Final Patient Information Leaflet

Information for the Patient about

ZOMEDRON INJECTION

Read this entire leaflet carefully before you receive ZOMEDRON.

- **Keep this leaflet, you may need to read it again.**
- **If you have further questions please ask your doctor or your pharmacist.**

SCHEDULING STATUS:

S4

PROPRIETARY NAME (AND DOSAGE FORM):

ZOMEDRON (Injection)

WHAT ZOMEDRON CONTAINS:

The active substance in **ZOMEDRON** is zoledronic acid. Zoledronic acid belongs to a class of medicines known as bisphosphonates, which primarily acts on bone. It prevents the breakdown of bone tissue.

Each vial of **ZOMEDRON** contains zoledronic acid monohydrate equivalent to zoledronic acid anhydrous 4 mg.

The inactive ingredients include mannitol and sodium citrate.

WHAT ZOMEDRON IS USED FOR:

ZOMEDRON is indicated for the treatment of:

- High blood levels of calcium due to cancer.
- Bone lesions resulting from multiple myeloma (a cancer that originates in bone marrow) in combination with standard therapy for this condition.
- Breast cancer that has spread to the bone in combination with appropriate anticancer therapy.
- Prostate cancer that has spread to the bone in patients who have increased levels of prostate specific antigen (PSA) despite hormone treatment.

Your oncologist (doctor specialising in the treatment of cancer) will decide whether you qualify for treatment with **ZOMEDRON** and what other therapy you should be receiving in combination with it.

BEFORE YOU RECEIVE ZOMEDRON:

Do NOT receive ZOMEDRON if you:

- Are known to be hypersensitive (allergic) to **ZOMEDRON**, any other bisphosphonates, or to any components of the formulation.
- Suffer from severely impaired kidney function.
- Suffer from severely impaired liver function.
- Are pregnant or breastfeeding (see **"Pregnancy and breastfeeding"**).

Take special care with ZOMEDRON:

Your doctor will perform regular blood tests to evaluate blood levels of certain minerals, such as calcium, phosphate, and magnesium, as well as serum creatinine (a marker of kidney function) after you have been started on **ZOMEDRON** therapy. Based on these results, your doctor may decide to prescribe mineral supplements for you, if indicated. If your kidney function should deteriorate while on **ZOMEDRON** treatment, your doctor may decide to discontinue it.

It is not known whether it is safe to use **ZOMEDRON** in children.

Pregnancy and breastfeeding:

The use of **ZOMEDRON** during pregnancy and breastfeeding is contra-indicated, since safety and efficacy have not been established.

If you are pregnant or breastfeeding your baby while receiving **ZOMEDRON**, please consult your doctor, pharmacist or other healthcare professional for advice.

Driving and using machinery:

No studies have been performed to assess the effect of **ZOMEDRON** on a patient's ability to drive or use machinery. However, **ZOMEDRON** may cause dizziness and you should refrain from driving or operating machinery if you experience dizziness.

Taking other medicines with ZOMEDRON?

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of **ZOMEDRON** with these medicines may cause

undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

In particular, tell your doctor if you are receiving:

- Antibiotics belonging to the aminoglycoside group of antibiotics.

HOW TO RECEIVE ZOMEDRON:

ZOMEDRON is administered intravenously (into a vein). Your doctor will decide the appropriate dosage and times of administration. Your doctor will also decide how long treatment with **ZOMEDRON** will last. He/she may decide to alter your dose should you develop any side-effects, such as kidney function abnormalities. **ZOMEDRON** is usually administered as a 15-minute intravenous infusion every 3 to 4 weeks.

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

POSSIBLE SIDE-EFFECTS:

What undesirable effects may ZOMEDRON have?

ZOMEDRON may have unintended or undesirable effects.

Some of the most serious, and potentially life-threatening, side-effects associated with **ZOMEDRON** therapy is low white or red blood cell counts as well as low platelet counts. White blood cells are necessary to maintain a healthy immune system and to fight infections. Red blood cells are responsible for carrying oxygen,

while platelets play in vital role in blood clotting. Low red blood cell counts (anaemia) will present with tiredness or shortness of breath, while low platelet counts will present with easy bruising, bleeding from the gums, or pinpoint red spots on your skin. You should immediately report to your doctor if you develop any of the above symptoms, or if you develop fever or chills, cough or hoarseness, lower back or flank pain, painful or difficult urination or a sore throat.

Other serious side-effects, which you should report to your doctor as a matter of urgency, include:

- Allergic or hypersensitivity reactions, presenting with swelling of the face, lips, or throat, skin rash or hives, fever or chills, and difficulty breathing, or shortness of breath.
- Shortness of breath or troubled breathing.
- Slow heart rate.
- Blood in the urine or inability to pass urine.

Other potentially serious side-effects, which you should report to your doctor as soon as possible, include:

- Confusion.
- Blurred vision.
- Inflammation of the membrane covering the whites of the eyes (conjunctivitis).
- Coughing.
- Painful or difficult urination.

- Chest pain.
- Injection site reactions, such as pain, irritation, swelling, and induration.
- Swelling of the feet, ankles or lower legs.

Other side-effects with **ZOMEDRON**, which you should report to your doctor if they continue or become bothersome, include:

- Headaches, dizziness, pins and needles, abnormal (unpleasant) sensation with normal stimulation, or tremor.
- Taste disturbances.
- Anxiety or sleep disturbances.
- Gut disorders, such as nausea, vomiting, diarrhoea, stomach pain, loss of appetite, constipation, dry mouth, and dyspepsia. Inflammation of the lips or mouth may also develop.
- Increased sweating, rash, or itching.
- Muscle or joint pain, bone pain, or muscle cramps.
- Fever, flu-like symptoms, and tiredness or weakness.
- Weight gain.

ZOMEDRON may also cause abnormal blood levels of certain minerals (see **"Take special care with ZOMEDRON"**).

Not all side-effects reported for this medicine are included in this leaflet. Should your general health worsen while taking **ZOMEDRON**, 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 ZOMEDRON:

The centre where you receive your treatment will store and dispose of **ZOMEDRON** on your behalf.

Store at or below 25 °C. Protect from light.

The vial must not be removed from the outer carton until required for use.

STORE THIS MEDICINE OUT OF REACH OF CHILDREN.

After aseptic reconstitution and dilution, it is preferable to use the reconstituted and diluted product immediately. If not used immediately, the total time between reconstitution, dilution, storage in a refrigerator at 2 to 8 °C and end of administration must not exceed 24 hours.

PRESENTATION OF ZOMEDRON:

ZOMEDRON is available in a carton containing a 10 ml, transparent, clear glass vial sealed by an aluminium and dark red plastic flip-off seal and grey coloured bromobutyl slotted rubber stopper.

IDENTIFICATION OF ZOMEDRON:

Lyophilised powder: White to off white powder/cake.

Reconstituted solution: Clear, colourless solution.

REGISTRATION NUMBER:

To be allocated.

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

CIPLA MEDPRO (PTY) LTD

Rosen Heights

Pasita Street

Rosen Park

Bellville

7530

DATE OF PUBLICATION OF THIS PATIENT INFORMATION LEAFLET: