APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

PROPRIETARY NAME (and dosage form)

ODRON 35 mg TABLETS

(35 g Risedronate sodium hemipentahydrate)

Read all of this leaflet carefully before you start taking ODRON 35 mg TABLETS.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **ODRON 35 mg TABLETS** have 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.

1. WHAT ODRON 35 mg TABLETS CONTAIN

The active substance is risedronate sodium.

Each film-coated tablet contains risedronate sodium hemipentahydrate 35 mg equivalent to 32.5 mg risedronic acid. Contains lactose.

The other ingredients of **ODRON 35 mg TABLETS** are cellulose microcrystalline, crospovidone, hydroxy propyl cellulose and magnesium stearate.

The coating material of **ODRON 35 mg TABLETS** contains colloidal anhydrous silica, hydroxypropyl cellulose, hypromellose, iron oxide red, iron oxide yellow, macrogol / PEG 400, macrogol / PEG 8000 and titanium dioxide.

2. WHAT ODRON 35 mg TABLETS ARE USED FOR

ODRON 35 mg TABLETS are used to treat osteoporosis in postmenopausal women, in combination with calcium. Patients with a vitamin D deficiency, should also receive supplemental vitamin D.

3. BEFORE YOU TAKE ODRON 35 mg TABLETS

- **Do not take ODRON 35 mg TABLETS:**
  - If you are allergic to risedronate sodium, or any of the other ingredients of **ODRON 35 mg TABLETS.**
  - If your doctor has told you that you have a condition called hypocalcaemia (a low blood calcium level).
  - If you have severe kidney problems.
- **Take special care with ODRON 35 mg TABLETS:**

- **ODRON 35 mg TABLETS** can cause stomach or intestinal problems such as difficulty in swallowing, inflammation of the oesophagus, an oesophageal ulcer or a stomach ulcer.
- This may occur especially if you do not take **ODRON 35 mg TABLETS** while you are sitting up or standing, if you do not drink a full glass of plain water with **ODRON 35 mg TABLETS,** or if you lie down in less than 30 minutes after taking **ODRON 35 mg TABLETS** .
- Tell your doctor if:
  - You have had stomach or intestinal problems in the past or problems with your oesophagus (the tube that connects your mouth with your stomach).
  - You have pain or discomfort in your stomach or oesophagus.
  - You had or have pain, swelling or numbness of the jaw or a “heavy jaw feeling” or loosening of a tooth.
  - You have anaemia, clotting/bleeding disorders, an infection, cancer, are undergoing chemotherapy, are taking corticosteroids, are having dental procedures, or have poor oral hygiene or ill-fitting dentures. If you have any of these conditions and are taking **ODRON 35 mg TABLETS,** you are at a higher risk of developing bone loss in the jaw (called osteonecrosis of the jaw) and bone breakage (such as atypical fracture of the femur).
  - You have any kidney problems.
  - You have abnormal bone and mineral metabolism (for example lack of vitamin D, parathyroid hormone abnormalities, both leading to a low blood calcium level). If you have one (or more) of these problems, it should be corrected before taking.

If you are under dental treatment or will undergo dental surgery, tell your dentist that you are being treated with **ODRON 35 mg TABLETS.**

- **Taking ODRON 35 mg TABLETS with food and drink:**
    - Food and drinks (other than plain water) should not be taken at the same time of the day as **ODRON 35 mg TABLETS.**
    - Do not take **ODRON 35 mg TABLETS at** the same time as dairy products (such as milk) as they contain calcium (see **"Taking other medicines"**).
    - Therefore, take **ODRON 35 mg TABLETS at** least 30 minutes **before** taking your first food, drink (other than plain water) or other medicine of the day, or at least two hours away from food or drink at any other time of the day and at least 30 minutes before going to bed.
- **Pregnancy and Breast-feeding:**

Safety of **ODRON 35 mg TABLETS** in pregnant and breast-feeding women has not been established.

If you are pregnant or breast-feeding your baby, please consult your doctor, pharmacist or other health care professional for advice before taking **ODRON 35 mg TABLETS** .

- **Driving and using machinery:**

Treatment with **ODRON 35 mg TABLETS** is not known to affect your ability to drive and use machines.

