Applicant: Ranbaxy Pharmaceuticals (Pty) Ltd
Product name: CLOMIDEP
Dosage form: Film-coated tablets
Strength: 25 mg clomipramine hydrochloride /tablet

APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S5

CLOMIDEP Film-coated tablets

Clomipramine hydrochloride

Contains sugar: Lactose monohydrate 68,0 mg.

Read all of this leaflet carefully before you start taking CLOMIDEP

- 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.
- CLOMIDEP 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.

What is in this leaflet

1. What CLOMIDEP is and what it is used for

CLOMIDEP is used to treat depression, including recurrent depressive disorders or major depression.

Other psychological conditions that can be treated with CLOMIDEP are:

- Obsessive compulsive disorders
- Muscular weakness (cataplexy) associated with recurrent attacks of extreme sleepiness (narcolepsy) in adults.

-In children aged above 5 years, CLOMIDEP is used to treat obsessive-compulsive disorders.

2. What you need to know before you take CLOMIDEP

Do not take CLOMIDEP:

- if you are hypersensitive (allergic) to clomipramine, any other tricyclic antidepressants, or to any of the other ingredients in CLOMIDEP
- if you are taking MAO-inhibitors (certain medicines used for depression), a washout period of 14 days is required before you start or stop taking CLOMIDEP due to the potential for severe interactions, severe hypertensive reactions (very high blood pressure), hyperpyretic crisis (extremely high fever), convulsions and fatalities.

Warnings and precautions

Take special care with CLOMIDEP:

- if you have heart disease such as congestive heart failure; blockage of the heart where the electrical signal that controls your heartbeat is partially or completely blocked; irregular or abnormal heartbeats
- if you have narrow angle glaucoma (increased pressure within the eyeball
- if you have difficulty or problems passing urine
- if you have severe liver or kidney disease
- if you are prone to getting convulsions or seizures as a result of brain damage, epilepsy or alcoholism
- if you have a tumour of the adrenal medulla (an area close to the kidneys) in whom the medicine may provoke hypotensive crisis (huge drop in blood pressure).
- if you are thinking about suicide
- if you have schizophrenia or other mental disorders
- if you have any blood disorder
- if you have an overactive thyroid gland
- if you have persisting constipation
- if you have low blood pressure
- if you are diabetic

Your doctor will take these conditions into account before and during your treatment with CLOMIDEP.

Ensure that CLOMIDEP tablets is kept out of reach of children, as relatively small overdoses may be fatal to them.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking CLOMIDEP.

Before and during treatment your doctor may perform tests to assess your medical condition such as blood tests, chest X-rays and ECG (electrocardiogram) examinations.

Families and caregivers should monitor whether the depressed child/patient shows signs of behavioural changes such as unusual anxiety, restlessness, sleeping problems, irritability or aggressiveness, worsening of depression, or any other changes in behaviour or thoughts of suicide.

You should report these symptoms to the patient's doctor especially if they are severe, abrupt in onset or were not part of the patient's presenting symptoms before.

Symptoms such as these may be associated with an increased risk of suicide and indicate a need for very close monitoring and possibly changes in the medication.

CLOMIDEP may cause dry mouth which can increase the risk of tooth decay. Regular dental checks ups is required with long-term treatment.

If you wear contact lenses and experience eye irritation, talk to your doctor.

Before you have surgery or dental treatment tell the doctor or dentist that you are taking CLOMIDEP.

Other medicines and CLOMIDEP

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

CLOMIDEP may increase the effects of alcohol, central nervous system depressants (e.g. barbiturates, benzodiazepines or general anaesthetics), anticholinergics (e.g. atropine, biperiden, levodopa), noradrenaline; adrenaline, amphetamine, nasal drops or local anaesthetics containing sympathomimetics.

CLOMIDEP may decrease the effects of certain antihypertensive medication (bethanidine, debrisoquine, guanethidine and possibly clonidine) and medicines that are highly protein bound (warfarin, digoxin). Patients requiring co-medication for hypertension should therefore be given antihypertensives of a different type.

The effect of CLOMIDEP may be decreased by barbiturates, rifampicin and some anti-epileptics. CLOMIDEP should not be taken together with these medicines.

The use of cimetidine and methylphenidate, together with CLOMIDEP may increase the levels of CLOMIDEP, the dosage of CLOMIDEP may therefore need to be reduced.

Monitoring therapeutic response of tricyclic antidepressants at high dose oestrogen regimens (50 micrograms daily) is recommended and dose adjustments may be necessary.

CLOMIDEP should not be used together with anti-dysrhythmic medicines of the quinidine type (medication for the heart). The risk of arrhythmias may increase if CLOMIDEP is taken with cisapride, halofantrine or other anti-dysrhythmics.

Taking CLOMIDEP together with diuretics may lead to hypokalaemia, which increases the risk of cardiac effects, hypokalaemia must therefore be treated before you start taking CLOMIDEP.

CLOMIDEP must not be taken together with MOA-inhibitors or within two weeks of starting or stopping MAO-inhibitors (see section '**Do not take CLOMIDEP'**).

Taking CLOMIDEP with selective serotonin re-uptake inhibitors (e.g. fluoxetine and fluvoxamine), may lead to additive effects on the serotonergic system. For fluoxetine, a washout period of two to three weeks is advised before and after treatment with fluoxetine.

CLOMIDEP with food, drink and alcohol

Alcohol should not be consumed during treatment with CLOMIDEP.

Pregnancy and breastfeeding

Safety in pregnancy has not been established. CLOMIDEP is not recommended for use in pregnant women.

CLOMIDEP should not be used if you are breastfeeding.

If you are pregnant or breastfeeding your baby, 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 taking this medicine.

Driving and using machines

It is not always possible to predict to what extent CLOMIDEP 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 CLOMIDEP affects them.

