Paclitaxel NEAPOLIS
Paclitaxel 6 mg/ml
Solution à diluer pour perfusion
Paclitaxel NEAPOLIS
Paclitaxel 6 mg/ml
Solution à diluer pour perfusion
Informations réservées aux professionnels de santé
ان هذا الدواء
لا يشخّص الاصابة بالسرطان ولكن ليس عقاره من المستشفيات.
- الدواء مستخدم ويقدر على مساعدتك وتخفيف اعراض المرض.
- اتبع وبدقة وصفة الطبيب وطريقة التعامل المنصوص عليها.
- تكلم بالمعلومات الصيدلانية التي سيقدمها لك الطبيب والصيدلاني هما الخبيران بالدواء وبمنافعه وضرره.
- لا تتبع بدة العلاج المستعملة لك من قبل اصدقاء.
- لا تقدم دواءك مفيدا بدون استشارة الطبيب.
لا تشكوك الادوية في متناول ايدي الاطفال
CECI EST UN MEDICAMENT
GARDEZ LES MEDICAMENTS HORS DE LA PORTÉE DES ENFANTS
NEAPOLIS

B.A.T
Sogim
Meilleur Qualité
2020
Client : NEAPOLIS
Contact: Walid KHALFALLAH
Désignation :Paclitaxel NEAPOLIS 6MG-ML
Format : 24 x 36 cm
Impression : 2 couleur recto verso
logiciel : Indesign CS4, Illustrator CS4,
Grammage de papier : 60g
Opérateur : MARWA KARRA
Date : 15-05-2020
Code article : NON000 39
Version : 00
Couleur :Pantone 293 C / 361 C
Police : Swis721 Cn BT
Corps :
Interligne:
Preplié avec Bond 12x6,1cm fermé et ouvert F: 24x36cm
Signature client

PANTONE 293 C PANTONE 320 C

Paclitaxel NEAPOLIS

Paclitaxel 6 mg/ml

Concentrate 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 questions, ask your doctor, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any side effects not listed in this leaflet. See section 4.

What is in this leaflet?

1. What is PACLITAXEL NEAPOLIS 6 mg/ml, concentrate for solution for infusion and what causes it used?
2. What you need to know before you take PACLITAXEL NEAPOLIS 6 mg/ml, concentrate for solution for infusion?
3. How to take PACLITAXEL NEAPOLIS 6 mg/ml, concentrate for solution for infusion?
4. Possible side effects?
5. How to store PACLITAXEL NEAPOLIS 6 mg/ml, concentrate for solution for infusion?
6. Contents of the packaging and other information.

1. WHAT IS PACLITAXEL NEAPOLIS 6 mg/ml, concentrate for solution for infusion AND IN WHICH CASE IS IT USED?

pharmacotherapeutic Class: Antineoplastic agent, taxanes, cytotoxic agent ATC code: L01CD01.

PACLITAXEL NEAPOLIS is an antineoplastic belonging to taxanes group. These agents inhibit the growth of cancer cells. Paclitaxel is indicated in the treatment of:

Ovarian cancer

- As a first-line treatment after initial surgery in combination with a treatment based on platinum salts (cisplatin).
- After a standard treatment with platinum salts has been tried but not worked.

Breast cancer

- As a first-line treatment for an advanced disease after a disease that has spread to other parts of the body (metastatic disease). Paclitaxel is combined with either an anthracycline (an antibiotic) or trastuzumab (a medicine for cancer) for which treatment with anthracyclines is not suitable and whose cancer cells have a certain protein called HER-2, you the patient is limited by trastuzumab.
- As additional treatment after initial surgery followed by treatment with anthracycline and cyclophosphamide (AC).
- As a second-line treatment in patients who have not responded to standard anthracycline treatments, or for whom this type of treatment cannot be used.

Advanced non-small cell lung cancer

- In combination with cisplatin, when surgery and/or radiotherapy is not appropriate.

