

Applicant/PHRC: **Hetero Drugs South Africa (Pty) Ltd**

Product proprietary name: **CAPHET 60 mg/1,5 ml INJ**

Dosage form and strength: **Concentrate for Solution for infusion and 60 mg/1,5 ml**

PATIENT INFORMATION LEAFLET FOR CAPHET 60 mg/1,5 ml INJ

SCHEDULING STATUS

S4

CAPHET 60 mg/1,5 ml INJ

Concentrate for solution for infusion Cabazitaxel

Diluent (solvent) vial contains ethanol 96 % (573,3 mg), water for injection

CAPHET 60 mg/1,5 ml INJ is sugar free

Read all of this leaflet carefully before you are given CAPHET 60 mg/1,5 ml INJ

- Keep this leaflet. You may need to read it again.

If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.

What is in the leaflet

1. What **CAPHET 60 mg/1,5 ml INJ** is and what it is used for
2. What you need to know before **CAPHET 60 mg/1,5 ml INJ** is administered
3. How to receive **CAPHET 60 mg/1,5 ml INJ**
4. Possible side effects
5. How to store **CAPHET 60 mg/1,5 ml INJ**
6. Contents of the pack and other information

1. What CAPHET 60 mg/1,5 ml INJ is and what it is used for

CAPHET 60 mg/1,5 ml INJ belongs to a group of medicines called “taxanes” used to treat cancers. **CAPHET 60 mg/1,5 ml INJ** is used to treat prostate cancer that has progressed after having had other chemotherapy. It works by stopping cells from growing and multiplying.

2. What you need to know before CAPHET 60 mg/1,5 ml INJ is administered

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CAPHET 60 mg/1,5 ml INJ should not be administered to you:

- if you are hypersensitive (allergic) to cabazitaxel or to other taxanes or polysorbate 80 or to any of the other ingredients of **CAPHET 60 mg/1,5 ml INJ** (listed in section 6).
- if the number of your white blood cells is too low (neutrophil counts less than or equal to $1\,500/\text{mm}^3$)
- if you have severe abnormal liver function
- if you have recently received or are about to receive a vaccine against yellow fever.

Warnings and precautions

Before each treatment with **CAPHET 60 mg/1,5 ml INJ**, you will have blood tests to check that you have enough blood cells and sufficient liver and kidney functions to receive **CAPHET 60 mg/1,5 ml INJ**.

Tell your doctor or health care provider before being given the CAPHET 60 mg/1,5 ml INJ:

- If you have fever. During treatment with **CAPHET 60 mg/1,5 ml INJ**, it is more likely that your white blood cell count may be reduced. Your doctor will monitor your blood and general condition for signs of infections. He/she may give you other medicines to maintain the number of your blood cells. People with low blood counts can develop life-threatening infections. The earliest sign of infection may be fever, so if you experience fever, tell your doctor right away.
- If you have ever had any allergies. Serious allergic reactions can occur during treatment with **CAPHET 60 mg/1,5 ml INJ**.
- If you have severe or long lasting diarrhoea, you feel sick (nausea) or you are being sick (vomiting). Any of these events could cause severe dehydration. Your doctor may need to treat you.
- If you have feeling of numbness, tingling, burning or decreased sensation in your hands or feet.
- If you have any bleeding problems from the gut or have changes in the colour of your stool or stomach pain. If the bleeding or pain is severe, your doctor will stop your treatment with **CAPHET 60 mg/1,5 ml INJ**. This is because **CAPHET 60 mg/1,5 ml INJ** may increase the risk of bleeding or developing holes in the gut wall.
- If you have kidney problems.
- If liver problems occurring during the treatment.

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As part of your treatment, you will also take a corticosteroid medicine (prednisone or prednisolone) by mouth every day.

- If you experience any significant increase or decrease in daily urinary volume.
- If you have blood in your urine.
- If you develop breathing or heart problems

If any of the above applies to you, tell your doctor or healthcare provider immediately. Your doctor may reduce the dose of **CAPHET 60 mg/1,5 ml INJ** or stop the treatment.

Other medicines and CAPHET 60 mg/1,5 ml INJ

Always tell your health care provider if you are taking any other medicine. (This includes complementary or traditional medicines). This is because some medicines can affect the way **CAPHET 60 mg/1,5 ml INJ** works or **CAPHET 60 mg/1,5 ml INJ** can affect how other medicines work. These medicines include the following:

- Ketoconazole, rifampicin (used to treat infections),
- Carbamazepine, phenobarbital or phenytoin (used to treat seizures),
- St John's Wort (*Hypericum perforatum*) (herbal remedy for depression and other conditions),
- Statins, such as simvastatin, lovastatin, atorvastatin, rosuvastatin or pravastatin (used to reduce the cholesterol in your blood),
- Valsartan (used to treat hypertension),
- Repaglinide (used to treat diabetes).

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before receiving **CAPHET 60 mg/1,5 ml INJ**.

Pregnancy

CAPHET 60 mg/1,5 ml INJ should not be used in pregnant women or women of childbearing age not using contraception.

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Breastfeeding

CAPHET 60 mg/1,5 ml INJ should not be used during breast feeding.

Fertility

Use a condom during sex if your partner is or could become pregnant. **CAPHET 60 mg/1,5 ml INJ** could be present in your semen and may affect the foetus. You are advised not to father a child during and up to 6 months after treatment and to seek advice on conservation of sperm prior to treatment because **CAPHET 60 mg/1,5 ml INJ** may alter male fertility.

Driving and using machines

You may feel tired or dizzy when having this medicine. If this happens, do not drive or use any tools or machines until you feel better.

It is not always possible to predict to what extent **CAPHET 60 mg/1,5 ml INJ** may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which **CAPHET 60 mg/1,5 ml INJ** affects them.

CAPHET 60 mg/1,5 ml INJ contains ethanol (alcohol)

This medicine contains 15 % v/v ethanol (alcohol), equivalent to 14 ml of beer or 6 ml of wine. This medicine may be harmful for those suffering from alcoholism.

3. How to receive CAPHET 60 mg/1,5 ml INJ

Do not share medicines prescribed for you with any other person.

You will not be expected to give yourself **CAPHET 60 mg/1,5 ml INJ**. It will be given to you by a person who is qualified to do so.

Anti-allergic medicines will be given to you before you have **CAPHET 60 mg/1,5 ml INJ** to reduce the risk of allergic reactions. **CAPHET 60 mg/1,5 ml INJ** must be prepared (diluted) before it is given. **CAPHET 60 mg/1,5 ml INJ** will be given by a drip (infusion) into one of your veins (intravenously) in hospital for about an hour.

As part of your treatment, you will also take a corticosteroid medicine (prednisone or prednisolone) by mouth

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every day.

The usual dose depends on your body surface area. Your doctor will calculate your body surface area in square meters (m²) and will decide the dose you should have.

You will usually have an infusion once every 3 weeks.

Method of administration:

CAPHET 60 mg/1,5 ml INJ is administered as a 1 hour infusion.

An in-line filter of 0,22 micrometer nominal pore size (also referred to as 0,2 micrometer) is recommended during administration.

If you receive more CAPHET 60 mg/1,5 ml INJ than you should

Since your health care provider will administer **CAPHET 60 mg/1,5 ml INJ**, he/she will control the dosage. However, in the event of an overdosage your doctor will manage the overdosage.

If you missed a dose of CAPHET 60 mg/1,5 ml INJ

Since health care provider will administer **CAPHET 60 mg/1,5 ml INJ**, it is unlikely that the dose will be missed.

4. Possible side effects

CAPHET 60 mg/1,5 ml INJ can have side effects.

Not all side effects reported for **CAPHET 60 mg/1,5 ml INJ** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving **CAPHET 60 mg/1,5 ml INJ**, please consult your health care provider for advice.

If any of the following happens, stop administration of **CAPHET 60 mg/1,5 ml INJ** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- 'swelling of your hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing',
- 'rash or itching',
- 'fainting'

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These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **CAPHET 60 mg/1,5 ml INJ**. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Urinary tract infection
- Blood poisoning, Deep pyogenic infection, Influenza,
- Upper respiratory tract infection,
- Shingles (blistering skin rash),
- Thrush (oral cavity, gastrointestinal tract, vagina penis),
- Decrease in the number of red blood cells (anaemia), or white blood cells (which are important in fighting infection)
- Decrease in the number of platelets (which results in increased risk of bleeding)
- Lack of white blood cells associated with fever and infection
- Hay fever
- Loss of appetite (anorexia)
- Severe loss of body fluids (dehydration). This can occur if you have severe or long lasting diarrhoea, or fever, or if you are being sick (vomiting).
- Anxiety, Confusional state.
- Dullness,
- Back pain,
- Decrease of sensitivity (hypoesthesia).
- Alteration in sense of taste
- Feeling of numbness, tingling, burning or decreased sensations in hands and feet
- Conjunctivitis
- Excessive tearing eyes.
- Ear buzzing,
- Atrial fibrillation (abnormal heart rate),
- Decrease in blood pressure
- Shortness of breath