- **Important information about some of the ingredients of ODRON 35 mg TABLETS:**

ODRON 35 mg TABLETS contains lactose. Patients who are lactose intolerant should not take **ODRON 35 mg TABLETS.**

- **Taking other medicines with ODRON 35 mg TABLETS:**
    - **ODRON 35 mg TABLETS** has been used with aspirin and non-steroidal anti-inflammatory medicines, and may be used together with Hormone Replacement Therapy.
    - Medicines containing one of the following ingredients may reduce the effect of **ODRON 35 mg TABLETS** if taken at the same time as:
    - calcium
    - magnesium
    - aluminium *(for example some indigestion mixtures)*
    - iron.

- To avoid reducing the effect of **ODRON 35 mg TABLETS,** take these medicines at least 30 minutes after your **ODRON 35 mg TABLETS.**

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines).

4. How to take ODRON 35 mg TABLETS

Always take **ODRON 35 mg TABLETS** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. If you have the impression that the effect of **ODRON 35 mg TABLETS** is too strong or too weak, talk to your doctor or pharmacist.

- **Dosage:**

Usual adult dose:

- Take one **ODRON 35 mg TABLETS** once a week.
- Choose one day of the week that best fits your schedule. Every week, take the **ODRON 35 mg TABLETS** on your chosen day.
- Take the tablet whilst you are in an upright position (you may sit or stand).
- Do **not** lie down for 30 minutes after taking your tablet.
- Swallow it with at least one glass (120 ml) of plain water.
- Swallow it whole. Do **not** suck or chew it.
- The safe and effective use of **ODRON 35 mg TABLETS in** children and growing adolescents has not been established.

- **If you take more ODRON 35 mg TABLETS than you should:**

If you have accidentally taken more **ODRON 35 mg TABLETS than** prescribed, milk or antacids containing magnesium, calcium or aluminium can be taken, and medical attention must be sought.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

- **If you forget to take ODRON 35 mg TABLETS:**

If you have forgotten to take your tablet on your chosen day, take it on the day you remember.

Return to taking one tablet once a week on the day the tablet is normally taken.

Do **not** take two tablets in one day to make up for the tablet you missed.

5. POSSIBILE SIDE-EFFECTS

ODRON 35 mg TABLETS can have side-effects.

- Get emergency medical help if you have any of these **signs of an allergic reaction:**
  - hives, difficulty breathing, swelling of your face, lips, tongue, or throat.
- Call your doctor at once if you have any of these serious side-effects:
  - symptoms from oesophagus such as pain when you swallow, difficulties in swallowing, chest pain or new or worsening heartburn
  - black or tar-like stools, vomiting blood
  - severe joint, bone or muscle pain
  - jaw pain, numbness or swelling
  - severe skin reactions that can include blistering of the skin
  - eye inflammation, usually with pain, redness and light sensitivity.
- Tell your doctor if any of the side-effects below are severe, bothersome, do not go away or about any concerns you have while taking **ODRON 35 mg TABLETS.**
  - Urinary tract infection
  - lack of energy, headaches, dry eyes, red painful eyes with a possible change in vision, ringing in the ears
  - persistent cough, inflammation or narrowing of the throat, inflammation of the sinuses, lung infection
  - heartburn, indigestion, nausea, vomiting, belching, stomach pain, constipation, diarrhoea, inflammation of the large intestine, inflammation or ulcer of the oesophagus, inflammation of the stomach
  - feeling anxious
  - pain in your bones, muscles or joints, muscle weakness, leg cramps
  - skin rash, itching.

Not all side-effects reported for **ODRON 35 mg TABLETS** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **ODRON 35 mg TABLETS** , please consult your doctor, pharmacist or other health care professional for advice.

6. STORING AND DISPOSING OF ODRON 35 mg TABLETS

Store at or below 30 °C (room temperature). Do not remove the blister strip from the carton until required for use.

Keep all medicines out of reach of children.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF ODRON 35 mg TABLETS

Blister Pack:

Tablets are packed in clear PVC/PE/PVdC and printed aluminium foil with heat seal lacquer.

Each blister contains 4 tablets.

Pack size: **4's** – Each carton contains one blister of 4 tablets.

8. IDENTIFICATION OF ODRON 35 mg TABLETS

Light orange coloured, circular shaped, film-coated biconvex tablets debossed with 'F27' on one side and plain on the other side.

9. REGISTRATION NUMBER

45/3.2/0869

NAME AND ADDRESS OF REGISTRATION HOLDER

Aurogen South Africa (Pty) Ltd

Woodhill Office Park, Building 1,

53 Phillip Engelbrecht Avenue

Meyersdal, Ext. 12, 1448

Johannesburg

South Africa

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