AIDS-related Kaposi's sarcoma

- When another treatment failed or is not appropriate. Treatment with this medicine should only be initiated if the patient's blood count is not too low and if the patient's condition is not too poor as a result of the disease.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE PACLITAXEL NEAPOLIS 6 mg/ml, concentrate for solution for infusion?

Do not take PACLITAXEL NEAPOLIS:

- If you are allergic (hypersensitive) to paclitaxel or to any of the other components contained in this medicine, listed in section 6, especially castor oil.
- If you are pregnant.
- If the neutrophils of your white blood cells (medical blood) is too low. This most will be carried out by medication.
- If you have a severe or uncontrolled infection and paclitaxel is used to treat Kaposi's sarcoma.

Even if the above conditions apply, talk to your doctor before starting treatment with PACLITAXEL NEAPOLIS.

Paclitaxel is not recommended for children (under 18 years).

Warnings and precautions

Talk to your doctor before using PACLITAXEL NEAPOLIS.

- In case of an allergic reaction, you will be given other medicines before starting treatment with PACLITAXEL NEAPOLIS.
- If you have severe allergic reactions (e.g. difficulty breathing, shortness of breath, tightness in the chest, drop in blood pressure, dizziness, headache, skin reactions such as hives or rash or swelling).
- If you have a low blood cells (neutrophils) or thrombocytes (platelets) count, your doctor will monitor your blood cells.
- If you have a lung or tendinous or nerve pain, and/or signs of peripheral neuropathy, lower doses of paclitaxel may be necessary.

If you have severe liver problems, lower dose. Are not recommended in severe problems.

- If you have heart conduction problems.
- If you develop severe or persistent diarrhea, with fever and stomach pain. Rarely or shortly after treatment with paclitaxel. Your doctor may be informed immediately.
- If you previously had radiation to your blood vessels may increase the risk of lung inflammation.
- If you have swelling or redness of the mouth, sign of ulcers and/or bleeding mucosa for Kaposi's sarcoma. You may need a lower dose. Paclitaxel should always be given into the vein. Administering paclitaxel into the veins can cause inflammation of the veins, and you may experience pain, swelling, redness, and warmth.

Other medicines and PACLITAXEL NEAPOLIS

Tell your doctor if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

Before PACLITAXEL NEAPOLIS or for which emergency may cause an effect on or especially if you may be forced to be in an adverse situation, that is the reason that of the medicine may affect each other, for your doctor when taking paclitaxel along with one of the following products:

- Medicines for blood infections (i.e. antibiotics) such as: erythromycin, chloramphenicol, etc., all your doctor, nurse or pharmacist be aware that you are taking, or potentially taking medicines for the treatment of fungal infections (e.g. ketoconazole).
- Medicines for treatment of depression (e.g. nefazodone).
- Medicines used to treat high blood pressure (e.g. verapamil).
- Medicines for treatment of diseases (e.g. cimetidine).
- Medicines used to treat the call HIV (e.g. ritonavir, saquinavir, indinavir, nelfinavir, nevirapine).
- Cyclosporin (medicine used to prevent transplant rejection).
- Tamoxifen (a medicine used to treat breast cancer).
- Carboplatin (a medicine used to treat ovarian cancer).
- Cisplatin (a medicine used to treat ovarian cancer).
- Doxorubicin (a medicine used to treat cancer).
- Vitamin D (a medicine used to treat osteoporosis).
- Hormones (e.g. estrogens, progestogens).
- Medicines that affect the blood clotting.
- Vaccines and medicines that suppress immune system (a protection of immunity).

Pregnancy, breastfeeding and fertility

If you are pregnant, or think you are pregnant, talk to your doctor before receiving paclitaxel treatment. If there is a chance you could get pregnant, use a safe and effective method of contraception during treatment. Paclitaxel should not be given during pregnancy unless clinically necessary. Female and male patients of reproductive age and/or their partners should use contraception for at least 6 months after treatment with paclitaxel.

