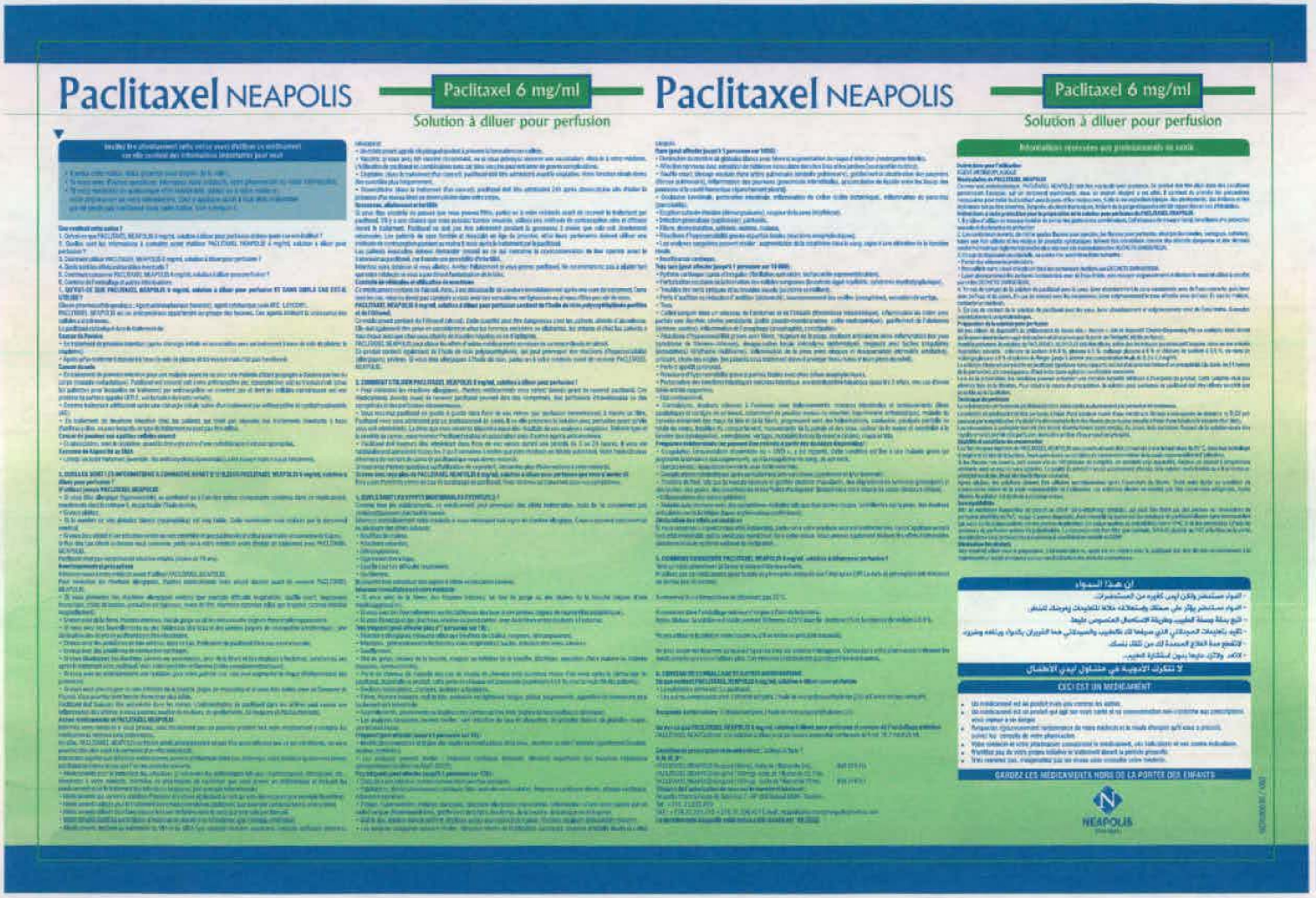
Paclitaxel NEAPOLIS

Paclitaxel 6 mg/ml

Solution à diluer pour perfusion



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Informations nécessaires aux professionnels de santé

ان هذا الدواء

- الدواء مستخدم ولكن أيضا كغيره من المستحضرات.
- الدواء مستخدم يؤثر على صحتك وصحة طفلك للتخلص وعرضك للتبعيض.
- اتبع بدقة وسيلة الطبيب وطريقة الاستعمال الخصوص عليها.
- لكتبه باعتبارات الجرعاتي الذي سيرفعا لك بالطبيب والصيدلاني هما الخبيران بالدواء يراعاه ويتبره.
- لاتضع مبة العلاج المسمة لك من قلك بنفسك.
- لاتكرر وإذا عاوما بدون استشارة الطبيب.

لا تتكرات الأدوية في متناول أيدي الأطفال

CECI EST UN MEDICAMENT

- Un médicament est un produit pas comme les autres.
- Un médicament est un produit qui agit sur votre santé et sa consommation non conforme aux prescriptions vous expose à un danger.
- Respecter rigoureusement renseignements de votre médecin et le mode d'emploi qu'il vous a prescrit, suivez les conseils de votre pharmacien.
- Votre médecin et votre pharmacien connaissent le médicament, ils sont experts en ses usages indications.
- N'utilisez pas de votre propre initiative le médicament durant la période grossesse.
- Très mauvaise idée, n'expérimentez pas un nouveau mode de votre traitement.

