Gemtek

200mg INJECTION
(Gemcitabine hydrochloride)
(concentrate for solution for infusion)
Must be Diluted Before Use

COMPOSITION:
Each Vial contains:
Gemcitabine as hydrochloride …….. 200mg
Product complies Innovator's specifications

INDICATIONS:
Gemcitabine belongs to a group of medicines called "cytotoxic". These medicines kill dividing cells, including cancer cells. Gemcitabine may be given alone or in combination with other anti-cancer medicines, depending on the type of cancer. Gemcitabine is used in the treatment of the following types of cancer:
• Non-small cell lung cancer (NSCLC), alone or together with cisplatin • Bladder cancer, together with cisplatin.
• Breast cancer, together with paclitaxel • Ovarian cancer, alone or together with carboplatin • Pancreatic cancer

CONTRAINDICATIONS:
Gemcitabine should not be administered to you:
• If you are hypersensitive (allergic) to gemcitabine. • If you are pregnant or breastfeeding.

WARNINGS AND PRECAUTIONS:
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 GEMTEK. 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.

Tell your doctor or health care provider before being given GEMTEK , if:
• You have, or previously had liver disease, heart disease or vascular disease, problems with your lungs or your kidneys as you may not be able to receive Gemcitabine.
• You have recently, or are going to have radiotherapy as there may be an early or late radiation reaction with Gemcitabine.
• You have been vaccinated recently (especially against yellow fever) as this can possibly cause bad effects with Gemcitabine Injection.
• You develop breathing difficulties or feel very weak and are very pale as this may be a sign of kidney failure or problems with your lungs.
• You develop generalized swelling, shortness of breath or weight gain as this may be a sign of fluid leaking from your small blood vessels into the tissue.
• During treatment with this medicine, you get symptoms such as headache with confusion, seizure (fits) or changes in vision, call your doctor immediately. This could be a very rare nervous system side effect named posterior reversible encephalopathy syndrome.

Children
Do not give Gemcitabine to children under the age of 18 years due to the insufficient data on safety and efficacy.

Other medicines and Gemcitabine
Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)
• If you are receiving radiotherapy, also called radiation therapy (used to treat patients with cancer).
• If you are given vaccinations (a treatment which makes the body stronger against a particular infection) e.g. yellow fever.

Pregnancy, breastfeeding and fertility
If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask a pharmacist or another healthcare professional for advice before taking this medicine.

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

Breastfeeding:
If you are breastfeeding, tell your doctor. You must discontinue breastfeeding during Gemcitabine treatment.

Fertility:
Males are advised not to father a child during and up to 6 months following treatment with GEMTEK. If you would like to father a child during the treatment or in the 6 months following treatment, please consult your doctor, pharmacist or health care provider. You may want to seek counselling on sperm storage before starting your therapy.

Driving and using machinery
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 has not made you feel sleepy. It is not always possible to predict to what extent Gemcitabine may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which Gemcitabine affects them.

METHOD OF ADMINISTRATION:
Gemcitabine will be administered in hospital, by a healthcare professional with an injection. You will not be expected to give yourself Gemcitabine . It will be given to you by a person who is qualified to do so. The usual dose of GEMTEK is 1000 to 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 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 GEMTEK infusion depends on the type of cancer that you are being treated for. You will always receive GEMTEK only after dilution by infusion into one of your veins. The infusion will last approximately 30 minutes. If you have any further questions on the use of this medicine ask your doctor or pharmacist.

If you take more Gemcitabine than you should
Since a health care provider will administer Gemcitabine he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to take of Gemcitabine
Since a health care provider will administer Gemcitabine, it is unlikely that the dose will be missed.

