Gemcitabine NEAPOLIS

Gemcitabine 200mg -1000mg

Powder for solution for infusion

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist, or nurse. This applies to any side effect that is not mentioned in this leaflet. See section 4.

What is in this leaflet :

1. WHAT IS GEMCITABINE NEAPOLIS, powder for solution for infusion AND IN WHICH CASE IS IT USED ?

pharmacotherapeutic Class
GEMCITABINE NEAPOLIS belongs to a medicinal group called « cytotoxic ». These medicines kill dividing cells, including cancer cells.

Therapeutic indications
GEMCITABINE NEAPOLIS can be given alone or in combination with other anti-cancer medicines depending on the type of cancer.

GEMCITABINE NEAPOLIS is used to treat the following types of cancer :
- locally advanced or metastatic non-small cell lung cancer.
- locally advanced or metastatic pancreatic adenocarcinoma.
- locally advanced or metastatic bladder cancer.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE GEMCITABINE NEAPOLIS, powder for solution for infusion ?

List of information needed before taking the medicine
Not applicable.

Contraindications
Never take GEMCITABINE NEAPOLIS :
- if you are allergic (hypersensitive) to gemcitabine or to one of the components contained in GEMCITABINE NEAPOLIS,
- if you are breastfeeding.

Precautions for use ; special warnings
Warnings and precautions
Before the first infusion, blood samples will be carried out to check whether your liver and your kidneys are working well enough to receive this medication. Before each infusion, blood samples will be taken to check that you have enough blood cells to receive GEMCITABINE NEAPOLIS. Your doctor may decide to change the dose or delay the treatment depending on your general condition and if your blood cell count is too low. Periodically, blood samples will be taken to check the functioning of your kidneys and your liver.
Talk to your doctor, nurse or hospital pharmacist before using GEMCITABINE NEAPOLIS.
If you have or have had liver disease, heart disease, vascular disease or problems with your kidneys, talk to your doctor or hospital pharmacist as you may not be able to be treated with GEMCITABINE NEAPOLIS.
If you have had recently, or are going to have radiation therapy, talk to your doctor, as there may sometimes be early or late reactions due to irradiation with GEMCITABINE NEAPOLIS.
If you have been recently vaccinated, tell your doctor as this may cause harmful effects with GEMCITABINE NEAPOLIS.
If during your treatment with this medicine you develop symptoms such as headache with confusion, convulsions (seizures) or visual disturbances, contact your doctor immediately. It could be a very rare neurological side effect called reversible posterior encephalopathy syndrome.
If you have trouble breathing or feel very weak and very pale, talk to your doctor as it may be a sign of kidney failure or a problem with your lungs.
If you have generalized edema, shortness of breath or weight gain, talk to your doctor as this may be a sign of fluid leaking from your small blood vessels to the tissues.

Children and adolescents
This medication should not be used in children and adolescents under 18 years of age due to the lack of data on safety and efficacy.

Interactions with other medicines
Other medicines and GEMCITABINE NEAPOLIS
If you are taking or have recently taken any other medicines, including vaccines and medicines obtained without prescription, tell your doctor or hospital pharmacist.

Interactions with food and drinks
Not applicable.
Interactions with phytotherapy products or alternative therapies
Not applicable.

Use during pregnancy and breastfeeding
Pregnancy
If you are pregnant or plan to become pregnant, or think you can be pregnant, tell your doctor. The use of GEMCITABINE NEAPOLIS should be avoided during pregnancy. Your doctor will discuss with you the potential risks when GEMCITABINE NEAPOLIS is given during pregnancy.
Breastfeeding
If you are breastfeeding, tell your doctor.
You must stop breastfeeding while taking GEMCITABINE NEAPOLIS.
Fertility
Men are not advised to conceive a child during treatment and within 6 months of treatment with GEMCITABINE NEAPOLIS. If you plan to have a child during treatment or within 6 months of treatment, tell your doctor or pharmacist. Information and advice on how to store sperm before starting your treatment can be given to you.

Sports
Not applicable.

Effects on the ability to drive and use machines
Driving and using machines
GEMCITABINE NEAPOLIS can make you feel drowsy, especially if you have been drinking alcohol. Do not drive or use machines while you feel drowsy from treatment with GEMCITABINE NEAPOLIS.

List of excipients with known effect
GEMCITABINE NEAPOLIS contains sodium

3. HOW TO TAKE GEMCITABINE NEAPOLIS, powder for solution for infusion ?

Instructions for good use
Not applicable.

