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 belongs to a group of medicines called tricyclic antidepressants. CLOMIDEP is believed to work by increasing the levels of two naturally occurring chemicals within the brain, noradrenaline and 5-hydroxytryptamine (also called serotonin).

CLOMIDEP is used to treat depression and mood disorders. Other psychological conditions that can be treated with CLOMIDEP are obsessions and 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 (listed in section 6).
- 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.
- If you are taking other medicines for depression.
- If you have recently had a heart attack or if you suffer from a serious heart disease.
- If you have heart disorders such as abnormal heart rhythm.
- If you have any serious liver disease.
- If you have low levels of potassium in your blood (hypokalaemia).
- If you have glaucoma (increased pressure in the eye).
- If you have difficulty in passing urine.
- If you have a mental health condition called mania.

Warnings and precautions

Take special care with CLOMIDEP:

- If you are thinking about suicide.

- If you are prone to getting epileptic fits, 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 have had a head injury or have suffered brain damage.
- If you are going to have electric shock therapy (ECT).
- If you have schizophrenia or other mental disorders.
- If you have a mental health condition called mania.
- 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 low levels of potassium in your blood (hypokalaemia).
- If you have severe liver or kidney disease.
- If you have any blood disorder.
- If you have an overactive thyroid gland.
- If you have persisting constipation.
- If you easily faint or have low blood pressure.
- If you are diabetic.
- If you have cancer in a gland called the adrenal gland, which produces hormones.
- If you are elderly, as the chances are greater that you could get side effects.

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.

Further safety measures

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.

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.

CLOMIDEP may cause your skin to be more sensitive to sunlight. Stay out of direct sunlight, and wear protective clothing and sunglasses.

Thoughts of suicide and worsening of your depression or anxiety disorder:

If you are depressed and/or have anxiety disorders, you can sometimes have thoughts of harming or killing yourself. These may be increased when first starting antidepressants, since these medicines all take time to work, usually about two weeks or sometimes longer.

You may be more likely to think like this:

• If you have previously had thoughts about killing or harming yourself.

• If you are a young adult. Information from clinical trials has shown an increased risk of suicidal behaviour in young adults (less than 25 years old) with mental health conditions who were treated with an antidepressant.

If you have thoughts of harming or killing yourself at any time, contact your doctor or go to a hospital straight away.

You may find it helpful to tell a relative or close friend that you are depressed or have an anxiety disorder, and ask them to read this leaflet. You might ask them to tell you if they think your depression or anxiety is getting worse, or if they are worried about changes in your behaviour.

Information for families, and caregivers

You should monitor whether your depressed child/patient shows signs of behavioural changes such as unusually anxiety, restlessness, sleeping problems, irritability, aggressiveness, over-excitedness or other unusual changes in behaviour, worsening of depression or thinking about suicide. You should report any such 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. You should evaluate the emergence of such symptoms on a day-to-day basis, especially early during antidepressant treatment and when the dose is increased or decreased, since changes may be abrupt.

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

Children and adolescents

CLOMIDEP is only indicated for the use of obsessive–compulsive syndromes in children 5 years of age and older.

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 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 together with diuretics (known as water pills) may lead to hypokalaemia, which increases the risk of cardiac effects, hypokalaemia must therefore be treated before you start taking CLOMIDEP.

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

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.

Terbinafine, used orally to treat skin, hair or nail infections due to fungus may increase the effect of CLOMIDEP.

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.

Sedatives, tranquillisers and other medicines for other mental health conditions such as schizophrenia or bipolar disorder e.g., thioridazine, lithium, clozapine, pimozide, benzodiazepines e.g., alprazolam.

Medicines, used to treat attention deficit/hyperactivity disorder (ADHD) such as methylphenidate.

The effect of CLOMIDEP may be decreased by barbiturates (such as phenobarbital, phenytoin, carbamazepine or valproate), rifampicin (used to treat TB) and some anti-epileptics. CLOMIDEP should not be taken together with these medicines.

