1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S5

CILIFT 20 mg TABLET

Citalopram hydrobromide

Contains sugar: Lactose monohydrate 75 mg

Read all of this leaflet carefully before you start taking CILIFT 20 mg TABLET

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- CILIFT 20 mg TABLET 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 CILIFT 20 mg TABLET is and what it is used for
2. What you need to know before you take CILIFT 20 mg TABLET
3. How to take CILIFT 20 mg TABLET
4. Possible side effects
5. How to store CILIFT 20 mg TABLET
6. Contents of the pack and other information

1. What CILIFT 20 mg TABLET is and what it is used for

CILIFT 20 mg TABLET belongs to a group of antidepressants called Selective Serotonin Reuptake Inhibitors (SSRIs). These medicines act on the serotonin-system in the brain by increasing the serotonin level. Disturbances in the serotonin-system are considered an important factor in the development of depression and related diseases.

CILIFT 20 mg TABLET is used for the:

- Treatment of depression and prevention of the return of the depression.
- Treatment of panic disorder with or without fear of public places or open spaces (agoraphobia).
- Treatment of obsessive compulsive disorder (OCD).

2. What you need to know before you take CILIFT 20 mg TABLET

Do not take CILIFT 20 mg TABLET:

- if you are hypersensitive (allergic) to citalopram or any of the other ingredients of CILIFT 20 mg TABLET (listed in section 6).
- if you are suffering from severe kidney impairment.
- if you are younger than 18 years.
- if you are receiving monoamine oxidase inhibitors (MAOIs), a class of antidepressant medicine prescribed for the treatment of depression, or for at least 14 days after stopping their use. MAOIs should not be introduced for 7 days after stopping CILIFT 20 mg TABLET.
- if you are born with or have had an episode of abnormal heart rhythm (seen on an ECG; an examination to evaluate how the heart is functioning) (QT prolongation).
- if you are taking medicines for heart rhythm problems or that may affect the heart's rhythm, as an additive effect of CILIFT 20 mg TABLET and these medicines cannot be excluded. These medicines include, but are not limited to, medicines that treat:

- Irregular heartbeat (referred to as CLASS IA and III antidysrhythmics) e.g. amiodarone and quinidine.
- Psychoses e.g. phenothiazine derivatives, pimozide, haloperidol.
- Depression referred to as tricyclic antidepressants (e.g. imipramine, desipramine) or moclobemide.
- Parkinson´s disease e.g. selegiline.
- Certain antibiotics e.g. moxifloxacin, erythromycin IV (intravenous), pentamidine.
- Malaria particularly halofantrine.
- Allergies e.g. mizolastine.
- HIV e.g. ritonavir, saquinavir, lopinavir.

- if you are taking a medicine containing linezolid (an antibiotic).

Warnings and precautions

Take special care with CILIFT 20 mg TABLET:

- if you suffer from reduced liver or kidney function. Your doctor may need to adjust your dosage.
- if you need to undergo electro-convulsive treatment, as there is limited experience with the combination.
- if you enter a manic state (feeling excessively cheerful and euphoric) you should stop taking CILIFT 20 mg TABLET immediately.
- if you have just started taking CILIFT 20 mg TABLET, you should be closely monitored during early therapy until improvement in depression is observed because suicide is an inherent risk in depressed patients.
- 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**, as there can be an increased risk of suicidal behaviour in adults aged younger than 25 years with psychiatric conditions who are 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 can 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.
- if you notice any changes in your heart rhythm as CILIFT 20 mg TABLET can cause dose dependent changes in the heart rhythm. This was found predominantly in female patients, patients with low blood potassium levels and pre-existing abnormalities in heart rhythm or cardiac diseases.
- if you suffer or have suffered from heart problems or have recently had a heart attack. Caution is advised in patients with slow heartbeat, recent heart attack or uncompensated heart failure (a condition in which the heart can no longer pump enough blood to the rest of the body).
- if you have 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).
- if you have electrolyte disturbances such as hypokalaemia (low blood potassium) and hypomagnesaemia (low blood magnesium), as they increase the risk for malignant dysrhythmias (irregular heartbeats) and should be corrected before treatment with CILIFT 20 mg TABLET is started.