GARDEZ LES MEDICAMENTS HORS DE LA PORTEE DES ENFANTS

NEAPOLIS

NOVEMBRE / 2020

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	Client : NEAPOLIS Contact: Walid KHALFALLAH Désignation : Paclitaxel NEAPOLIS 6MG-ML Format : 24 x 36 cm Impression : 2 couleur recto verso logicial : Indesign CS4, Illustrator CS4, Grammage de papier : 60g Opérateur : MARWA KARRA	Date : 15-05-2020 Code article : NON000039 Version : 00 Couleur :Pantone 293 C / 361 C Police : Swis721 Cn BT Corps : Interligne: Pleplié avec Bond 12x8,2cm 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
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- If any of the side effects get worse, talk to your doctor, pharmacist or nurse.
- This leaflet is for you only. Do not give it to others. It may harm them, even if their illness is similar to yours.

What is in this leaflet?

1. What is PACLITAXEL NEAPOLIS 6 mg/ml, concentrate for solution for infusion and what it is used for?
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?

Antineoplastic agents. Other antineoplastic agent. Taxanes. Cytotoxic agent ATC code: L01CD01.

PACLITAXEL NEAPOLIS is an anticancer medicine 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 for an advanced disease or for a disease that has spread to other parts of the body (metastatic disease). Paclitaxel is considered with other cytotoxic agent (platinum based) or in monotherapy in patients for whom treatment with antineoplastic of platinum is not suitable with which cancer cells have a certain protein called HER-2 on the surface (called HER-2 overexpressing).
- 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 antineoplastic treatments, or in cases that type of treatment cannot be used.

Advanced non-small cell lung cancer

- In combination with cisplatin, when surgery and/or radiotherapy is inappropriate.

AIDS-related Kaposi's sarcoma

- When another treatment (example: liposomal anthracycline) was not effective or was not tolerated.

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 one of the other components contained in the medicine. Refer to section 6, especially cremophor.
- If you breastfeed.
- If the number of your white blood cells (neutrophils) is too low. The result will be carried out by medical test.
- If you have a severe persistent infection and uncontrolled cardiac insufficiency.

If any of the above conditions apply, tell to your doctor before starting treatment with PACLITAXEL NEAPOLIS. Paclitaxel is not recommended in children (under 18 years).

Warnings and precautions

Talk to your doctor before using PACLITAXEL NEAPOLIS:

In addition, allergic reactions, you will be given the premedication before receiving PACLITAXEL NEAPOLIS.

- If you have severe allergic reactions e.g. difficulty breathing, wheezing, of hands, tightness in the chest, drop in blood pressure, dizziness, headache, skin reactions such as rash or swelling.
- If you have a heart disease (risk, you should be treated with care or stopped treatment).
- If you have diabetes or weakness in your arms and legs (peripheral neuropathy). These signs of neurotoxicity are the most common side effects.
- If you have kidney problems. In this case, the dose of paclitaxel is to be reduced.
- If you have liver problems.
- If you develop severe or persistent diarrhea, with fever and stomach pain, during or shortly after treatment with paclitaxel. Your doctor is to interrupt treatment with paclitaxel.
- If you have mouth sores, paclitaxel should be stopped or dose reduced.
- If you have higher or weaker than normal blood pressure, you should be monitored.
- If you have heart problems. In this case, the dose of paclitaxel is to be reduced.
- If you develop severe or persistent diarrhea, with fever and stomach pain, during or shortly after treatment with paclitaxel. Your doctor is to interrupt treatment with paclitaxel.
- If you have a decrease in the number of your blood cells (red blood cells, white blood cells, platelets). Your doctor will carry out blood tests before each treatment with paclitaxel. Your doctor may decide to change the treatment if your blood cells are too low.
- If you have peripheral neuropathy (nerve damage affecting your hands and feet), your doctor may decide to change the treatment.
- If you have a decrease in your blood cells (red blood cells, white blood cells, platelets). Your doctor will carry out blood tests before each treatment with paclitaxel. Your doctor may decide to change the treatment if your blood cells are too low.
- If you have a severe persistent infection and uncontrolled cardiac insufficiency.
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Other medicines and PACLITAXEL NEAPOLIS

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

Before PACLITAXEL NEAPOLIS is administered, you will be given premedication, such as dexamethasone, diphenhydramine and cimetidine or ranitidine.

- Medicines to treat infections (e.g. antibiotics such as rifampicin, etc., and other medicines such as phenobarbital, carbamazepine and phenytoin and medicines to treat fungal infections).
- Medicines used to treat cancer (e.g. doxorubicin, etc.).
- Medicines to treat heart problems (e.g. verapamil).
- Medicines to treat high cholesterol (e.g. simvastatin).
- Medicines to treat HIV infection (e.g. ritonavir, saquinavir, nelfinavir, indinavir, efavirenz, nevirapine).
- Medicines called corticosteroids (e.g. dexamethasone).
- Vaccines. If you have been recently vaccinated or if you plan to receive a vaccination, tell your doctor. The use of paclitaxel in combination with live vaccines may lead to serious infections.
- Cisplatin (cancer medicine), oxaliplatin (cancer medicine), carboplatin (cancer medicine).
- Other medicines.

