PANTONE 293 C PANTONE 320 C

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 any get you side effects, talk to your doctor, pharmacist or nurse.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their signs of illness 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 or pharmacist.

What is in this leaflet :

1. WHAT IS GEMCITABINE NEAPOLIS, powder for solution for infusion AND IN WHICH CASE IS IT USED ?
2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE GEMCITABINE NEAPOLIS, powder for solution for infusion ?
3. HOW TO TAKE GEMCITABINE NEAPOLIS, powder for solution for infusion ?
4. POSSIBLE SIDE EFFECTS, HOW TO STORE GEMCITABINE NEAPOLIS, powder for solution for infusion ?
5. ADDITIONAL INFORMATION

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 :

- Inoperable advanced or metastatic non-small cell lung cancer.
- Inoperable advanced or metastatic pancreatic cancer patients.
- Inoperable advanced or metastatic breast 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 substances 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 know 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 cells 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, cardiac disease or problems with your kidneys, talk to your doctor or hospital pharmacist as you may need to take extra care.

If you have had a stroke, or are going to have radiation therapy, talk to your doctor or pharmacist as medicine may interact with GEMCITABINE NEAPOLIS.

If you take oral coumarin anticoagulant, tell your doctor or this may cause bleeding effects with GEMCITABINE NEAPOLIS.

If during your treatment with this medicine you develop symptoms such as nausea and vomiting, stomachache, diarrhoea or mouth ulcerations, contact your doctor immediately. It could be a very rare condition or side effect called « mucositis » which is usually reversible.

If you have trouble breathing or have very weak and very pale, tell to your doctor as it may be a sign of anemia, failure of a problem with your lungs.

If you have prolonged edema, shortness of breath or weight gain, talk to your doctor as this may be a sign of fluid building up from your small blood vessels into the tissues.

Children and adolescents

This medicine should not be used in children and adolescents under 18 years of age as its safety and efficacy

Interactions with other medicines

Other medicines and GEMCITABINE NEAPOLIS

If your are taking or have recently taken any other medicine, including vaccines and medicines obtained without prescription, tell your doctor or hospital pharmacist.

Interactions with food and drink

Not applicable.

Interactions with other laboratory tests or alternative therapies

Not applicable.

Use during pregnancy and breastfeeding

Pregnancy

If you are pregnant or plan to become pregnant, or think your can be pregnant, tell your doctor. The use of cytotoxic medicines such as GEMCITABINE NEAPOLIS during pregnancy. Your doctor will discuss with you the potential risk of using GEMCITABINE NEAPOLIS during pregnancy.

Breastfeeding

If you are breastfeeding, inform doctor.

You must stop breastfeeding while using 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 are available 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 in 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 dilute 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.

Just in Case: If you or more doctor not advised

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 every person gets them.

You should contact your doctor immediately if you experience one 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 your cut hurts more platelets than normal) which is not in contact.
- Fatigue, feeling weak, short of breath, or pale. Because you may have fewer than normal red cells, which is very common.
- MRSA. Staphylococcus very common, being common, or very very common, (pilloric conditions).
- A temperature of 38 °C or more, if you cause or have other signs of infection because you may have fewer white blood cells than normal accompanied by fever, sweating or little neutrophils, which is common.
- Pain, redness, swelling, or ulcers in the mouth (stomatitis) or anus.
- Difficulty in breathing (shortness of breath).
- Extreme tiredness and feeling of weakness, pallor or small areas of skin bleeding (bruising), acute neutrophilic dermatosis (rash) or unusual bruising, which is very common.
- Cough, difficulty breathing or shortness of breath, fever or chills, which is very common.
- Severe skin rash or itching, hives, blisters or peeling or red skin (Stevens-Johnson syndrome, toxic epidermal necrolysis) very rare.
- Extreme tiredness and weakness, pallor or small areas of bleeding or bruises with symptoms, which may be very rare.
- Swelling of the face, lips, tongue or throat, difficulty in swallowing or breathing, wheezing, which may be very rare.
- Unexpected bleeding or bruising, which is very rare.
- Unexpected pain in the chest, which is very rare.
- Unexpected weakness, numbness, tingling, or loss of feeling in one side of the body, difficulty in speaking, which is very rare.
- Sudden or severe stomach pain, which is very rare.
- Sudden or severe pain in the back, which is very rare.
- Sudden or severe pain in the joints, which is very rare.
- Sudden or severe pain in the muscles, which is very rare.
- Sudden or severe pain in the bones, which is very rare.
- Sudden or severe pain in the eyes, which is very rare.
- Sudden or severe pain in the ears, which is very rare.
- Sudden or severe pain in the nose, which is very rare.
- Sudden or severe pain in the mouth, which is very rare.
- Sudden or severe pain in the teeth, which is very rare.
- Sudden or severe pain in the skin, which is very rare.
- Sudden or severe pain in the hair, which is very rare.
- Sudden or severe pain in the nails, which is very rare.
- Sudden or severe pain in the genitals, which is very rare.
- Sudden or severe pain in the anus, which is very rare.
- Sudden or severe pain in the rectum, which is very rare.
- Sudden or severe pain in the bladder, which is very rare.
- Sudden or severe pain in the kidneys, which is very rare.
- Sudden or severe pain in the liver, which is very rare.
- Sudden or severe pain in the spleen, which is very rare.
- Sudden or severe pain in the pancreas, which is very rare.
- Sudden or severe pain in the gallbladder, which is very rare.
- Sudden or severe pain in the thyroid, which is very rare.
- Sudden or severe pain in the adrenal glands, which is very rare.
- Sudden or severe pain in the pituitary gland, which is very rare.
- Sudden or severe pain in the hypothalamus, which is very rare.
- Headache, which is very rare.
- Insomnia, which is very rare.
- Sleepiness, which is very rare.
- Cough, which is very rare.
- Runny nose, which is very rare.
- Constipation, which is very rare.
- Diarrhea, which is very rare.
- Itching, which is very rare.
- Excessive sweating, which is very rare.
- Hives, which is very rare.
- Rash, which is very rare.
- Acne, which is very rare.
- Feeling weak, which is very rare.
- Chills, which is very rare.

Uncommon side effects (may affect up to 1 in 100 people)

- Loss of appetite (anorexia).
- Sleepiness, abnormal feeling, or loss of feeling in one side, or the other side.
- Numbness or tingling sensation in the skin and burning of the skin.
- Injection site reactions.
- Swelling of the eyes, difficulties in seeing, impaired vision (blurred vision), or eye pain.
- Inflammation of the eyes (conjunctivitis).
- Inflammation of the eyelids (blepharitis).
- Inflammation of the lining of the eye (conjunctivitis) and other eye problems affecting the tear ducts.