Dosage, Method and/route (s) of administration, Frequency of administration and Duration of treatment
The usual dose of GEMCITABINE NEAPOLIS is 1,000-1,250 mg per square meter of your body surface. Your height and body weight are measured to determine your body surface. Your doctor will use this body surface to determine the exact dose you will be given. This dose can be adjusted or the treatment postponed depending on the results of your blood tests and your general condition.
The frequency with which you receive your GEMCITABINE NEAPOLIS infusion depends on the type of cancer you are being treated for.
A hospital pharmacist, nurse or doctor will dissolve GEMCITABINE NEAPOLIS powder before giving it to you.
You will always receive GEMCITABINE NEAPOLIS 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 for more information.

Symptoms and instructions in case of overdose
Not applicable.

Instructions if one or more doses are missed
Not applicable.

Risk of withdrawal syndrome
Not applicable.

4. POSSIBLE SIDE EFFECTS ?

Description of side effects
Like all medicines, GEMCITABINE NEAPOLIS can cause side effects, although not everybody gets them.
You should contact your doctor immediately if you experience any of the following :
- Bleeding from the gums, nose, or mouth, or if the bleeding doesn't stop, if your urine is pink or red, if you have unexpected bruises (because you may have fewer platelets than normal, which is very common).
- Fatigue, feeling weak, short of breath, or pale (because you may have lower than normal hemoglobin, which is very common).
- Mild to moderate rash (very common) / itching (common), or fever (very common) ; (allergic reactions).
- A temperature of 38ºC or more, if you sweat or have other signs of infection (because you may have fewer white blood cells than normal accompanied by fever, also known as febrile neutropenia, which is common).
- Pain, redness, swelling, or sores in the mouth (stomatitis) (common).
- Irregular heartbeat (arrhythmia) (uncommon).
- Extreme tiredness and feeling of weakness, purpura or small areas of skin bleeding (bruising), acute renal failure (low urine flow / or no urine flow), and signs of infection (hemolytic uremic syndrome). This can be fatal (uncommon).
- Difficulty breathing (it is very common to have slight breathing difficulties soon after the infusion of GEMCITABINE NEAPOLIS which disappear quickly, however more serious lung problems may occur uncommonly or rarely).
- Severe chest pain (myocardial infarction) (rare).
- Severe hypersensitivity / allergic reaction with severe rash, including redness of the skin and itching, swelling of the hands, feet, ankles, face, lips, mouth or throat (may cause difficulty swallowing or breathing), wheezing, rapid heartbeat, and fainting (anaphylactic reaction) (very rare).
- Generalized edema, shortness of breath, or weight gain, as you may leak fluid from your small blood vessels to the tissue (capillary leak syndrome) (very rare).
- Headache with visual disturbance, confusion, seizures or seizures (reversible posterior encephalopathy syndrome) (very rare).
- A severe rash, with itching, bullous lesions or peeling of the skin (Stevens-Johnson syndrome, toxic epidermal necrolysis) (very rare).
- 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 haemolytic uraemic syndrome, which may be fatal.

Other side effects with GEMCITABINE NEAPOLIS may include :
Very common side effects (may affect more than 1 in 10 people)
- Low white blood cell count.
- Difficulty breathing.
- Vomiting.
- Nausea.
- Hair loss.
- Liver problems : discovered from abnormal blood test results.
- Blood in the urine.
- Abnormal urine tests : protein in the urine.
- Flu symptoms including fever.
- Swelling of the ankles, fingers, feet, face (edema).

Common side effects (may affect up to 1 in 10 people)
- Weak appetite (anorexia).
- headache.
- Insomnia.
- Sleepiness.
- Cough.
- Runny nose.
- Constipation.
- Diarrhea.
- Itching.
- Excessive sweating.
- Muscle aches.
- Back pain.
- Fever.
- Feeling weak.
- Chills.

Uncommon side effects (may affect up to 1 in 100 people)
- Lesions in the alveoli of the lung (interstitial lung disease).
- wheeze (spasms in the airways).
- Lung lesions (abnormality in chest x-ray).
- Heart failure.
- Renal failure.
- Severe liver damage, including liver failure.
- Stroke.

Rare side effects (may affect up to 1 in 1,000 people))
- Low blood pressure.
- Desquamation, ulceration of the skin or formation of bubbles on the skin.
- Formation of large bubbles on the skin and oozing of the skin.
- Injection site reactions.
- Severe pulmonary inflammation causing respiratory failure (adult respiratory distress syndrome).
- A skin rash such as a severe sunburn that may occur on skin that has previously been exposed to radiation therapy (booster reactions).
- Fluid in the lungs.
- Involvement of the alveoli of the lung combined with radiotherapy (toxicity linked to radiation).
- Gangrene of the fingers or toes.
- Inflammation of the blood vessels (peripheral vasculitis).

Very rare side effects (may affect up to 1 in 10,000 people)
- Increased number of blood platelets.
- Inflammation of the lining of the large intestine due to reduced blood supply (ischemic colic).