The effect of CLOMIDEP may be decreased by nicotine (e.g., if you smoke or are using nicotine replacement therapy).

The effect of CLOMIDEP may be decreased by colestipol, cholestyramine, used to treat high cholesterol levels.

The effect of CLOMIDEP may be decreased by St. John’s wort (Hypericum perforatum), a herbal product used to treat depression and other conditions.

CLOMIDEP may increase the effects of medicines used to treat allergies, called antihistamines and medicines used to treat Parkinson's disease e.g., biperiden, entacapone or selegiline.

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.

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, eye drops or local anaesthetics containing sympathomimetics.

CLOMIDEP may cause hypertensive crisis when used with anaesthetics (used for the temporary loss of bodily sensation) and norepinephrine (noradrenaline) - used to treat low blood pressure) or decongestants used for colds and flu such as ephedrine, phenylephrine or phenylpropanolamine.

CLOMIDEP may increase the effect of medicines used to thin blood (anticoagulants).

The effect of CLOMIDEP may be increased by quinine (for cramp or malaria treatment) and antidepressants such as amitriptyline, pentamidine (a medicine used to treat pneumonia).

CLOMIDEP may cause increase bleeding with medicines known as NSAID's (e.g., aspirin).

CLOMIDEP, when used with altretamine (a medicine used to treat cancer), may decrease your blood pressure.

CLOMIDEP, when used with strong painkillers, may have the following effects: tramadol – increased risk of convulsions, nefopam, opioid medicines – increased sedation and levacetylmethadol (used to treat heroin addiction) – effects on heartbeat.

CLOMIDEP may increase the muscle relaxant effects of baclofen (medicine used in the treatment of multiple sclerosis and spinal damage).

CLOMIDEP with food, drink and alcohol

Take care when eating grapefruit, or drinking grapefruit juice or cranberry juice as this may increase your chance of experiencing side effects.

Alcohol should not be consumed during treatment with CLOMIDEP.

Pregnancy and 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.

Pregnancy

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

Breastfeeding

CLOMIDEP should not be used if you are breastfeeding as the active ingredient of CLOMIDEP passes into the breast milk.

Fertility

CLOMIDEP has no significant effects on fertility.

Driving and using machines

CLOMIDEP may affect your ability to drive or use machines. You should not drive during the first few days of starting treatment with CLOMIDEP, until you know how it affects you, as it may affect your ability to make decisions whilst driving, which could cause an accident.

CLOMIDEP may make some people drowsy or less alert, or it may cause blurred vision. Other side effects, such as attention difficulty, feeling confused, feeling disorientated and feeling more depressed have been reported. If you experience these side effects, you should not drive, use machinery, or perform other tasks that need full attention. Drinking alcohol may increase drowsiness.

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.

CLOMIDEP contains lactose

If you have been told by your doctor that you have an intolerance to some sugars (e.g., lactose) , 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.

If you have low blood potassium levels (hypokalaemia), your doctor will treat this before you can start treatment with CLOMIDEP.

Your doctor will decide on the most suitable dosage for your particular case.

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.

CLOMIDEP and older people

Elderly patients generally need lower doses than young and middle-aged patients. Side effects are more likely to occur in older patients. Your doctor will provide any special information about careful dosage and close observation needed.

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:

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.
- A lower than normal level of sodium in the blood, which may make you feel weak and confused with sudden contraction of the muscles, muscle spasms. This may be due to inappropriate ADH secretion, a hormone that causes the body to retain water and dilute the blood, reducing the amount of sodium.
- Irregular heartbeat (racing, pounding), and fainting (especially if you have low potassium levels in your blood).
- Yellowing of the skin and eyes, dark urine, and tiredness which may be symptoms of liver problems.
- Serotonin syndrome (caused by an increase in naturally occurring messenger, serotonin, in the brain; symptoms include agitation, confusion, diarrhoea, high temperature, increased blood pressure, excessive sweating and rapid heartbeat).
- Fits.
- A nervous system disorder characterized by muscle stiffness, high fever and impaired consciousness. These may be the symptoms of a serious condition known as neuroleptic malignant syndrome.
- Thoughts of suicide or self-harm.
- Seeing or hearing things that are not really there.

