Proposed Patient Information Leaflet

Information for the Patient about

CIPLA-VINORELBINE 10

CIPLA-VINORELBINE 50

Read this entire leaflet carefully before you receive CIPLA-VINORELBINE.

- Keep this leaflet, you may need to read it again.

- If you have further questions please ask your doctor or your pharmacist.

- CIPLA-VINORELBINE has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

SCHEDULING STATUS:

S4

PROPRIETARY NAME (AND DOSAGE FORM):

CIPLA-VINORELBINE 10 (Intravenous injection)

CIPLA-VINORELBINE 50 (Intravenous injection)

WHAT CIPLA-VINORELBINE CONTAINS:

The active substance is vinorelbine. Vinorelbine belongs to a class of medicines known as cytostatic agents, in other words medicines for the treatment of cancer.

CIPLA-VINORELBINE 10: Each single dose vial contains 13.85 mg vinorelbine tartrate equivalent to 10 mg vinorelbine base per millilitre of solution.

CIPLA-VINORELBINE 50: Each single dose vial contains 69.25 mg vinorelbine tartrate equivalent to 50 mg vinorelbine base per 5 millilitre of solution.

WHAT CIPLA-VINORELBINE IS USED FOR:

CIPLA-VINORELBINE is indicated for the treatment of cancer, specifically advanced non-small cell lung cancer (NSCLC) that cannot be removed by surgery. It may be used as a single agent or in combination with other anti-cancer medicines. Combination of medicines has been proven to be more effective that treatment with a single medicine.

CIPLA-VINORELBINE is also indicated in patients with breast cancers, which have spread to other organs (i.e., metastatic breast cancer) and who have failed to respond satisfactorily to single medicine treatment with anti-cancer medicines known as anthracyclines. **CIPLA-VINORELBINE** is also indicated in patients with metastatic breast cancer who have relapsed within 6 months of anthracycline-based add-on therapy.

BEFORE YOU RECEIVE CIPLA-VINORELBINE:

Do not receive **CIPLA-VINORELBINE** in the following conditions:

- If you are known to be hypersensitive (allergic) to **CIPLA-VINORELBINE**.
- If you have low white cell counts or low platelet counts due to the use of medicines.
- If you are pregnant or breast feeding.
- If you suffer from severe liver impairment or dysfunction.

Take special care with CIPLA-VINORELBINE:

Please inform your doctor if you suffer from any liver disease or impairment, as **CIPLA-VINORELBINE** should be administered with caution to patients with liver problems. Your doctor may decide to adjust your dose of **CIPLA-VINORELBINE** if you develop increased bilirubin (pigment produced by the liver) levels during treatment.

Your doctor will periodically perform blood tests to evaluate your blood cell counts and liver enzymes, since therapy with **CIPLA-VINORELBINE** may negatively influence these parameters (see **"POSSIBLE SIDE-EFFECTS"**).

Please inform your doctor if you use any of the following medicines, as combination therapy with **CIPLA-VINORELBINE** may lead to undesirable interactions:

- Mitomycin for the treatment of cancer, since combination therapy may cause acute lung reactions.
- Paclitaxel for the treatment of cancer, since concomitant or sequential use may result in nerve damage.

- Cisplatin for the treatment of cancer, since combination therapy may increase the incidence of certain toxic effects, such as low white blood cell counts (see **"POSSIBLE SIDE-EFFECTS"**).

If you are also receiving radiation therapy, the use of **CIPLA-VINORELBINE** may increase the bone marrow depressant of effect of such therapy.

Since **CIPLA-VINORELBINE** may suppress your body's normal defence mechanisms, you should not undergo vaccination with either killed or live viruses, but especially not live viruses. Anyone with whom you have close contact, especially family members, should postpone immunisation with oral poliovirus vaccine until your doctor considers it safe. Please discuss this with your treating doctor.

Receiving CIPLA-VINORELBINE with food and drinks:

CIPLA-VINORELBINE will be administered intravenously (into your veins) The presence of food in the stomach will therefore not impact on its availability in your body.

See **"HOW TO RECEIVE CIPLA-VINORELBINE"**.

Use in pregnancy and breast feeding:

The safety of **CIPLA-VINORELBINE** in pregnancy and breast feeding has not been established. Thus use in pregnancy and breast feeding is not recommended. Adequate contraception to avoid pregnancy is essential.