Male patients should seek advice regarding conservation of their semen before paclitaxel treatment, as there is a possibility of sterility.

Tell your doctor if you are breastfeeding. Stop breastfeeding if you are taking paclitaxel. Do not start breastfeeding without your doctor has given you permission to do so.

Driving and using machines

This medicine contains alcohol. Thus, it is not recommended to drive immediately after a treatment course, in any case, you should not drive if you feel dizziness or are not aware of your skill.

PACLITAXEL NEAPOLIS 6 mg / ml, concentrate for solution for infusion contains paclitaxel polyoxyethylene castor oil and ethanol.

This medicine contains ethanol (alcohol). This amount or be dangerous in patients with alcoholism. It should also be taken into account in pregnant or breastfeeding women, children and high-risk patients as well as in those with liver problems or epilepsy.

PACLITAXEL NEAPOLIS may affect the effects of other medicines due to its high alcohol content.

This product also contains polyoxyethylene castor oil, which can cause severe hypersensitivity (allergic) reactions. If you are allergic to castor oil, tell your doctor before receiving PACLITAXEL NEAPOLIS.

3. HOW TO TAKE PACLITAXEL NEAPOLIS 6 mg/ml, concentrate for solution for infusion?

- To minimize allergic reactions, you will be given other medicines before you are given paclitaxel. These medicines prevent allergic reactions. Paclitaxel can be in tablets, intravenous injections or tablets and intravenous infusions.
- The will receive paclitaxel this rate one of your veins (by intravenous infusion) through a drip. Paclitaxel will be given by your by a healthcare professional. He or she will prepare the solution for infusion before it is given to you. The dose you receive will also depend on the results of your blood tests. Depending on the type and severity of the cancer, you will receive Paclitaxel once or in combination with other anticancer agents.
- Paclitaxel treatment cycle is usually given to you every 2 to 3 weeks. It is usually given to you every 2 to 3 weeks unless your doctor decides otherwise. Your doctor will tell you how many paclitaxel courses you will need to receive. If you have any further questions on the use of this product, ask your doctor, pharmacist or nurse.

If you have received more PACLITAXEL NEAPOLIS 6 mg / ml concentrate for solution for infusion than you should

There is no known antidote for overdose of paclitaxel. You will receive treatment for your symptoms.

4. POSSIBLE SIDE EFFECTS?

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Tell your doctor immediately if you notice any signs of an allergic reaction. These may cause to one or more of the following effects:

- Hot flushes.
- Hypotension.
- Itching.
- Chest tightness.
- Shortness of breath or difficulty breathing.
- Swelling.

Very rare allergic reaction of severe type effects:

Severe your doctor immediately

- If you have fever, bruises or bleeding, mouth sores, signs of myelosuppression.
- If you have tingling or numbness in your arms and legs (signs of peripheral neuropathy).
- If you develop severe or persistent diarrhea, with fever and stomach pain.

Very common (may affect more than 1 in 10 persons):

- Mild allergic reactions such as flushing, redness, itching.
- Infections, mostly upper respiratory tract infections, urinary tract infections.
- Anemia.
- Low blood, neutrophil count, indicating a reduction in immunity, that may lead to infection, fever, feeling very ill or very severe. Rarely, in cases of leukaemia and in rare cases in the treatment of breast cancer, this condition is more serious and may lead to death. Your doctor will tell you how many paclitaxel courses you will need to receive. If you have any further questions on the use of this product, ask your doctor, pharmacist or nurse.
- Thrombocytes (platelets) count, indicating a reduction in thrombocytes, that may lead to bleeding and/or a bruise. Rarely, in cases of leukaemia and in rare cases in the treatment of breast cancer, this condition is more serious and may lead to death. Your doctor will tell you how many paclitaxel courses you will need to receive. If you have any further questions on the use of this product, ask your doctor, pharmacist or nurse.
- Nausea, vomiting, diarrhea, loss of appetite, white blood cells, thrombocytopenia.
- Hair loss, alopecia, rashes, itchiness, redness, pallor, bleeding, bruising marks easily than normal.
- Tingling, stinging or pain in the hands or feet, peripheral neuropathy (rare).
- Muscle, joint or bone pain, arthralgia (severe or persistent), which usually starts 2 to 4 days after paclitaxel administration.
- Temporary and slight modification of the nails and modification of the skin, reactions of the injection site (redness and swelling, pain, sensitivity).
- Temporary hair loss, temporary heart pain, significant alteration of liver enzymes (alkaline phosphatase, AST, ALT).

