihydrate, USP, Sodium Hydroxide USP/NF, Hydrochloric Acid, USP/NF and Water for Injection.

What Gemcitabine powder for solution for infusion looks like and contents of the pack

Gemcitabine powder for solution for infusion is a White to off white lyophilized plug contained in a flint glass vial.

Gemcitabine powder for solution for infusion available in glass vials of:

Glass Vials: 12' count (10 mL glass vial, 20 mm rubber stopper with 20 mm flip of seal)

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

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