- Breakdown of muscle, causing muscle pain, weakness or tenderness accompanied by dark urine (rhabdomyolysis).
- Frequent infection with fever and sore throat (due to decreased number of white blood cells).
- Increase pressure in the eye.
- Difficulty in passing urine.

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:

- Loss of appetite.
- Muscle weakness or stiffness.
- Difficulty in speaking.
- Confusion, delirium.
- Inability to coordinate movement.
- Hyperpyrexia (extremely high fever).
- Palpitations (heart beating faster than normal), Dysrhythmias (heart beating faster or slower than normal).
- Cold sweats.
- Chest pain.
- Hypertension (high blood pressure).
- Hypotension (low blood pressure) symptoms of hypotension may include light headedness, dizziness, fainting, blurred vision; fast shallow breathing, fatigue
- Severe or persistent diarrhoea.
- Oedema (swelling in the feet, ankles, legs or hands, usually due to fluid build-up).

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.
- Drowsiness.
- Tiredness.
- Dizziness.
- Increase in appetite.
- Dry mouth.
- Constipation.
- Problem with your eye sight including blurred vision.
- Trembling.
- Headache.
- Nausea.
- Sweating.
- Changes to the amount of urine you produce or frequency of urination.
- Weight gain.
- Changes in the amount of sugar in the blood.
- Disorientation.
- Agitation.
- Palpitations.
- Minor changes to your electrocardiogram (ECG – a test, which shows how your heart conducts electricity) may show up if your heart is tested.
- Disturbance in attention.
- Sleep disturbances.
- Over-excitedness.
- Aggressiveness.

- Poor memory.
- 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).
- Fall in blood pressure associated with dizziness after abrupt standing or sitting up.
- Vomiting, abdominal disorders, diarrhoea.
- Hot flushes.
- 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).
- Skin sensitivity to sunlight.
- Worsening depression.
- Women may not be able to orgasm.
- Unpleasant taste.
- Feeling detached from a situation (like watching it from afar).
- Changes in liver function tests.

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).
- Vomiting or diarrhoea.
- Swelling of the lungs which can cause flu-like effects such as coughing, chest tightness, chills, wheezing and difficulty breathing.
- Abnormal reading of the electrical activity of the brain (as seen in an electroencephalogram).
- Changes in how you think and feel.
- Vaginal bleeding.
- Oedema (swollen ankles and/or hands and/or swelling of any other part of the body).
- Patients aged 50 years or older and taking a medicine of this group are more likely to experience bone fractures.
- Abdominal cramps or stomach pain.
- Taste perversion (sour or metallic taste).

- Dry mouth.
- Swelling and redness inside the mouth or individual painful sores that can make it uncomfortable to eat (stomatitis).
- Hair loss.
- Urinary retention.

The frequency of the following side effects are unknown:

- Repetitive, uncontrollable movements.
- Inability to ejaculate or a delay in ejaculation.
- Increase in prolactin (a hormone) level in the blood.

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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform {who-umc.org) found on SAHPRA website.
Suspected adverse reactions can also be reported directly to the Holder of registration via email: pharmacovigilance.africasme@sunpharma.com or Tel: +27(0) 126432000. 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 E100), brilliant blue lake, isopropyl alcohol, Macrogol 6000, 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.

Aluminium-aluminium strip pack

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

AL/PVC cold form blister pack

CLOMIDEP tablets are available in AL/PVC cold form blister pack. Five of such blisters of 10 tablets each are packed in an outer carton.

Not all pack types may be marketed simultaneously

Holder of Certificate of Registration

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Access to the corresponding PIL translation:

The PIL is available in one other language (Afrikaans), a copy is accessible

on the company website: https://sunpharma.com/south-africa-products/