

PACKAGE LEAFLET: INFORMATION FOR THE USER

Gemcitabine "Ebewe" 10 mg/ml concentrate for solution for infusion

Gemcitabine

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- 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 gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

What is in this leaflet:

1. What Gemcitabine „Ebewe“ is and what it is used for
2. What you need to know before you use Gemcitabine „Ebewe“
3. How to use Gemcitabine „Ebewe“
4. Possible side effects
5. How to store Gemcitabine „Ebewe“
6. Content of the pack and other information

1. What Gemcitabine „Ebewe“ is and what it is used for

Gemcitabine „Ebewe“ belongs to a group of medicines called “cytotoxics”. These medicines kill dividing cells, including cancer cells.

Gemcitabine „Ebewe“ may be given alone or in combination with other anti-cancer medicines, depending on the type of cancer.

Gemcitabine „Ebewe“ is used either alone or in combination with other drugs in the treatment of the following types of cancer:

- non-small cell lung cancer (NSCLC)
- pancreatic cancer
- breast cancer
- ovarian cancer
- bladder cancer

2. What you need to know before you use Gemcitabine „Ebewe“

Do not use Gemcitabine „Ebewe“:

- if you are allergic (hypersensitive) to gemcitabine or any of the other ingredients of Gemcitabine „Ebewe“.
- if you are breast-feeding.

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 Gemcitabine „Ebewe“. 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.

Talk to your doctor before using Gemcitabine “Ebewe” if:

- you have, or have previously had liver disease, heart disease or problems with your veins
- you have problems with your lungs or your kidneys
- you have recently had, or are going to have radiotherapy.
- you have been vaccinated recently (especially against yellow fever)
- you develop breathing difficulties or feel very weak and are very pale (may be a sign of kidney failure or problems with your lungs).
- you develop generalised swelling, shortness of breath or weight gain (this may be a sign of fluid leaking from your small blood vessels into the tissue).
- you are pregnant or planning to have a baby

Children and adolescents

There is no relevant use of Gemcitabine in the paediatric population

Other medicines and Gemcitabine “Ebewe”

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, breast-feeding and fertility

Pregnancy

If you are pregnant, or thinking about becoming pregnant, tell your doctor.

The use of Gemcitabine „Ebewe“ should be avoided during pregnancy. Your doctor will discuss with you the potential risk of taking Gemcitabine „Ebewe“ during pregnancy.

Breast-feeding

If you are breast-feeding, tell your doctor.

You must discontinue breast-feeding during Gemcitabine „Ebewe“ treatment.

Fertility

Men are advised not to father a child during and up to 6 months following treatment with Gemcitabine „Ebewe“. 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

Gemcitabine „Ebewe“ 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 „Ebewe“ treatment has not made you feel sleepy.

Important information about some of the ingredients of Gemcitabine „Ebewe“

Gemcitabine „Ebewe“ contains 1.07 mg sodium per milliliter (0.05 mmol). This should be taken into consideration by patients on a controlled sodium diet.

3. How to use Gemcitabine “Ebewe”

The usual dose of Gemcitabine „Ebewe“ is 1000-1250 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 Gemcitabine „Ebewe“ infusion depends on the type of cancer that you are being treated for.

You will always receive Gemcitabine „Ebewe“ 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 „Ebewe“ 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 38°C 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 „Ebewe“ infusion which soon passes, however uncommonly or rarely there can be more severe lung problems).

Side effects with Gemcitabine „Ebewe“ 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 neutropaenia)
- 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)
- Stroke
- Irregular heart beat (arrhythmia)
- Heart failure
- Kidney failure
- Serious liver damage, including liver failure and death
- Hemolytic uraemic syndrome (a disease characterized by haemolytic anaemia, acute renal failure and a low platelet count)
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Rare side effects

- Heart attack (myocardial infarction)
- Low blood pressure
- Severe skin reactions including skin scaling, ulceration or blister formation
- Injection site reactions
- Gangrene of fingers or toes
- Radiation recall-(a skin rash like severe sunburn) which can occur on skin that has previously been exposed to radiotherapy.
- Radiation toxicity- scarring of the air sacs of the lung associated with radiation therapy
- Fluid in the lungs
- Acute Respiratory Distress Syndrome (severe lung inflammation causing respiratory failure)
- Inflammation of the blood vessels