If you are pregnant or breast feeding your baby while receiving **CIPLA-VINORELBINE**, please consult your doctor, pharmacist or other healthcare professional for advice.

Taking other medicines with CIPLA-VINORELBINE?

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of **CIPLA-VINORELBINE** with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

Please see **"Take special care with CIPLA-VINORELBINE"**.

HOW TO RECEIVE CIPLA-VINORELBINE:

CIPLA-VINORELBINE is administered intravenously (into a vein). Your doctor will decide the appropriate dosage and times of administration. He/she may decide to alter your dose should you develop any side-effects, such as low white cell counts or liver function abnormalities. Your doctor will also tell you how long treatment with **CIPLA-VINORELBINE** will last.

If you have the impression that **CIPLA-VINORELBINE** is too strong or too weak for you, please discuss this with your treating doctor.

POSSIBLE SIDE-EFFECTS:

What undesirable effects may CIPLA-VINORELBINE have?

CIPLA-VINORELBINE may have unintended or undesirable effects.

The most serious side-effect associated with **CIPLA-VINORELBINE** therapy is low white blood cell counts. White blood cells are necessary to maintain a healthy immune system and to fight infections. You should immediately report to your doctor if you develop fever or chills, cough or hoarseness, lower back or flank pain, painful or difficult urination or a sore throat.

The most common side-effects associated with **CIPLA-VINORELBINE** therapy include asthenia (unusual tiredness or weakness) and inflammation at the site of injection.

Other side-effects with **CIPLA-VINORELBINE** include:

- Blood and lymphatic system disorders, such as low red blood cell counts (presenting with tiredness or shortness of breath) and low platelet counts (presenting with easy bruising or bleeding from the gums).
- Nervous system disorders, such pins and needles or a decreased sensitivity to touch and pain, as well as general weakness after prolonged treatment.
- Chest pain.
- Shortness of breath that may occur within minutes, but sometimes hours after **CIPLA-VINORELBINE** administration.
- Gut disorders, such as constipation, nausea, vomiting and loss of appetite, which occur frequently, as well ulcers in the mouth, diarrhoea, inflammation of the pancreas and obstruction of the small bowel, which occur less frequently.

- Hair loss (frequently) and skin rash.
- Joint or muscle pain.
- Blood in urine with inflammation of the bladder.
- Pain in the jaw.

Some patients who were treated with **CIPLA-VINORELBINE** showed increases in their liver enzymes, including bilirubin levels. Although this might have been due to therapy with **CIPLA-VINORELBINE**, it might also have been due to the spread of the cancer.

Not all side-effects reported for this medicine are included in this leaflet. Should your general health worsen while taking **CIPLA-VINORELBINE**, please consult your doctor, pharmacist or other healthcare professional for advice.

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

STORAGE AND DISPOSING OF CIPLA-VINORELBINE:

Store this medicine out of reach of children.

Store between 2 – 8°C. Do not freeze.

Do not use after the expiry date stated on the packaging material.

Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems, for example toilets.

PRESENTATION OF CIPLA VINORELBINE:

CIPLA-VINORELBINE 10: A carton containing one 2 ml transparent flint glass vial with a rubber stopper and red coloured aluminium flip off seal.

CIPLA-VINORELBINE 50: A carton containing one 5 ml transparent flint glass vial with a rubber stopper and red coloured aluminium flip off seal.

IDENTIFICATION OF CIPLA-VINORELBINE:

CIPLA-VINORELBINE 10: A clear solution filled in a 2 ml transparent flint glass vial.

CIPLA-VINORELBINE 50: A clear solution filled in a 5 ml transparent flint glass vial..

REGISTRATION NUMBER:

42/26/**00**83

NAME AND BUSINESS ADDRESS OF THE HOLDER CERTIFICATE OF REGISTRATION:

CIPLA MEDPRO (PTY) LTD

Rosen Heights

Pasita Street

Rosen Park

Bellville

7530

DATE OF PUBLICATION OF THIS PATIENT LEAFLET:
09 October 2009

REFERENCES TO PATIENT INFORMATION LEAFLET

REFERENCES	MRF1 PAGES

1. Central Clinical Committee recommendation dated 15 March 2009; received 15 May 2009.
2. Proposed PI initially submitted by CIPLA-MEDPRO (PTY) LTD
3. MRF 1, Part 3B – Formulation
4. Guideline on the requirements for patient information leaflets, May 2004