- if you have stable cardiac disease and are being treated, an ECG (an examination to evaluate how the heart is functioning) review should be considered before treatment is started.
- if you have signs of irregular heartbeat (e.g. skipped or accelerated heartbeats, ringing in the ears, fainting, convulsions, collapse or dizziness on standing up) which may occur during treatment with CILIFT 20 mg TABLET, the treatment should be withdrawn and an ECG should be performed.
- if you have epilepsy as CILIFT 20 mg TABLET should be used with caution if you suffer from epilepsy or a history of such disorders (and should be avoided if your epilepsy is poorly controlled). Treatment with CILIFT 20 mg TABLET should be stopped if seizures (fits) occur or if there is an increase in the seizure frequency.
- if you have diabetes. Treatment with CILIFT 20 mg TABLET may alter glycaemic control therefore you may need an adjustment of your anti-diabetic medicine.
- if you have high fever, agitation, confusion, trembling and abrupt contractions of muscles as this may be signs of a rare condition called serotonin syndrome. Serotonin syndrome is more likely to occur after an increase in dose.
- if therapy with CILIFT 20 mg TABLET is to be discontinued, it is recommended that the dose is decreased gradually in order to prevent the possibility of a withdrawal syndrome.
- if you have a bleeding disorder, a history of bleeding disorders (e.g von Willebrand disease, haemophilia A, deficiency in F VIII, and haemophilia B), comorbid bleeding disorders (e.g multiple pregnancy, gestational hypertension or preeclampsia) or if you are pregnant (see Pregnancy, breastfeeding and fertility).
- if you have ever suffered from bleeding of the stomach or intestines or if you develop bruises.
- if you have problems with your eyes, like certain kinds of glaucoma (increased pressure in the eye).

- if you are an elderly patient.
- if you experience intensified anxiety symptoms at the start of treatment with CILIFT 20 mg TABLET. This paradoxical reaction usually subsides within the first two weeks of starting treatment.
- if you have a decreased level of sodium in the blood. Low levels of sodium in the blood have been reported, especially in elderly females.
- if you are being treated for psychosis (it refers to an abnormal condition of the mind, and is a generic psychiatric term for a mental state often described as involving a “loss of contact with reality”).
- if you experience symptoms such as restlessness or difficulty in sitting or standing still as these symptoms can also occur during the first weeks of treatment.
- if you have symptoms of sexual dysfunction as CILIFT 20 mg TABLET may cause symptoms of sexual dysfunction. In some cases, these symptoms have continued after stopping treatment.
- if you experience complex movements or behaviours during sleep, including abnormal dreaming, nightmares and sleepwalking.

Children and adolescents

CILIFT 20 mg TABLET should not be used for children and adolescents under 18 years. Children and adolescents under 18 years, have an increased risk of side effects such as suicide attempts, suicidal thoughts and hostility (predominately aggression, oppositional behaviour and anger) when they take this class of medicines.

Other medicines and CILIFT 20 mg TABLET

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

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

- Non-selective monoamine oxidase inhibitors (MAOIs), containing phenelzine, iproniazid, isocarboxazid, nialamide, and tranylcypromine as an active medicine. If you have taken any of these medicines you will need to wait 14 days before you start taking CILIFT 20 mg TABLET. After stopping CILIFT 20 mg TABLET you must allow 7 days before taking any of these medicines.
- Reversible, selective MAO-A inhibitors, containing moclobemide (used to treat depression).
- Irreversible MAO-B inhibitors, containing selegiline (used to treat Parkinson's disease); these increase the risk of side effects. The dose of selegiline must not exceed 10 mg per day.
- Buspirone (used to treat anxiety disorders).
- Linezolid (an antibiotic).
- Sumatriptan and similar medicines (used to treat migraine) and tramadol (used against severe pain).
- Lithium (used in the treatment of manic-depressive disorder) and tryptophan.
- Buprenorphine (used to treat opioid use disorder, acute pain, and chronic pain).
- St. John’s Wort (*Hypericum perforatum*), a herbal remedy used for depression. Concomitant intake with CILIFT 20 mg TABLET may increase the risk of side effects.
- Warfarin, dipyridamol (medicines used to thin the blood, so called anti-coagulants). Your doctor will check the coagulation time of your blood when starting and discontinuing CILIFT 20 mg TABLET in order to verify that your dose of anti-coagulant is still adequate.
- Medicines known to affect the platelet function (e.g. dipyridamole, ticlopidine), some antipsychotic medicines, aspirin (used as pain relievers), non-steroidal anti-inflammatory medicines (used for arthritis); slightly increased risk of bleeding abnormalities.
- Medicines that can produce low potassium or magnesium in your blood.
- Desimipramine, imipramine (anti-depressant medicines).

- Cimetidine, omeprazole, lansoprazole (used to treat stomach ulcers).
- Metoprolol, flecainide and propafenone (medicines used in the treatment of heart conditions); the blood levels of metoprolol are increased.
- Neuroleptics (used to treat schizophrenia, psychosis; e.g phenothiazines, thioxanthenes and butyrophenones), mefloquine (used to treat malaria), bupropion (used to treat depression) due to a possible risk of a lowered threshold for seizures (fits).
- Class IA and III antidysrhytmics (medicines taken for irregular heartbeats e.g. amiodarone and quinidine), 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).
- Ritonavir, saquinavir, lopinavir (used to treat HIV).
- Fluconazole (used to treat fungal infections).
- Certain other medicines used in depression or similar conditions e.g. fluvoxamine.

CILIFT 20 mg TABLET with food, drink and alcohol

CILIFT 20 mg TABLET may be taken with or without food.

CILIFT 20 mg TABLET has been shown not to increase the effects of alcohol. Nevertheless, it is recommended not to drink alcohol during treatment with CILIFT 20 mg TABLET.

Pregnancy, breastfeeding and fertility

You should not take CILIFT 20 mg TABLET if you are pregnant or breastfeeding your baby.

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 healthcare provider for advice before taking this medicine.

If you take CILIFT 20 mg TABLET 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: trouble with breathing, bluish skin, fits, body temperature changes, feeding difficulties, vomiting, low blood sugar, stiff or floppy muscles, vivid reflexes, tremor, jitteriness, irritability, lethargy, constant crying, sleepiness and sleeping difficulties. If your newborn baby has any of these symptoms, please contact your doctor immediately.

Make sure your midwife and/or doctor know you are on CILIFT 20 mg TABLET. When taken during pregnancy, particularly in the last 3 months of pregnancy, CILIFT 20 mg TABLET 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 CILIFT 20 mg TABLET 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 CILIFT 20 mg TABLET so they can advise you.

The impact of CILIFT 20 mg TABLET on human fertility has not been observed as yet.

Driving and using machinery

CILIFT 20 mg TABLET may cause you to become drowsy, to have trouble thinking, or to have problems with movement.

It is not always possible to predict to what extent CILIFT 20 mg TABLET may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which CILIFT 20 mg TABLET affects you (see section 4).

CILIFT 20 mg TABLET contains lactose

CILIFT 20 mg TABLET contains lactose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

Patients with the rare hereditary conditions of lactose/fructose or galactose intolerance should not take CILIFT 20 mg TABLET.

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

3. How to take CILIFT 20 mg TABLET

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

Always take CILIFT 20 mg TABLET exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose depends on the condition it is used for and your age.

Dosages range from 10 mg (half a tablet) daily to 40 mg (two tablets) daily, as instructed by your doctor.

Adults

Treating depression

The usual dose is 20 mg (1 tablet) per day. The dose may be increased by your doctor to a maximum of 40 mg (2 tablets) per day.

Treating panic disorder

The starting dose is 10 mg (half a tablet) per day for the first week before increasing the dose to 20 mg (1 tablet) per day. The dose may be increased by your doctor to a maximum of 40 mg (2 tablets) per day.

Treating obsessive-compulsive disorder (OCD)

The starting dose is 20 mg (1 tablet) per day. The dose may be increased by your doctor to a maximum of 40 mg (2 tablets) per day.

Elderly patients (above 65 years of age)

The starting dose should be decreased to half of the recommended dose, e.g. 10 mg to 20 mg per day. Elderly patients should not receive more than 20 mg (1 tablet) per day.

Patients with special risks

For patients with liver complaints, the starting dose should be 10 mg daily for the first two weeks of treatment. The dose may be increased by your doctor to a maximum of 20 mg (1 tablet) per day.

Children and adolescents (< 18 years)

CILIFT 20 mg TABLET should not be given to children or adolescents under the age of 18 years.

How and when to take CILIFT 20 mg TABLET

CILIFT 20 mg TABLET is taken as a single daily dose.

CILIFT 20 mg TABLET can be taken with or without food, in the morning or in the evening.

Duration of treatment

For depression, panic disorder and OCD these tablets may take a few weeks before you feel any improvement. Continue to take CILIFT 20 mg TABLET even if it takes some time before you feel any improvement in your condition.

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

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 depressions benefit from continued treatment, sometimes for several years, to prevent the occurrence of new depressive episodes.

Your doctor will tell you how long your treatment with CILIFT 20 mg TABLET will last.
If you have the impression that the effect of CILIFT 20 mg TABLET is too strong or too weak, tell your doctor or pharmacist.
Do not take more than, or more often than prescribed.

If you take more CILIFT 20 mg TABLET than you should

Some of the signs of an overdose could be life-threatening; irregular heartbeat, convulsion, change in heart rhythm, drowsiness, coma, vomiting, tremor, decreased or increased blood pressure, Serotonin syndrome (see Side effects), agitation, dilated pupils of the eye, sweating, blue-ish skin, hyperventilation, tiredness, weakness, sedation, dizziness, tremor, nausea and somnolence.
In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.
Do this even if there are no signs of discomfort or poisoning.

If you forget to take CILIFT 20 mg TABLET

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

If you have missed a dose of CILIFT 20 mg TABLET, take the dose that you have missed as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose. If you have forgotten to take several doses, contact your doctor without delay.

If you stop taking CILIFT 20 mg TABLET

Do not stop CILIFT 20 mg TABLET suddenly. Dosage should be reduced gradually and then stopped to reduce the risk of withdrawal symptoms. Consult your doctor before you stop taking CILIFT 20 mg TABLET. If stopped suddenly, withdrawal reactions may occur including dizziness, feeling of “pins and needles”, headache, feeling or being sick, sleep disturbances, feeling anxious, sweating, feeling restless or agitated, tremor, feeling confused, feeling emotional or irritable, diarrhoea (loose stools), visual disturbances and pounding heartbeat (palpitations).

4. Possible side effects

CILIFT 20 mg TABLET can have side effects.

Not all side effects reported for CILIFT 20 mg TABLET are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking CILIFT 20 mg TABLET please consult your healthcare provider for advice.

If any of the following happens, stop taking CILIFT 20 mg TABLET and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing;
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to CILIFT 20 mg TABLET. 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:

- Suicidal ideation, suicidal behaviour,
- in children hostility, suicidal ideation and self-harm. Symptoms include, but are not limited to anxiety, agitation, panic attacks, sleeplessness, irritability, hostility (aggressiveness), impulsivity, restlessness, constant elevated or irritable mood,
- if you have palpitations, dizziness, fainting, shortness of breath and chest discomfort as this can be symptoms of irregular heartbeat or abnormal heart rhythm,
- swelling and inflammation of the liver, symptoms include, but are not limited to, abdominal pain, dark urine and pale or clay-coloured stools, fatigue, fever, yellowing of the skin or eyes, loss of appetite,
- memory loss,
- unusual bleeding, including bleeding in the stomach with symptoms such as stomach cramps, blood in vomit, black or tarry stools,
- heavy vaginal bleeding shortly after birth (postpartum haemorrhage),
- high fever, agitation, confusion, trembling and abrupt contractions of muscles; this may be signs of a rare condition called serotonin syndrome,
- a life-threatening reaction called neuroleptic malignant syndrome, characterised by a very high fever, altered mental status, muscle rigidity, accelerated heartbeat, increased rate of breathing,
- fitting (convulsions, seizures).