Very rare side effects

- Increased platelet count
- Anaphylactic reaction (severe hypersensitivity / allergic reaction)
- Sloughing of skin and severe skin blistering (Toxic epidermal necrolysis, Stevens-Johnson Syndrome)
- Ischaemic colitis (inflammation of the lining of the large bowel, caused by reduced blood supply)
- Capillary leak syndrome (fluids from your small blood vessels leak out into the tissue)
- Posterior Reversible Encephalopathy Syndrome (PRES) (a neurologic condition with symptoms including seizures, headache, confusion, and changes in vision)

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.

Reporting of side effects

If you get any 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 directly via IMB Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.imb.ie; e-mail: imbpharmacovigilance@imb.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Gemcitabine “Ebewe”

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and label after EXP. The expiry date refers to the last day of that month.

Do not refrigerate or freeze.

If the solution appears discoloured or contains visible particles, it should be discarded.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Content of the pack and other information

What Gemcitabine „Ebewe“ contains

The active substance is gemcitabine (as hydrochloride).

The other ingredients are: Sodium acetate trihydrate, sodium hydroxide, water for injects.

What Gemcitabine „Ebewe“ looks like and contents of the pack

This medicinal product is a concentrate for solution for infusion.

1 ml of each vial contains 10 mg gemcitabine (as hydrochloride) as active ingredient.

Gemcitabine „Ebewe“ is a concentrate for solution for infusion and a clear, colourless or almost colourless solution.

200 mg vial: Each vial contains 200 mg gemcitabine (as hydrochloride) in 20 ml.

500 mg vial: Each vial contains 500 mg gemcitabine (as hydrochloride) in 50 ml.

1000 mg vial: Each vial contains 1000 mg gemcitabine (as hydrochloride) in 100 ml.

It is available in packs containing 1 vial, 5 vials or 10 vials with or without a protective plastic overwrap (Onco-Safe). The Onco-Safe has no contact with the drug product and increases safety during transport for medical and pharmaceutical personnel.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing authorisation holder:

EBEWE Pharma Ges.m.b.H. Nfg. KG
4866 Unterach
Austria
Tel: +43 / 7665 / 8123-0
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Manufacturer:

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[To be completed nationally]

The following information is intended for medical or healthcare professionals only:

Compatibility with other drugs has not been studied; therefore, it is not recommended to mix Gemcitabine „Ebewe“ with other drugs.

Parenteral drugs should be inspected visually for particulate matter and discolouration, prior to administration, whenever solution and container permit.

Transfer the required quantity of solution under aseptic conditions into a suitable infusion bag or bottle. The solution may be administered as prepared or further diluted with 0.9%

sodium chloride solution or 5% glucose solution as appropriate. Mix the liquids thoroughly by rotating by hand.

Handling

The normal safety precautions for cytostatic agents must be observed when preparing and disposing of the infusion solution. Handling of the solution for infusion should be done in an isolator or a cytotoxic safety cabinet. Protective clothing should be used as required (protective coat, gloves, mask, protective goggles).

If the preparation comes into contact with the eyes, this may cause serious irritation. The eyes should be rinsed immediately and thoroughly with water. If there is lasting irritation, a doctor should be consulted. If the solution is spilled on the skin, rinse thoroughly with water.

Any unused product or waste material should be disposed of in accordance with local requirements.

Shelf life

As packaged for sale:

30 months

Stability after first opening:

Chemical and physical stability has been demonstrated for 28 days at room temperature (20°C to 25°C).

From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user

Shelf life after dilution:

Chemical and physical in-use stability has been demonstrated for 28 days at 2 to 8°C and at room temperature (20°C to 25°C) in glucose 5 % or sodium chloride 0.9 % (0.1 mg/ml and 7.5mg/ml).

From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2°C to 8°C, unless dilution has taken place in controlled and validated aseptic conditions.