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- Deep vein thrombosis (blood clot forms in a deep vein), Hypertension, upright hypotension, Hot flush, Flushing.
- Lung fever (pneumonia)
- Cough
- Pain in both the mouth and the pharynx,
- Haemorrhoids (swollen veins in your anus and lower rectum)
- Short term hair loss (in most cases normal hair growth should return)
- Muscle spasm
- Muscle discomfort, aches or pain
- Blood in the urine
- Painful or frequent urination
- Urinary incontinence
- Rectal haemorrhage, Dry mouth, Abdominal enlargement.
- Kidney disease or problems
- Severe stomach pain or stomach pain that doesn't go away. This can occur if you have a hole in the stomach, food pipe, gut or bowel (gastrointestinal perforation). This can sometimes lead to death.
- Dry skin, Sun burn (Erythema).
- Musculoskeletal chest pain, Flank pain, Pain in extremity, hurting (Myalgia).
- Pelvic pain
- Chest pain, Oedema, Chills, Malaise.
- Weight decreased
- Aspartate aminotransferase (enzyme that promotes transfer of an amino group from glutamic acid to oxaloacetic acid) increased,
- Transaminases increased.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor as soon as possible if you notice any of the following:

Frequent:

- Dizziness
- Headache

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- Cough
- Loose or watery stools (diarrhoea)
- Feeling sick (nausea)
- Being sick (vomiting)
- Constipation
- Uncomfortable feeling in the stomach, heart burn or belching
- Indigestion
- Back pain
- Joint pain
- Feeling tired, weak or lack of energy
- Fever (high temperature)

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za>. or to the Holder of certificate of registration through the mail: pvg.cdma@heterogroups.com. By reporting side effects, you can help provide more information on the safety of **CAPHET 60 mg/1,5 ml INJ**.

5. How to store CAPHET 60 mg/1,5 ml INJ

- Store at or below 25 °C. Do not refrigerate.
- Store all medicines out of reach of children.
- Protect from light and moisture.
- Keep the vials in the outer carton until required for use.
- **After opening:** Concentrate and solvent vials must be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user.
- **After initial dilution:** Chemical and physical in-use stability for the resulting concentrate-solvent mixture has been demonstrated for one hour at ambient temperature. From a microbiological point

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of view, the concentrate-solvent mixture should be used immediately.

- **After final dilution:** Chemical and physical stability of the infusion solution has been demonstrated for 8 hours at ambient temperature (including the 1-hour infusion time) and for 48 hours under refrigerated conditions. From a microbiological point of view, the infusion solution should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user and would normally not be longer than 24 hours at 2 °C to 8 °C unless dilution has taken place in controlled and validated aseptic conditions.
- As the infusion solution is supersaturated, it may crystallise over time. In this case, the solution must not be used and should be discarded.
- Do not store in a bathroom.
- Do not use after the expiry date stated on the label / carton / vial.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

For single use only. Discard any unused contents.

6. Contents of the pack and other information

What CAPHET 60 mg/1,5 ml INJ contains

- The active substance is cabazitaxel.
- The other ingredients are ethanol, nitrogen, polysorbate 80 and water for injection.

What CAPHET 60 mg/1,5 ml INJ looks like and contents of the pack

Concentrate for solution for infusion is a clear yellow to brownish yellow viscous solution and diluent (solvent) is a clear colorless solution.

Contents of the pack

Concentrate for solution for infusion: 1,5 ml (deliverable volume) of **CAPHET 60 mg/1,5 ml INJ** concentrate for solution for infusion in a 15 ml type-I, round clear tubular glass vial with 20 mm serum rubber GCB stopper with flurotec coating and 20 mm purple colour flip off aluminium seal.

Diluent (solvent): 4,5 ml (deliverable volume) of solvent in a 15 ml type-I, round clear tubular glass vial with 20 mm serum rubber GCB stopper with flurotec coating and 20 mm white colour flip off aluminium seal.

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Pack size: 1 vial of concentrate for solution for infusion and 1 vial of diluent (solvent) together are packed in an outer carton.

Holder of Certificate of Registration

Hetero Drugs South Africa (Pty) Ltd

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74 Waterfall Drive

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2066

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Access to the corresponding Professional Information

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