All read of this leaflet carefully before you start using this medicine because it contains important information for you.

- Never use Paclitaxel Injection if you have further questions, ask your doctor, pharmacist or nurse.
- If you are given the wrong dose of this medicine, tell your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet
- Basic information about the medicine and what it is used for.
- What you need to know before you use Paclitaxel Injection.
- How Paclitaxel Injection is given to you.
- Possible side effects
- How to store Paclitaxel Injection.
- Contents of the pack and other information.

1. What Paclitaxel Injection is and what it is used for

The name of your medicine is Paclitaxel 6 mg/ml Concentrate for Solution for Infusion but in the rest of the leaflet it will be called "Paclitaxel Injection".

Paclitaxel Injection belongs to a group of anti-cancer medicines called taxanes. These agents inhibit the growth of cancer cells.

Paclitaxel Injection is used to treat:

- Ovarian cancer: 
  • as first therapy (after initial surgery in combination with the platinum-containing medicine cisplatin).
  • after standard platinum-containing medicines have been tried but did not work.
- Breast cancer:
  • as first therapy for advanced disease or disease which has spread to other parts of the body (metastatic disease).
  • Paclitaxel Injection is either combined with an anthracycline (e.g. doxorubicin) or with a medicine called capecitabine (if the patients for whom anthracyclines are not suitable due to severe cardiac impairment).
- As a second-line treatment for patients who have not responded to standard treatments using anthracyclines, or for whom such treatment should not be used.

Advanced non-small-cell lung cancer:
- In combination with cisplatin, when surgery and/or radiation therapy aren’t suitable.

AIDS-related Kaposis sarcoma:
- where another treatment (e.g. liposomal anthracyclines) has been tried but not worked.

2. What you need to know before you use Paclitaxel Injection

You should not be given Paclitaxel Injection:
- If you are allergic (hypersensitive) to paclitaxel or to any of the other ingredients of this medicine listed in section 6 (except polyethylene glycol 350 and water).
- If you have had a severe allergic reaction (e.g. anaphylaxis) to Paclitaxel Injection.
- If you have any conditions that may cause bone marrow suppression (see section 4).
- If you have too few red or white blood cells (e.g. you are anaemic or you have a low white blood cell count).
- If you are pregnant or breastfeeding.

3. How to take Paclitaxel Injection

- Tell your doctor immediately if any of these apply to you.
  Paclitaxel Injection should always be administered into veins.
  Tell your doctor immediately if any of these apply to you.
  Administration of Paclitaxel Injection in the arteries can cause inflammation.

Other medicines and Paclitaxel Injection
- Tell your doctor if you are taking, have recently taken or may take any other medicines.

4. Possible side effects

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

The following information is intended for healthcare professionals only:

Preparation of infusion solutions:
- Contaminants and infusion sets used with Paclitaxel Injection must be DEHP-free. This will minimise patient exposure to the plasticiser DEHP (di-(2-ethylhexyl) phthalate), which may leach from PVC infusion containers or sets. Use of filter devices (e.g. VEK-2) which incorporate short path length DEHP contaminated PVC tubing has not resulted in significant leaching of DEHP.
- Take care when handling Paclitaxel Injection as there may be anaphylactic agents. Always wear protective gloves when handling vials containing paclitaxel. Solution should be performed under aseptic conditions by trained personnel in a designated area. In the event of contact with the skin, wash the area with soap and water. In the event of contact with the mucous membranes, flush thoroughly with water.
- Do not use the Chemo-Dispersing Pin device or similar devices with spikes since they can cause the vial stopper to collapse, resulting in loss of sterile integrity.

If you are breast feeding, tell your doctor. It is not known if paclitaxel passes into breast milk at a level that may cause harm to the infant. Stop breast-feeding if you are taking Paclitaxel Injection. Do not restart breast-feeding unless your doctor has allowed you to.

Fertility
- Paclitaxel may have an anti-fertility effect which could be irreversible. Male patients are therefore advised to seek advice on conservation of sperm prior to treatment.

Driving and using machines
- Paclitaxel Injection may cause side effects such as tiredness (very common and dizziness) that may affect your ability to drive and use machines. If you experience these symptoms, do not drive or operate machinery until they have fully resolved. If you are given other medicines that may cause sedation as a side effect, you should ask your doctor for advice on driving and using machines.

This medicine contains alcohol which may be harmful to the environment. These measures will help protect the environment.
"www.hpra.ie, e-mail: medsafety@hpra.ie"

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"www.hpra.ie, e-mail: medsafety@hpra.ie"
Tell your doctor immediately if you notice any signs of allergic reactions. These may include one or more of the following:
- flushing,
- skin rash,
- itching,
- shortness or difficulty in breathing,
- swelling.
These can all be signs of serious side effects.

