CLEAN PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S5

CILATE 20 mg film-coated tablets

Citalopram

CILATE contains sugar: lactose monohydrate (45,72 mg per tablet).

Read all of this leaflet carefully before you start taking CILATE.

- 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.
- CILATE 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 CILATE is and what it is used for
2. What you need to know before you take CILATE
3. How to take CILATE
4. Possible side effects
5. How to store CILATE
6. Contents of the pack and other information

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1. What CILATE is and what it is used for

CILATE is a Selective Serotonin Reuptake Inhibitor (SSRI) and belongs to a group of medicines known as antidepressants. These medicines help to correct certain chemical imbalances in the brain that are causing the symptoms of your illness.

CILATE contains citalopram and is used for the treatment of depression and, when you feel better, to help prevent these symptoms recurring. CILATE is also used for long-term treatment to prevent the occurrence of new episodes of depression if you have recurrent depression.
Your doctor may also prescribe CILATE to treat panic attacks and obsessive-compulsive disorder (OCD).

2. What you need to know before you take CILATE

Do not take CILATE

- if you are allergic to citalopram or to any of the other ingredients of this medicine (listed in section 6). Consult your doctor if you think you might be.
- If you are under 18 years of age as the safety and efficacy of use has not been established.
- at the same time as taking medication known as monoamine oxidase inhibitors (MAOIs). MAOIs include medicines such as selegiline (used in the treatment of Parkinson's disease) and linezolid (an antibiotic). Even if you have finished taking one of the following MAOI you will need to wait 14 days before you start taking your CILATE tablets.
  After stopping CILATE you must allow 7 days before taking any MAOI.
- if you are taking pimozide an antipsychotic drug.

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- if you are born with or have had an episode of abnormal heart rhythm (seen at ECG; an examination to evaluate how the heart is functioning).
- if you take medicines for heart rhythm problems or that may affect the heart's rhythm (see **Other medicines and CILATE** below).
- If your kidney function is severely impaired.

Warnings and precautions

Take special care with CILATE

Please tell your doctor if you have any medical problems, especially if you have

- Liver disease.
- Kidney disease.
- Diabetes (you may need an adjustment of your antidiabetic therapy).
- Epilepsy or a history of seizures or fits.
- A bleeding disorder or have ever suffered from bleeding in the stomach or intestine. Talk to your doctor before taking **CILATE** if you have a history of bleeding disorders.
- If you are pregnant (see "**Pregnancy, breastfeeding and fertility**").
- Mania or panic disorder.
- Low blood levels of sodium.
- ECT (electroconvulsive therapy).
- Problems with your eyes, such as certain kinds of glaucoma.
- Suffered or suffer from heart problems or have recently had a heart attack.
- A low resting heart-rate and/or you know that you may have salt depletion as a result of prolonged severe diarrhoea and vomiting (being sick) or usage of diuretics (water tablets).
- Experienced a fast or irregular heartbeat, fainting, collapse or dizziness on standing up which may indicate abnormal functioning of the heart rate.

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Please consult your doctor, even if these statements were applicable to you at any time in the past.

Please note:

Some patients with manic-depressive illness may enter into a manic phase. This is characterized by unusual and rapidly changing ideas, inappropriate happiness and excessive physical activity. If you experience this, contact your doctor.

Symptoms such as restlessness or difficulty in sitting or standing still can also occur during the first weeks of the treatment. Tell your doctor immediately if you experience these symptoms.

Special information relating to depression or related diseases

As with other medicines used to treat depression or related diseases, the improvement is not achieved immediately. After the start of CILATE treatment it may take several weeks before you experience any improvement. In the beginning of the treatment certain patients may experience increased anxiety, which will disappear during continued treatment. Therefore, it is very important that you follow exactly your doctor's orders and do not stop the treatment or change the dose without consulting your doctor.

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 but 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 studies has shown an increased risk of suicidal behaviour in adults aged less than 25 years with psychiatric conditions who were treated with an antidepressant.

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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.

Use in children and adolescents under 18 years of age

CILATE should normally not be used for children and adolescents under 18 years.
Patients under 18 have an increased risk of side effects such as suicide attempt, suicidal thoughts and hostility (predominantly aggression, oppositional behaviour and anger) when they take this class of medicines. Despite this, your doctor may prescribe CILATE for patients under 18 because he/she decides that this is in their best interests.
If your doctor has prescribed CILATE for a patient under 18 and you want to discuss this, please go back to your doctor.
You should inform your doctor if any of the symptoms listed above develop or worsen when patients under 18 are taking CILATE. Also, the long-term safety effects concerning growth, maturation and cognitive and behavioural development of CILATE in this age group have not yet been demonstrated.