Low hemoglobin (anemia) and low white blood cells and platelets will be detected by blood sample.
You may have one of these symptoms. You should tell your doctor as soon as you start having any of these side effects.
If you have one or more symptoms, tell your doctor.

Reporting side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This also applies to any side effect that is not mentioned in this leaflet. You can also report side effects directly via the national reporting system.

5. HOW TO STORE GEMCITABINE NEAPOLIS, powder for solution for infusion ?

Keep out of the sight and reach of children.
Do not use GEMCITABINE NEAPOLIS after the expiry date (EXP) mentioned on the box.
Do not store above 30 °C.
After reconstitution and dilution : the product is stable for 24 hours at 25 ° C in sodium chloride.
If necessary, warnings against certain visible signs of deterioration
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist what to do with unused medication. These measures will help protect the environment.

6. ADDITIONAL INFORMATION

Complete list of active substances and excipients
What GEMCITABINE NEAPOLIS contains ?
The active substance is : gemcitabine.
GEMCITABINE NEAPOLIS 200mg : Each vial contains 200 mg of gemcitabine (as gemcitabine hydrochloride).
GEMCITABINE NEAPOLIS 1000mg : Each vial contains 1000 mg of gemcitabine (as gemcitabine hydrochloride).
The other components are : Mannitol, Sodium acetate, Hydrochloric acid (for pH adjustment), Sodium hydroxide (for pH adjustment)

Pharmaceutical form and content
what GEMCITABINE NEAPOLIS looks like and content of the outer packaging ?
GEMCITABINE NEAPOLIS 200mg and GEMCITABINE NEAPOLIS 1000mg is a powder for solution for infusion, contained in a glass vial. Each box contains 1 vial.

Supply and prescription Condition : Table A/ list 1
M.A.N. :
GEMCITABINE NEAPOLIS 200mg, box of 1 vial : 9393081H
GEMCITABINE NEAPOLIS 1000mg, box of 1 vial : 9393082H

Marketing autorisation holder and manufacturer :
Neapolis Pharma Tunis Road Km 7 - BP 206 Nabeul 8000 - Tunisia.
Phone : +216. 31.833.400
FAX : +216.72.235.016 +216.31.338.421
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This leaflet was last reviewed : 04/2020

Gemcitabine NEAPOLIS

Gemcitabine 200mg -1000mg

Powder for solution for infusion

Information reserved for healthcare professionals

The following information is intended exclusively for healthcare professionals :
Instructions for use, handling and disposal
1. Use aseptic techniques for reconstitution and any further dilution of the gemcitabine solution for administration by intravenous infusion.
2. Calculate the dose and the number of vials of GEMCITABINE NEAPOLIS needed.
3. Reconstitute the 200 mg vials with 5 ml of sterile sodium chloride 9 mg / ml (0.9%) solution for injection, without preservative. Shake until dissolved. The total volume after reconstitution is 5.26 ml (200 mg vial). This dilution leads to a gemcitabine concentration of 38 mg / ml, which takes into account the displaced volume of lyophilized powder. Additional dilution with sterile sodium chloride 9 mg / ml (0.9%) solution for injection, without preservatives can be made. The solution obtained is clear between colorless and slightly straw yellow.
4. Prior to administration, substances for parenteral use should be visually inspected for particles and discoloration. If particles are present, do not administer.
5. The product should be used immediately. In the event of non-immediate use, the storage periods and conditions after reconstitution and before use are the sole responsibility of the user.
Reconstructed gemcitabine solutions should not be refrigerated as crystallization may occur.
6. Gemcitabine solutions are for single use only. Any unused product and waste must be disposed of in accordance with local procedures.
Preparation and administration precautions
Normal safety precautions for cytotoxic agents should be observed when preparing and applying the solution for infusion. The handling of the solution for infusion must be done in a controlled atmosphere zone or isolator with wearing of a gown and protective gloves. In the absence of a controlled atmosphere zone or isolator, the equipment must be supplemented by a mask and protective glasses.
If the preparation comes into contact with the eyes, this may cause serious irritation. Eyes should be flushed immediately with plenty of water. If irritation persists, a doctor should be consulted. If the solution has spilled on the skin, rinse thoroughly with water.
Destruction
Any unused product should be disposed of in accordance with local procedures.

Other
Not applicable.

THIS IS A MEDICINE

- A medicine is a product but not like the others.
- A medicine is a product that affects your health and its consumption without compliance to the prescription exposes you to danger.
- Strictly follow your doctor's prescription and directions for use, follow the advice of your pharmacist.
- Your doctor and pharmacist are familiar with the medicine, its indications and contraindications.
- Do not stop treatment on your own initiative during the prescribed period.
- Do not take it again, do not increase the doses without consulting your doctor.

KEEP THE MEDICINES OUT OF THE REACH OF CHILDREN

NEAPOLIS
PHARMA