Common (may affect up to 1 in 100 persons):

- Blood clots in the deep veins in legs (deep).
- Palpitations, heart pulsations (abnormally strong, irregular or rapid, heart beat, heart rate).
- Fatigue, weakness, discomfort (malaise), severe allergic reactions, inflammation of a vein caused by blood clot (phlebitis and thrombosis), swelling of the face, mouth, tongue or throat.
- Sensory disorders, pain, paralysis (numbness and tingling, pain and/or paralysis of the).
- Blood tests reveal certain abnormalities (bilirubin (jaundice), high blood sugar, anemia).

Rare (may affect up to 1 in 1000 persons):

- Serious reaction of the skin (skin rash that may cause a serious and life-threatening condition).
- Nerve damage with loss of muscle coordination in the arms or legs (ataxia, ataxia).
- Shortness of breath, sudden coughing, of a pulmonary edema (pulmonary, thrombosis, swelling and tightness in the lungs (pulmonary fibrosis). Inflammation of the lungs, interstitial pneumonitis, acute lung disease. Acute pneumonitis, the lungs and lung tissue, lung scarring (pulmonary fibrosis).
- Liquid accumulation, inflammation of the water (ascites), inflammation of a vein caused by blood clot (phlebitis and thrombosis), swelling of the face, mouth, tongue or throat.
- Nausea, vomiting, diarrhea, loss of appetite, white blood cells, thrombocytopenia.
- Severe pain, discomfort, pain, pulsation, pressure, and/or swelling in the chest.
- Hot flushes, sweating, increased sensitivity to the blood, signs of impaired kidney function.
- Hiccuppings.

Very rare (may affect up to 1 in 10 000 persons):

- Fever and irregular heartbeat (atrial fibrillation), supraventricular tachycardia).
- Sudden disruption of blood cells in the blood (acute myeloid leukemia, myelodysplastic syndrome).
- Optic nerve and/or visual disturbances (scintillating scotomas).
- Hearing loss or hearing reduction (ototoxicity), ringing in the ears (tinnitus), dizziness.
- Cough.
- Blood clot in a vessel in the abdomen and intestine (mesenteric thrombosis), inflammation of the colon with conditions particular severe diarrhea (pseudomembranous colitis, inflammation of the abdomen (peritonitis, perforation), esophagus inflammation (esophagitis), constipation.
- Severe hypersensitivity reactions with fever, redness of the skin, joint pain and / or inflammation of the eyes (Stevens-Johnson and/or toxic, local scaling (epidermal necrolysis), redness with irregular (exudative) rash (erythema multiforme), inflammation of skin with blisters and flaking (exfoliative dermatitis). Rare, falling hair (alopecia) cases treatment could not be ruled from the list).
- Loss of appetite (anorexia).
- Severe and sometimes fatal hypersensitivity reactions with shock (anaphylactic shock).
- Disruption of liver functions (hepatic necrosis, hepatic encephalopathy, the such effects, cases of fatal outcome have been reported).
- Contractional pain.
- Convulsions, severe stomach pain with bleeding, intestinal cramps and vomiting (cramps, fever and dizziness when getting up, especially when sitting or lying down (orthostatic hypotension), heart disease causing headache and fever, progressing towards hallucinations, confusion, partial or total paralysis of the body, behavioral disorders, speech and eye movements, with loss and sensitivity to light (photophobia) (hallucinations, dizziness, instability when walking (ataxia), headache).