Use in elderly patients

CILATE should be used with caution in elderly patients.

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Other medicines and CILATE

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of CILATE with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional, for advice, especially if you are taking any of the following medicines:

- The herbal remedy St John's wort (*Hypericum perforatum*), should not be taken at the same time as CILATE.
- Monoamine oxidase inhibitors (MAOIs). These should not be taken at the same time as CILATE (see below **Do not take CILATE**).

Tell your doctor if you are taking any of the following medicines:

- Linezolid (an antibiotic).
- Sumatriptan (used to treat migraine) or tramadol (a pain killer). If you feel unwell when using these medicines with CILATE you should see your doctor.
- Lithium (used to prevent and treat mania) and tryptophan (an antidepressant).
- Pimozide (a neuroleptic). This should not be taken at the same time as CILATE.
- Imipramine and desipramine (used to treat depression).
- Medicines containing selegiline (used to treat Parkinson's disease).
- Cimetidine (used to treat stomach ulcers).
- Mefloquine (used to treat malaria).
- Bupropion (used to treat depression).
- Medicines known to affect the blood platelets (e.g., anticoagulant medicines used to treat or prevent blood clots; aspirin and non-steroidal anti-inflammatory medicines (NSAIDs) such as ibuprofen and diclofenac used as painkillers and some antipsychotic medicines and tricyclic antidepressants).

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- Metoprolol, a beta blocker used to treat migraine, some heart conditions and high blood pressure. The effects of either medicine could be increased, decreased or altered.
- Neuroleptics (used in the treatment of schizophrenia).

Do not take CILATE

- if you take medicines for heart rhythm problems or medicines that may affect the heart's rhythm, e.g., such as Class IA and III antiarrhythmics, antipsychotics (e.g., phenothiazine derivatives, pimozide, haloperidol), tricyclic antidepressants, certain antimicrobial agents (e.g., sparfloxacin, moxifloxacin, erythromycin IV, pentamidine, anti-malarial treatment particularly halofantrine), certain antihistamines (astemizole, mizolastine).
- If you have any further questions about this you should speak to your doctor.

CILATE with food, drink and alcohol

CILATE can be taken with or without food (see section 3: **How to take CILATE**).

As with all antidepressants, it is sensible to avoid drinking alcohol whilst receiving treatment although CILATE has not been shown to increase the effects of alcohol.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, 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.

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Pregnancy

Ask your doctor or pharmacist for advice before taking any medicine. If you are pregnant, think you might be pregnant, or are trying to become pregnant, tell your doctor. Do not take CILATE if you are pregnant unless you and your doctor have discussed the risks and benefits involved. Make sure your midwife and/or doctor know you are on CILATE.

If you take CILATE near the end of your pregnancy there may be an increased risk of heavy vaginal bleeding shortly after birth, especially if you have a history of bleeding disorders. Your doctor or midwife should be aware that you are taking CILATE so that they can advise you.

When taken during pregnancy, particularly in the last 3 months of pregnancy, medicines like CILATE may increase the risk of a serious condition in babies, called persistent pulmonary hypertension of the newborn (PPHN), making the baby breathe faster and appear bluish. These symptoms usually begin during the first 24 hours after the baby is born. If this happens to your baby you should contact your midwife and/or doctor immediately.

If you take CILATE during the last 3 months of your pregnancy and until the date of birth, you should be aware that the following effects may be seen in your newborn: fits, being too hot or cold, feeding difficulties, vomiting, low blood sugar, stiff or floppy muscles, overactive reflexes, tremor, jitteriness, irritability, lethargy, constant crying, sleepiness or sleeping difficulties. If your newborn baby gets any of these symptoms please contact your midwife and/or doctor immediately.

Breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine. If you are breastfeeding, ask your doctor for advice. You should not breastfeed your baby when taking CILATE because small amounts of the medicine can pass into the breast milk.

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Fertility

Impact on human fertility has not been observed as yet.

Driving and using machines

CILATE does not usually affect the ability to carry out normal daily activities. However, if you feel dizzy or sleepy when you start to take this medicine, you should be careful when driving, operating machinery or performing jobs that need you to be alert until these effects wear off.

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

CILATE contains sugar (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 CILATE

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

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

Adults

Depression

The usual dose is 20 mg per day. This may be increased by your doctor to a maximum of 40 mg per day.

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Panic disorder

The starting dose is 10 mg per day for the first week before increasing the dose to 20 mg per day. The dose may be increased by your doctor to a maximum of 40 mg per day.

Obsessive-Compulsive Disorder

The usual dose is 20 mg per day. This may be increased by your doctor to a maximum of 40 mg per day.

Elderly patients (above 65 years of age)

The starting dose should be decreased to half of the recommended dose, e.g., 10 - 20 mg per day. Elderly patients should not usually receive more than 20 mg per day.

Children and adolescents (less than 18 years of age)

CILATE should not be given to children or adolescents (see section 2: **What you need to know before you take CILATE**).

Patients with special risks

Patients with liver complaints should not receive more than 20 mg per day.

How and when to take CILATE

CILATE is taken every day as a single daily dose. CILATE can be taken any time of the day with or without food. Swallow the tablets with a drink of water. Do not chew them.

Duration of treatment

Like other medicines for depression and panic disorder these tablets may take a few weeks before you feel any improvement. Continue to take CILATE even if it takes some time before you feel any improvement in your condition. The duration of treatment is individual, usually at least 6 months. Continue to take the tablets for as long as your doctor recommends. Do not stop taking them even if you begin to feel better, unless you are told to do so by your doctor. The underlying illness may persist for a long time and if you stop your treatment too soon your symptoms may return.

Patients who have recurrent depression benefit from continued treatment, sometimes for several years, to prevent the occurrence of new depressive episodes.

Never change the dose of the medicine without talking to your doctor first.

If you take more CILATE than you should

If you think that you or anyone else may have taken too many CILATE tablets contact your doctor or nearest hospital emergency department or poison centre immediately. Do this even if there are no signs of discomfort or poisoning. Take the CILATE box/container with you if you go to a doctor or hospital. Some of the signs of an overdosage could be life-threatening.

Symptoms of overdosage may include:

- Irregular heart beat
- Seizures
- Changes in heart rhythm
- Feeling sick (nausea)
- Vomiting
- Sweating

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- Drowsiness
- Unconsciousness
- Fast heart beats
- Tremor
- Changes in blood pressure
- Serotonin syndrome (see section 4)
- Agitation
- Dizziness
- Enlarged eye pupils
- Bluish skin
- Breathing too quickly

If you forget to take CILATE

If you have missed a dose by only a few hours, take the missed dose as soon as you remember. If it is almost time for your next dose, skip the missed dose and take CILATE at the next regularly scheduled time. Do not take a double dose to make up for the forgotten individual doses.

If you stop taking CILATE

Stopping this medicine quickly may cause symptoms such as dizziness, nausea and numbness or tingling in hands or feet, sleep disturbances (vivid dreams, nightmares, inability to sleep), feeling anxious, headaches, feeling or being sick, sweating, feeling restless or agitated, tremor, feeling confused or disorientated, feeling emotional or irritable, diarrhoea (loose stools), visual disturbances, fluttering or pounding heartbeat (palpitations). These are usually non-serious and disappear within a few days. When you have completed your course of treatment, the dose of CILATE is usually reduced gradually over a couple of weeks.

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If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

CILATE can have side effects.

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

Several of the effects listed below can also be symptoms of your illness and may disappear as you start to get better.

Serious side effects

Stop taking CILATE and seek medical advice immediately if you have any of the following symptoms:

- Difficulty in breathing.
- Swelling of the face, lips, tongue or throat that causes difficulty in swallowing or breathing.
- Severe itching of the skin (with raised lumps).
- Fast, irregular heartbeat, fainting which could be symptoms of a life-threatening condition known as torsades de pointes.

If you notice any of the following symptoms you should contact your doctor immediately as your dose may need to be reduced or stopped:

- You start having fits for the first time or fits that you have suffered from in the past become more frequent.

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- Your behaviour changes because you feel elated or over excited.
- You experience high fever, agitation, confusion, trembling or abrupt contractions of muscles. These may be signs of a rare condition called serotonin syndrome.
- Tiredness, confusion and twitching of your muscles. These may be signs of a low blood level of sodium (hyponatraemia).