Tell your doctor immediately:
- if you have fever, severe chills, sore throat or mouth ulcers (signs of bone marrow suppression).
- if you develop numbness or weakness of the arms or legs (signs of peripheral neurotoxicity).
- if you develop severe or persistent diarrhoea, with fever and stomach pain.

Very common (may affect more than 1 in 10 people)
- minor skin rashes such as flushing, red, itching.
- reactions: mainly upper respiratory infection, urticarial infection
- shortness of breath
- sore throat or mouth ulcers, sore and red mouth, diarrhoea, feeling or being sick (nausea, vomiting)
- loss of hair. When it happens, hair loss is pronounced (over 50%) in the majority of patients
- pain in the muscles, cramps, pain in the joints
- fever, severe chills, headache, dizziness, tiredness, looking pale, bleeding, bruising more easily than normal
- numbness, tingling or weakness in arms and legs (all symptoms of peripheral neuropathy)
- tests may show: reduction of blood platelet count, while or red blood cells count, low blood pressure

Common (may affect up to 1 in 10 people)
- temporary mild rash and skin changes, reactions at injection sites (localised swelling, pain, and redness of the skin)
- tests may show: slower heart rate, severe elevation in liver enzymes (alkaline phosphatase and AST - SGOT)

Uncommon (may affect up to 1 in 100 people)
- shock due to infections (known as septic shock)
- palpitations, cardiac dysrhythmia (air, fast beating of the heart, respiratory distress
- painful gums, mouth sores (stomatitis), significant allergic reactions, phlebitis (inflammation of a vein), swelling of the face, lips, mouth, tongue, throat
- hair脱落
- black, pain, chest pain, pain around hands and feet, chills, abdominal turmoil (stomach upset)
- tests may show: severe elevation of bilirubin (jaundice), high blood pressure, and blood clots

Rare (may affect up to 1 in 1000 people)
- shortage of white blood cells with fever and increased risk of infection (bacterial neutropenia)
- affection of nerves with feeling of weakness in muscles of arms and legs (motor neuropathy)
- shortness of breath, pulmonary embolism, lung fibrosis, interstitial pneumonia, drooping eyelids, pleural effusion
- bowel obstruction, bowel perforation, inflammation of colon (ischaemic colitis), inflammation of the pancreas (pancreatitis)
- pruritus, rash, skin redness (erythema)
- blood poisoning (sepsis), paralysia
- pyrexia, dehydration, asthma, oedema, malaise
- serious and potentially fatal hypersensitivity reactions (anaphylactic reactions)
- test may show: increase in blood creatinine indicating renal function impairment.
- heart failure

Very rare (may affect up to 1 in 10,000 people)
- irregular heartbeat rhythm (atrial fibrillation, supraventricular tachycardia) or heart attack
- tumours (caused by myeloid leukaemia, myelodysplastic syndrome)
- optic nerve and/or visual disturbances (scotomatous scotoma)
- hearing loss or reduction in hearing (cochlear damage, vertigo)
- cough
- blood clot in a blood vessel of abdomen and bowel (mesenteric thrombosis), inflammation of colon sometimes with persistent severe diarrhoea (pseudo-membranous colitis), neutropenia (neutrophils)
- depressed (depression, dysthymia), constipation
- Serious hypersensitivity reactions including fever, skin rash, pain in joints and/or inflammation of the eye (Stevens-Johnson syndrome), local peeling of the skin (epidermal necrolysis), redness with irregular red (sesamoid) spots (erythema multiforme), inflammation of the skin with blisters and peeling of the skin (bullous dermatitis), urticaria, toxic shock (patients on therapy should wear sun protection on hands and feet).
- loss of appetite (anorexia)
- bunion and potentially fatal hypersensitivity reactions with shock (anaphylactic shock)
- Disturbed liver function (hepatic necrosis, hepatic echolalia with both hepatic cases and 75% of deaths)
- Confusional state.
- Not known (the frequency cannot be determined based on the available data)
- Handshaking/flushing of the skin (flushing)
- Tumour lysis syndrome
- Myocardial oedema, photosensitivity, rhabdomyolysis
- Phlebitis
- Systemic lupus erythematosus
- Disseminated intravascular coagulation, or DIC.

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. By reporting side effects, you can help provide more information on the safety of this medicine. For UK. - You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellcard.
- For Ireland. - You can also report side effects directly via HPRA Pharmacovigilance Service.
- Tel: +353 1 6764972, Fax: +353 1 6769209.
- Website: www.hpra.ie, e-mail: medsafe@hpra.ie

5. How to store Paclitaxel Injection

Keep this medicine out of the sight of children and not store above 25°C.