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:

- Weight loss, weight gain, decreased appetite,
- nervousness, confusional state, anxiety, agitation,
- decreased libido, abnormal orgasm (female), ejaculation disorder, impotence, ejaculation failure,
- sleep disorders, abnormal dreams, sleeplessness, sleepiness, drowsiness,
- feeling indifferent or lacking emotion,
- feeling of 'needles and pins' in the extremities,
- headaches of varying intensity, sometimes with nausea and sensitivity to light and sound,
- tremor, dizziness,
- disturbance in attention,
- blurred vision, eye strain, eye fatigue (eye accommodation disturbances),
- ringing in the ears,
- yawning,
- stuffy or runny nose,
- dry mouth, nausea, vomiting, indigestion, constipation, diarrhoea,
- stomach pain, wind, increased saliva,
- increased sweating,
- muscle pain, body aches, joint pain or stiffness,
- abnormal physical weakness or lack of energy,
- fainting shortly after or during urination or other abnormalities in the process of urinating,
- tiredness (fatigue).

Less frequent side effects:

- Low sodium levels in the blood, symptoms may include but are not limited to weakness, seizures, headache, confusion (especially in elderly patients),
- increased appetite,
- elevated or irritable mood, aggression, depersonalisation,
- hallucination (seeing and hearing things that are not real),
- excessive grinding of the teeth,
- restlessness, panic attacks,
- confusion, fainting,
- taste disturbances,
- movement disorders, uncontrolled, unusual, involuntary muscle movements or stiffness,
- nasal congestion and/or bleeding,
- coughing,
- hair loss,
- dilated pupils,
- head rush or dizzy spell, when you stand up or stretch,
- the passage of blood from ruptured blood vessels into subcutaneous tissue, marked by a purple discolouration of the skin or bruising,
- sensitivity to light,
- urinary retention,
- fever,
- abnormal bleeding between regular menstrual periods or menstrual periods with abnormally heavy or prolonged bleeding,
- increased sexual desire, priapism (a potentially painful medical condition in which the erect penis does not return to its flaccid state),
- milky secretions from the breast,

- general sense of feeling unwell,
- water retention.

Side effects with an unknown frequency:

- Vision disturbances,
- low blood levels of potassium which can cause muscle weakness, twitching or abnormal heart rhythm.

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: https://www.sahpra.org.za/health-products-vigilance/

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088/ +27 (0)11 239-6200

By reporting side effects, you can help provide more information on the safety of CILIFT 20 mg TABLET.

5. How to store CILIFT 20 mg TABLET

Store all medicines out of reach of children.

Store at or below 25 °C.

Protect from moisture.

Keep the blisters in the carton until required for use.

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

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 CILIFT 20 mg TABLET contains

The active substance is citalopram hydrobromide equivalent to 20 mg of citalopram.

The other ingredients are colloidal silicon dioxide, lactose monohydrate, magnesium stearate, methocel, polyethylene glycol 400, purified talc, starch maize, starch maize (pregelatinised), titanium dioxide (C.I. no. 77891).

Contains sugar: Lactose monohydrate 75 mg

What CILIFT 20 mg TABLET looks like and contents of the pack

CILIFT 20 mg TABLET is a round, white to off-white, biconvex film-coated tablet, bisected on one side.

Blister packs of 30 and 90 tablets packed in red, transparent polyvinyl chloride or polyvinylidine chloride blisters with silver tempered aluminium foil with a leaflet in each pre-printed carton.

Blister packs of 30 and 90 tablets packed in clear, rigid polyvinyl chloride, laminated with polyethylene and coated with polyvinylidine chloride with silver tempered aluminium foil with a leaflet in each pre-printed carton.

Metalised lay flat bankbags of 28 tablets each sealed on the top with a lay-flat zip.

Not all packs and pack sizes are necessarily marketed.

Holder of Certificate of Registration

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Access to the corresponding Professional Information

SAHPRA Repository of Professional Information and Patient Information Leaflets:

https://www.sahpra.org.za/pi-pil-repository/

Aspen Pharmacare:

E-mail: Medinfo@aspenpharma.com

Tel: 0800 118 088

Namibia: NS3 04/1.2/1727

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