Tell your doctor if you are taking any other medicine.

- Paclitaxel may be administered in combination with other cytotoxic agents.

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 absolutely necessary. Female and male patients of reproductive age, and in that case they should use contraception for at least 6 months after treatment with paclitaxel.

Male patients should seek advice regarding cryopreservation of their sperm prior to paclitaxel treatment, as there is a possibility of infertility.

Tell your doctor if you are breastfeeding. Stop breastfeeding if you are taking paclitaxel. Do not start breastfeeding until your doctor has given you permission to do so.

Driving and using machines

The medicine contains alcohol. Thus, it is not recommended to drive immediately after a maximum course, in any case, you should not drive if you feel dizzy or are not sure of yourself.

PACLITAXEL NEAPOLIS 6 mg/ml, concentrate for solution for infusion contains purified polyoxyethylene castor oil (Kolliphor EL) (Cremophor EL).

This medicine contains alcohol (ethanol). This amount can 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 USE PACLITAXEL NEAPOLIS 6 mg/ml, concentrate for solution for infusion?

- To minimize allergic reactions, you will be given steroid medicines before you are given paclitaxel. These medicines given before receiving paclitaxel are to reduce the risk of allergic reactions and other side effects.
- The infusion via a blood drip (intravenous) of your veins (by intravenous infusion) through a filter. Paclitaxel will be given to you 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 be given Paclitaxel alone or in combination with other anticancer agents.
- Paclitaxel must always be given as an infusion of your veins for a period of 3 or 24 hours. It is usually given to you every 3 to 4 weeks unless your doctor decides otherwise. Your doctor will tell you how many paclitaxel courses you will receive in months. If you have any further questions on the use of this product, ask your doctor or nurse or pharmacist.

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 relate to one or more of the following effects:

- Hot flushes.
- Skin rashes.
- Itching.
- Dizziness.
- Difficulty in breathing.
- Swelling.

Also you other signs of severe side effects:

Blood and lymphatic system disorders:

- If you experiences some chills, sore throat, or mouth ulcers signs of infection (neutropenia).
- If you have fatigue or weakness in your arms and legs (peripheral neuropathy).
- If you develop severe or persistent diarrhea, with fever and stomach pain.

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

- Hair loss (alopecia) (reversible).
- Nausea, vomiting, diarrhea, inflammation of the mouth, thrombosis, loss of appetite.
- Muscle, joint and bone pain (myalgia, arthralgia).
- Tingling, numbness and pain in the hands and feet (peripheral neuropathy).
- Tiredness, weakness, fever, chills, sweating, loss of weight, rash, redness and swelling of the skin.
- Coughing, difficulty in breathing or shortness of breath, runny nose, sore throat, inflammation of the lungs (pneumonitis).
- Allergic reactions (rash, redness, swelling of the face, difficulty breathing, wheezing, cough, tightness in the chest, sweating, fever, chills, nausea, vomiting, diarrhea, headache, and low blood pressure).
- Changes in liver function (increase in the liver enzymes).
- Changes in the number of your blood cells (red blood cells, white blood cells, platelets).
- Changes in the electrical activity of your heart (ECG).
- Pain in your chest, tightness in your chest, heart attack, irregular heartbeat, slow heartbeat, cardiac arrest, cardiac failure, low blood pressure.
- Changes in the electrical activity of your heart (ECG).
- Changes in the number of your blood cells (red blood cells, white blood cells, platelets).
- Inflammation of the veins (phlebitis).
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Common (may affect up to 1 in 100 patients):

- Short-term blurred vision or visible errors.
- Palpitations, irregular heartbeats (tachycardia), low blood pressure, fainting, high blood pressure, hot flushes, redness, flushing.
- Hives, swelling, skin rashes, flushing, allergic reactions, inflammation of a vein caused by a blood clot (thrombophlebitis), swelling of the face, flushes, rash, itching or itchy.
- Back pain, stomach pain, pain around the nose, chest, and in the joints and bones.
- Blurred vision, loss of vision, vision alterations in the eye, glaucoma, eye disorder, conjunctivitis.
- Changes in the number of your blood cells (red blood cells, white blood cells, platelets).
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Rare (may affect up to 1 in 1000 patients):

- Chemical burns (tissue damage caused by a chemical), swelling, pain, redness and hot to the touch at the injection site.
- Blood clots, inflammation of veins in deep veins of the arm or other deep vein thrombosis.
- Inflammation of the skin, yellow discoloration of skin and/or eyes (jaundice), swelling and pain in the abdomen, liver problems, inflammation of the liver, hepatitis, enlargement of the liver.
- Changes in the number of your blood cells (red blood cells, white blood cells, platelets).