POSSIBLE SIDE EFFECTS
Gemcitabine can have side effects. Not all side effects reported for Gemcitabine are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Gemtek please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking GEMTEK and tell your doctor immediately or go to the casualty department at your nearest hospital:
• Serious reaction where swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing, rash or itching (anaphylactic reaction), • Fainting.
These are all very serious side effects. If you have them, you may have a serious allergic reaction to GEMTEK. You may need urgent medical attention or hospitalization.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:
• 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 frequent).
• Tiredness, feeling faint, becoming easily breathless or if you look pale (since you might have less haemoglobin than normal which is frequent).
• Mild to moderate skin rash/ itching, or fever (frequent); (allergic reactions).
• Temperature of 38 ºC or greater, sweating or other signs of infection (since you might have less white blood cells than normal accompanied by fever also known as febrile neutropenia) (frequent).
• Pain, redness, swelling or sores in your mouth (stomatitis) (frequent).
• Irregular heart rate (arrhythmia) (less frequent).
• 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 (hemolytic uremic syndrome). It may be fatal (less frequent).
• Difficulty breathing.
• Severe chest pain (myocardial infarction) (less frequent).
• Generalized swelling, shortness of breath or weight gain, as you might have fluid leakage from small blood vessels into the tissues (capillary leak syndrome) (less frequent).
• Headache with changes in vision, confusion, seizures or fits (posterior reversible encephalopathy syndrome) (less frequent).
• Severe rash with itching, blistering or peeling of the skin (Stevens-Johnson syndrome, toxic epidermal necrolysis) (less frequent).
• 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 hemolytic uremic syndrome, which may be fatal.
These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:
Frequent side effects:
• Low white blood cells • Vomiting • Nausea • Liver problems: Found through abnormal blood test results
• Blood in urine • Hair loss • Abnormal urine tests: Protein in urine • Headache • Cough • Infections
• Flu like symptoms including fever • Swelling of ankles, fingers, feet, face (edema) • Poor appetite (anorexia)
• Sleeping problems • Sleepiness • Runny nose • Constipation • Diarrhea • Itching • Sweating
• Muscle pain • Back pain • Fever • Weakness • Chills • Increased liver values (bilirubin).

Less frequent side effects:
• Scarring of the air sacs of the lung (interstitial pneumonitis) • Wheeze (spasm of the airways) • Stroke
• Scarring of the lungs (abnormal chest X-ray/scan) • Heart failure • Kidney failure • Fluid in the lungs
• Serious liver damage, including liver failure and death • Skin scaling, ulceration or blister formation
• Sloughing of the skin and severe skin blistering • Injection site reactions. • Increased liver values (GGT)
• A skin rash like severe sunburn which can occur on skin that has previously been exposed to radiotherapy (radiation recall) • Severe lung inflammation causing respiratory failure (adult respiratory distress syndrome).
• Scarring of the air sacs of the lung associated with radiation therapy (radiation toxicity)
• Gangrene of fingers or toes • Inflammation of the blood vessels • Increased platelet count.
• Inflammation of the lining of the large bowel, caused by reduced blood supply (ischemiccolitis).
• *Thrombotic microangiopathy:* Clots forming in small blood vessels.

Frequency unknown side effects:
• *Sepsis:* When bacteria and their toxins circulate in the blood and starts to damage the organs.
• *Pseudo cellulitis :* Skin redness with swelling.
• Low hemoglobin level (anemia), will be detected by a blood test.

DOSAGE AND INSTRUCTIONS:
• As directed by the physician.
• Store at or between 2°C to 8°C (in a refrigerator) • Do not freeze. Protect from heat & light.
• Keep all medicines out of the reach of children • Improper storage may deteriorate the medicines.
• Do not use Gemtek, if the solution appears discolored or contains visible particles, it should be discarded.
• Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).
• Do not use after the expiry date stated on the label or carton.

HOW SUPPLIED
Gemtek-200mg Injection
Gemtek 200mg/5.26ml (38mg/ml) sterile solution in a single dose glass vial packed in a unit carton with insertion of leaflet.

جیمٹیک انجیکشن 200 ملی گرام

(جیمسیٹابائین ہائیڈروکلورائیڈ)

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔
ہدایات: 2 سے 8 ڈگری سینٹی گریڈ درجہ حرارت پر رکھیں۔
منجمد ہونے سے بچائیں۔
دوا کو روشنی اور گرمی سے محفوظ رکھیں۔
دوا کو بچوں کی پہنچ سے دور رکھیں۔ صرف مستند ڈاکٹر کے نسخہ پر فروخت کریں۔

Manufactured by :
Pharmedic Laboratories (Pvt) Limited.
16-Km.Multan Road, Lahore-Pakistan.