At the time of commencement of treatment with CLOMIDEP, do not drive a motor vehicle, climb dangerous heights or operate machinery for at least several days. In these situations, impaired decision making can lead to accidents.

CLOMIDEP contains lactose monohydrate

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take CLOMIDEP

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

Always take CLOMIDEP exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Adults: The usual dose is 1 tablet (25 mg) 2 to 3 times daily and gradually increased by 1 more tablet (25 mg), as tolerated, every 3 to 4 days up to a total daily dose of 6 tablets (150 mg).

Children (5 years of age and older) and adolescents:

The usual dose is 1 tablet (25 mg) daily during the first two weeks and gradually, increased over several weeks, up to a total daily dose of 3 mg/kg or 8 tablets (200 mg), whichever is smaller.

Your doctor will tell you how long your treatment with CLOMIDEP will last. Do not stop treatment early because the tablets take a while before they start to have an effect. If you have the impression that the effect of CLOMIDEP is too strong or too weak, tell your doctor or pharmacist.

If you take more CLOMIDEP than you should

You may feel drowsy, confused, experience dryness of the mouth, enlarged pupils, vomiting, cyanosis, restlessness, agitation, severe perspiration, hyperactive reflexes, muscle rigidity and convulsions.

An extremely high fever, bowel and bladder paralysis and respiratory and cardiac depression may also occur.

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 CLOMIDEP

Do not take a double dose to make up for forgotten individual doses.

If you stop taking CLOMIDEP

It is important for you to keep taking CLOMIDEP tablets until your doctor decides to stop them. If you stop taking CLOMIDEP, the depressive conditions may return. This could be dangerous.

4. Possible side effects

CLOMIDEP can have side effects.

Not all side effects reported for CLOMIDEP are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking CLOMIDEP, please consult your health care provider for advice.

If any of the following happens, stop taking CLOMIDEP and tell you doctor immediately or go to the casualty department at your nearest hospital:

- You have an allergic reaction. The signs may include: shortness of breath, wheezing, difficulty breathing, rash, itching, hives on the skin, swelling of your lips, face or throat.
- You get a headache, dizziness, feel confused or have a seizure.

These are all very serious side effects. If you have them, you may have had a serious reaction to CLOMIDEP. 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:

- acute or persistent infections which present as a severe sore throat, fever, fatigue.
- hyperpyrexia (extremely high fever)
- palpitations
- dysrhythmias
- cold sweats
- chest pain
- hypertension
- hypotension (low blood pressure) symptoms of hypotension may include light headedness, dizziness, fainting, blurred vision; fast shallow breathing, fatigue
- severe or persistent diarrhoea
- yellowing of the skin and eyes, dark urine, and tiredness which may be symptoms of liver problems
- oedema.

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- anorexia
- increased appetite
- weight gain
- speech disorders

- tremor
- feeling of pins and needles in the fingers or toes
- sudden, brief involuntary twitching or jerking of a muscle or group of muscles
- impaired memory
- Impaired concentration
- manic disorders
- aggravated depression
- restlessness
- seeing or hearing things
- feeling disorientated
- anxiety, nervousness
- nightmares
- yawning
- inability to sleep (insomnia)
- visual changes such as dilation of the pupils with blurred vision or increased eye pressure
- ringing in ears(tinnitus)
- hot flushes
- sweating
- high levels of a family of liver enzymes called transaminases
- pink or red skin rash with blotchy blisters, scaly patches, or raised spots on areas directly exposed to the sun that may burn or itch (photosensitivity)
- muscle weakness
- tension in the muscles
- changed libido, ejaculatory failure, or impotence
- enlargement of breast
- persistent or intermittent milky nipple discharge (galactorrhoea).

Less frequent side effects:

- blood disorders such as:
  - a low platelet level (thrombocytopenia) that causes bleeding into the tissues, bruising, and slow blood clotting after injury
  - increase in the number of eosinophils (eosinophilia) in the blood that causes difficulty in swallowing or food getting stuck in the oesphagus, or a persistent chest pain that does not respond to antacids.
  - purple spots on the skin (purpura).
- nausea (feeling sick), vomiting or diarrhoea
- abdominal cramps or stomach pain
- taste perversion (sour or metallic taste)
- dry mouth
- diarrhoea
- swelling and redness inside the mouth or individual painful sores that can make it uncomfortable to eat (stomatitis)
- hair loss
- urinary retention.

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, pharmacist or nurse. 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/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of CLOMIDEP.

5. How to store CLOMIDEP

- Store all medicine out of reach of children.
- Store at or below 25 °C in a cool, dry place, protected from light.
- Store in the original package.
- Keep the blister strip in the outer carton.
- Protect from moisture.

- Do not store in a bathroom.
- Do not use after the expiry date stated on the carton. The expiry date refers to the last day of that month.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What CLOMIDEP contains

The active substance is clomipramine hydrochloride 25 mg.

Preservative: Sodium methylparaben 0,028 % m/m

The other ingredients are:

Tablet core: Brilliant blue lake, colloidal anhydrous silica, lactose monohydrate, magnesium stearate, maize starch, microcrystalline cellulose, purified talc, sodium methyl paraben, sodium starch glycolate.

Film-coat: Acetone, amino methacrylic acid copolymer (Eudragit E 100), brilliant blue lake, isopropyl alcohol, Macrogol 6 000, magnesium stearate, purified talc, sodium lauryl sulphate, titanium dioxide.

What CLOMIDEP looks like and contents of the pack

A blue coloured, circular film-coated tablet having a break line on one side.

CLOMIDEP tablets are available in an aluminium-aluminium strip pack. Five such strips of 10 tablets each are packed in an outer carton.

Holder of Certificate of Registration

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