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

Other side-effects

The following side-effects have been reported frequently:

Sleepiness

Difficulty in sleeping

Headache

Changes in your sleeping pattern

Loss of body strength, weakness

Increased sweating

Dry mouth (a dry mouth increases the risk of tooth decay, so be sure to clean your teeth more often than usual)

Feeling sick (nausea)

Lack of appetite

Agitation

Decreased sex drive

Anxiety

Nervousness

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Confusion

Abnormal dreams

Reduced emotions, indifference (apathy)

Tremor

Tingling or numbness in the hands or feet

Dizziness

Problems concentrating

Migraine

Loss of memory (amnesia)

Ringing in the ears (tinnitus)

Palpitations

Yawning

Blocked or runny nose (rhinitis)

Diarrhoea

Vomiting

Constipation

Stomach pain

Flatulence (wind)

Increase in saliva (drooling)

Itching

Pain in muscles and joints

For men, problems with ejaculation and erection

For women, failing to reach an orgasm

Tiredness

Prickling of the skin

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Loss of weight

The following side-effects have been reported less frequently:

Bruising easily

Increased appetite

Aggression

Hallucinations

Mania

Fainting

Large pupils (the dark centre of the eye)

Fast heart beat

Slow heart beat

Nettle rash

Loss of hair

Rash

Sensitivity to sunlight

Difficulties urinating

Excessive menstrual bleeding

Swelling of the arms or legs

Increased weight

Increased sex drive

Convulsions

Involuntary movements

Taste disturbances

Bleeding

Coughing

Signature:

Hepatitis

Feeling unwell (malaise)

The following side-effects have been reported of an unknown frequency:

- Thoughts of harming or killing themselves, (see section 2: **What you need to know before you take CILATE**)
- An increase in bleeding or bruising caused by a decrease in blood platelets (thrombocytopenia)
- Heavy vaginal bleeding shortly after birth (postpartum haemorrhage), see "**Pregnancy, breastfeeding and fertility**" for more information.
- Rash (hypersensitivity)
- Low potassium levels in the blood (hypokalaemia), which can cause muscle weakness, twitching or abnormal heart rhythms
- Panic attack
- Grinding teeth
- Restlessness
- Unusual muscle movements or stiffness
- Involuntary movements of the muscles (akathisia)
- Low blood pressure
- Nosebleed
- Bleeding disorders including skin and mucosal bleeding (ecchymosis)
- Sudden swelling of skin or mucosa
- In men, painful erections
- Flow of breast milk in men or in women who are not breast-feeding (galactorrhoea)
- Irregular menstrual periods

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- Abnormal liver function tests
- An increased risk of bone fractures has been observed in patients taking this type of medicines
- Abnormal heart rhythm

SSRIs can (less frequently) increase the risk of bleeding, including stomach or intestinal bleeding. Let your doctor know if you vomit blood or develop black or blood-stained stools.

If you continue to have other symptoms associated with your depression let your doctor know. This might include hallucinations, anxiety, mania or confusion.

Any side effects that do occur will usually disappear after a few days. If they are troublesome or persistent, or if you develop any other unusual side effects while taking CILATE, please tell your doctor.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found on-line under SAHPRAs publications: https://www.sahpra.org.za/Publications/Index/8. Side effects must also be reported to Unicorn Pharmaceuticals (Pty) Ltd to enquiries@unicornpharma.co.za.

By reporting side effects, you can help provide more information on the safety of CILATE.

5. How to store CILATE

Store all medicines out of reach of children.

Store your tablets at or below 25 °C, protected from moisture.

Signature:

Do not use this medicine after the expiry date which is stated on the label or 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 CILATE contains

Each CILATE tablet contains 20 mg citalopram (active ingredient).

CILATE contains sugar (lactose monohydrate).

The other ingredients are copovidone, croscarmellose sodium, magnesium stearate, maize starch, microcrystalline cellulose, and film coating ingredient Opadry white (which contains hypromellose, macrogol 400 and titanium dioxide).

What CILATE looks like and contents of the packs

A white, biconvex, capsule shaped, film-coated tablet, debossed with '**A**' on one side and with a score line in between '**0**' and '**6**' on the other side.

Tablets are packaged in strips comprising clear transparent PVC film coated uniformly with PVC on the inner side with a backing of aluminium foil (coated with heat seal lacquer).

Blister pack is of 28's or 30's.

Holder of Certificate of Registration

Unicorn Pharmaceuticals (Pty) Ltd.

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Signature:

Cape Town,

South Africa, 8001

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