Unknown frequency (cannot be estimated from the available data):

- Disseminated intravascular coagulation, or "DIC" (an been problem). This condition is linked to a serious illness that increases the tendency for bleeding, or blood clotting, or both.
- Flattening, thickening of the skin (sclerodermia).
- Metastatic consolidation of the lung (interstitial pneumonitis) (lung inflammation).
- Eye disorders, such as blurred vision weather intensity, macular edema, blinking light (photopsia) and spots (floaters, scintillant and "cobweb" floating in your field of vision (glaucoma flashes).
- Inflammation of the pancreas (pancreatitis).
- Autoimmune disease with multiple symptoms such as skin, scintillating spots on the skin, joint pain or fatigue (systemic lupus erythematosus).

Reporting side effects

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

5. HOW TO STORE PACLITAXEL NEAPOLIS 6 mg/ml, concentrate for solution for infusion?

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

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

Store at a temperature not exceeding 25 °C.

Store in the original box to protect from light.

After dilution: the solution is stable for 78 hours at 25 °C ± 2 °C (medical and 0.9% sodium chloride).

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

Do not freeze. Keep the solution away from light.

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

6. CONTENT OF THE PACKAGING AND OTHER INFORMATION

WHAT PACLITAXEL NEAPOLIS 6 mg/ml, concentrate for solution for infusion contains:

- The active substance is: Paclitaxel.
- The other components are: Polyoxyl castor oil, ethanol, anhydrous citric acid.

Excipients with known effect: Polyoxyl castor oil, ethanol.

What PACLITAXEL NEAPOLIS 6 mg/ml, concentrate for solution for infusion looks like and contents of the outer packaging

PACLITAXEL NEAPOLIS is a concentrate for solution for infusion available in 5 ml, 16.7 ml and 50 ml vials.

Regulatory and production holder: Sogia S.A.L.

S.A.R

PACLITAXEL NEAPOLIS 6 mg/ml 5 ml	[illegible]
PACLITAXEL NEAPOLIS 6 mg/ml 16.7 ml	[illegible]
PACLITAXEL NEAPOLIS 6 mg/ml 50 ml	[illegible]

Marketing authorization holder and manufacturer

Hospira Pharmaceuticals Cyprus Ltd. [illegible]

Phone: [illegible]

Fax: [illegible]

E-mail: [illegible]

This leaflet was last revised: 10/2020

Paclitaxel NEAPOLIS

Paclitaxel 6 mg/ml

Concentrate for solution for infusion

Information intended for healthcare professionals

The following information is intended only for healthcare professionals:

Instructions for use

ANTIMICROTUBULE AGENT

Handling of PACLITAXEL NEAPOLIS

Like all antineoplastics, PACLITAXEL NEAPOLIS should be handled with caution. This product must be diluted under conditions guaranteeing asepsis, by experienced personnel, in a place designated for this purpose. Precautions should be taken to avoid contact with the skin and mucous membranes. Following topical exposure, tingling, burning and erythema have been observed. Dyspnea, chest pain, burning throat and nausea have been reported with cisplatin.

Preparation instructions for the preparation of the solution for infusion of PACLITAXEL NEAPOLIS.

1. Use a face mask and wear gloves and overalls. In the absence of a face mask, use wash protection and protective glasses.

2. Open containers, as well as vials for injection, vials for infusion, as well as cannulas, syringes, catheters, tubes must wear and residues of cytotoxic products should be considered as hazardous waste and be disposed of in accordance with local regulations on the handling of HAZARDOUS WASTE.

3. In the event of a colorless disease, comply with the following instructions.

- Wear protective clothing.
- Collect the broken glass and place it in the container intended for HAZARDOUS WASTE.
- Wash contaminated surfaces with copious amounts of cold water, then wipe thoroughly and dispose of the material used for this purpose from HAZARDOUS WASTE.