Do not store near a stove or in a car.

If you do not use this medicine product after the expiry date which is stated on the carton after the expiration date refers to the last day of that month.

Before opening
- Do not store above 25°C.
- Keep the vial in the outer carton in order to protect from light.
- Freezing does not adversely affect the product.

After opening before dilution (description of the conditions)
- From a microbiological point of view, the diluted product should be used immediately.
- If not used immediately, store in a refrigerator (2-8°C) for no more than 24 hours, unless disinfection has taken place in controlled and validated aseptic conditions. For more details on the stability after dilution, see the section for further precautions.
- Do not use this medicine if you notice a cloudy solution or an insoluble precipitate.
- 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. Contents of the pack and other information

What Paclitaxel Injection contains
- The active substance is Paclitaxel.
- Each vial contains for solution for infusion contains 6 mg of paclitaxel.
- Each vial contains 5, 7, 25, 50 and 100 ml (equivalent to 30, 150, 300 and 600 mg of paclitaxel respectively).
- The other ingredients are poly(vinyl) 35 castor oil (magnesium stearate 3%) and anthamine ethanol.

What Paclitaxel Injection looks like and contents of the pack
- Paclitaxel Injection is a clear colourless to slightly yellow solution free from visible particles.
- It is available in vials containing 5 ml, 16.7 ml, 25 ml, 50 ml and 100 ml of concentrate for solution for injection.
- Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:
- Accord Healthcare Limited
- Snape House, 319, Firmer Road, North Harrow, Middlesex, HA1 4HF, United Kingdom

This medicinal product is authorised in the Member States of the EEA under the following name:
- Name of the manufacturer:
- The Netherlands: Paclitaxel Accord 6 mg/ml, Concentraat voor oplossing voor intraveneus toedienen
- Austria: Paclitaxel Accord 6 mg/ml, Konzentration zur Herstellung ihrer Infusionslösung
- Belgium: Paclitaxel Accord 6 mg/ml, solution à diluer pour perfusion
- Bulgaria: Paclitaxel Accord 6 mg/ml, Concentrato per soluzione per infusione
- Cyprus: Paclitaxel Accord 6 mg/ml, Concentrato per Soluzione per Infusione
- Estonia: Paclitaxel Accord 6 mg/ml
- Spain: Paclitaxel Accord 6 mg/ml, concentrado para solución para perfusión
- France: Paclitaxel Accord 6 mg/ml, Solution à injecter pour perfusion
- Hungary: Paclitaxel Accord 6 mg/ml, Concentrato per Soluzione per Infusione
- Italy: Paclitaxel Accord 6 mg/ml, Concentrato per Soluzione per Infusione
- Latvia: Paclitaxel Accord 6 mg/ml, Infusionssuspensie, bloeiende lente
- Lithuania: Paclitaxel Accord 6 mg/ml, Infusionssuspensie, bloeiende lente
- Norway: Paclitaxel Accord 6 mg/ml, Infusionssuspensjon
- Poland: Paclitaxel Accord 6 mg/ml, Koncentrat do wlewania
- Portugal: Paclitaxel Accord 6 mg/ml, Infusão para perfusão
- Romania: Paclitaxel Accord 6 mg/ml, concentrato per soluzione per infusione
- Sweden: Paclitaxel Accord 6 mg/ml, Koncentrat till infusionslösning
- Slovenia: Paclitaxel Accord 6 mg/ml, koncentrat za raztajno za injekcije
- Slovak Republic: Paclitaxel Accord 6 mg/ml, infúzia koncentrát
- United Kingdom: Paclitaxel Accord 6 mg/ml, Concentrate for Solution for Infusion

This leaflet was last revised in 06/2017.

Do not re-administer Paclitaxel Injection until the next administration is 2 to 1,500 mg (≥ 1,000 mg for Kaposi’s sarcoma patients) and the platelet count is ≥ 100,000/ml (≥ 75,000/ml for Kaposi’s sarcoma patients).

Patients who experience severe neutropenia (neutrophil count < 500/ml for a week or longer) or severe peripheral neuropathy should receive a dose reduction of 25% subsequent courses (25% for Kaposi’s sarcoma patients) (see Summary of Product Characteristics).

Inadequate data are available to recommend dosage alterations in patients with mild to moderate hepatic impairment. Patients with severe hepatic impairment should not be treated with Paclitaxel Injection (see Summary of Product Characteristics).

Paclitaxel Injection is not recommended for use in children below 18 years due to lack of data on safety and efficacy.

Note: Artwork requires symbol of Scissor & dotted line. Perforation is not requiring in the artwork.