4. If the paclitaxel solution comes into contact with the skin, wash the contaminated area thoroughly with running water, then wash with soap and water. In case of contact with the mucosa, membranes, wash the affected area thoroughly with water. If you feel unwell, contact a doctor.

5. If the paclitaxel solution comes into contact with the eyes, wash thoroughly and thoroughly with cold water and immediately consult an ophthalmologist.

Preparing the solution for infusion

Do not use an outer "shield" since collection devices, such as the Chemo-Dispensing Pin device or similar, since they could damage the stopper and thus cause the loss of sterile integrity of the vial.

Before the infusion, the PACLITAXEL NEAPOLIS solution must be diluted, according to accessories parenteral solution, in one of the following intravenous solutions: 0.9% sodium chloride, 5% glucose, 5% glucose mixture and chloride of 0.45% sodium, in the mixture of 5% glucose and Ringer's solution, with a final concentration of 0.3 to 1.2 mg / ml to obtained.

The diluted solution is supersaturated with paclitaxel (some may require) have required the formation and precipitate related to the final concentration of the solution. Consequently, excessive agitation or vibrations should be avoided. For administration, the solution may have a cloudy appearance distributed in the recipient of the product. The turbidity is not associated during filtration. To reduce the risk of precipitation, paclitaxel solution for infusion should be used as soon as possible after dilution.

Infusion technique

Paclitaxel solution for infusion should only be administered by intravenous infusion.

The paclitaxel solution must be infused using a sterile filter with a microporous filter, polyvinyl with a diameter ≤ 0.22 μm to ensure the sterility and loss of activity was observed in simulated infusion studies in using IV tubing filled with a filter.

The necessary infusion should be done thoroughly before use. During the infusion, the appearance of the solution should be checked frequently and the infusion should be stopped in case of any cause.

Stability and storage conditions

Unopened vial from vials of PACLITAXEL NEAPOLIS must be stored at a temperature of 15 °C - 25 °C in their original packaging and protected from light, any other storage period or condition of the vial is the responsibility of the user.

If unopened vials are stored in the refrigerator or freezer, a precipitate may appear. It dissolves at room temperature with little or no stirring. The quality of the product is not affected in any way. If the solution remains cloudy or if an insoluble precipitate forms, the vial should not be the forwarded.

After dilution, the solution should be used immediately after reaching the vial. Any other storage periods or conditions is the sole responsibility of the user. Diluted solutions should not be kept refrigerated. After dilution, the solution is stabilized for six days.

Incompatibilities

Polyvinyl chloride (PVC) containers or polyethylene (PE) or polypropylene, which contain plasticizers, which can be dissolved by drugs in PVC, should not be used for infusion solutions, or by other diluents. It is advisable to store paclitaxel solutions diluted in non-PVC vials, glass or polypropylene, or polyethylene bags, polypropylene or polyethylene and administer them using polyethylene-lined infusion sets. Concentration is diluted with 5% (w / v) or 0.9% (w / v) in the vial or bottle of the infusion sets and have a polyethylene-lined or DEHP.

Waste disposal

Any medicine used for preparation, administration or having been in contact with paclitaxel must be disposed of in accordance with the regulations of local current regulations or of pharmacy products.

THIS IS A MEDICINE

- A medicine is a product but not like the others.
- A medicine is a product that affects your health and the 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

B.A.T

Sogim Meilleur Qualité

2020

Client : NEAPOLIS Contact: Walid KHALFALLAH Désignation :Paclitaxel NEAPOLIS 6MG-ML Format : 24 x 36 cm Impression : 2 couleur recto verso logiciel : Indesign CS4, Illustrator CS4, Grammage de papier : 60g Opérateur : MARWA KARRA	Date : 15-05-2020 Code article : NON00039 Version : 00 Couleur :Pantone 293 C / 361 C Police : Swis721 Cn BT Corps : Interligne: Preplié avec Bond 12x8.2cm forme et ouvert 7: 24x36cm	Signature client