**Approved Patient Information Leaflet for Medicines for Human Use:**
**DEPRECITEL**

**SCHEDULING STATUS:** S5

**DEPRECITEL 10 mg film-coated tablets**

**DEPRECITEL 20 mg film-coated tablets**

**DEPRECITEL 40 mg film-coated tablets**

**Citalopram (as hydrobromide)**

**Contains sugar (lactose monohydrate)**

DEPRECITEL 10 mg film-coated tablet contains 23,64 mg lactose monohydrate.

DEPRECITEL 20 mg film-coated tablet contains 47,27 mg lactose monohydrate.

DEPRECITEL 40 mg film-coated tablet contains 94,54 mg lactose monohydrate.

**Read all of this leaflet carefully before you start taking DEPRECITEL**

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

Dezzo Trading 392 (Pty) Ltd, 570134-6, DEPRECITEL 10 mg, 20 mg, & 40 mg Film-coated tablets

6. Contents of the pack and other information

## 1. What DEPRECITEL is and what it is used for

Each film-coated tablet contains citalopram hydrobromide equivalent to citalopram 10, 20 or 40 mg.

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

*DEPRECITEL is used for the treatment of the following:*

- depression and to prevent the symptoms and occurrence of depression recurring. Depression is characterised by feelings of sadness, despair and discouragement
- panic attacks with or without agoraphobia, which is characterised by an irrational fear of open spaces or going out alone in public places
- obsessive compulsive disorder, which is characterised by unreasonable thoughts and fears, that results in repetitive behaviours.

## 2. What you need to know before you take DEPRECITEL

**Do not take DEPRECITEL**

- if you are hypersensitive (allergic) to citalopram or any of the other ingredients of DEPRECITEL (listed in section 6)
- if you are undergoing a treatment with monoamine oxidase inhibitors (medicines used in the treatment of depression). After discontinuation of monoamine oxidase inhibitors, you will need to wait at least 14 days before you start taking DEPRECITEL. After discontinuation of DEPRECITEL, you must wait 7 days before you take monoamine oxidase inhibitors
- if you suffer from severe kidney failure

- if you taking medicines containing linezolid (antibiotic used in the treatment of serious infections)
- if you are born with or have had an episode of cardiac disease or abnormal heart rhythm, characterised by QT-interval prolongation or congenital long QT syndrome
- if you are taking medicines which may also affect your heart rhythm such as: medicines which are used to make your heart beat normally (e.g. quinidine, amiodarone), medicines to treat psychosis (e.g. phenothiazine (fentiazine) derivatives, pimozide, haloperidol), medicines to treat depression (tricyclic antidepressants), certain medicines used to treat infections (e.g. sparfloxacin, moxifloxacin, erythromycin, pentamidine), anti-malarial treatment such as halofantrine, and certain antihistamines (e.g. astemizole, mizolastine)
- if you are under 18 years of age.

**Warnings and precautions**

**Take special care with DEPRECITEL:**

If you:

- have a history of bleeding disorders, or have ever suffered from bleeding in the stomach or intestine, or if you are pregnant (see “Pregnancy, breastfeeding and fertility”)
- are an elderly patient
- have liver disease
- have kidney disease
- have a history of epilepsy, seizures or fits
- are diabetic
- have suffered or suffer from heart problems, such as a low heart rate, had a recent heart attack or have heart failure

- have a low resting heart-rate and/or experiencing a fast or irregular heartbeat, fainting, collapse or dizziness on standing up which may indicate abnormal functioning of the heart rate
- are depressed and/or have anxiety disorders (panic disorders) as you can sometimes have thoughts of harming or killing yourself or suffer from psychological problems. These may be increased when first starting to take DEPRECITEL
- have a history of mania, which is a phase of bipolar disorder, characterised by hyperactivity, hyperexcitability and increased speech
- have low blood levels of potassium, sodium, and magnesium, as these should be corrected before starting treatment with DEPRECITEL
- decide to stop your treatment with DEPRECITEL, as the dosage should be reduced gradually
- if you have or have previously had eye problems, such as certain kinds of glaucoma (increased pressure in the eye).

*Please note:*

*Suicidal thoughts*

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 clinical trials has shown an increased risk of suicidal behaviour in adults aged less than 25 years with psychiatric 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.

*Manic phase*

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.

*Sexual dysfunction*

Medicines like DEPRECITEL (so called SSRIs/SNRIs) may cause symptoms of sexual dysfunction (see “Possible Side effects”). In some cases, these symptoms have continued after stopping treatment.

**Children and adolescents under 18 years**

DEPRECITEL should not be used in the treatment of children and adolescents under the age of 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.
Also, the long-term safety effects in children and adolescents concerning growth, maturation and cognitive and behavioural development have not yet been demonstrated.

**Other medicines and DEPRECITEL**

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

DEPRECITEL should be used with caution in patients taking the following medicines:

- medicines to treat depression such as monoamine oxidase inhibitors (MAOIs), (e.g phenelzine, selegiline, tranylcypromine) and tricyclic antidepressants (e.g imipramine and desipramine)
- other serotonergic medicines such as lithium and tryptophan
- medicines known to affect blood platelets (e.g medicines used to treat or prevent blood clots such as warfarin, aspirin and non-steroidal anti-inflammatory drugs (NSAIDs)
- medicines used to reduce stomach acid such as cimetidine
- St. John's wort (*Hypericum perforatum*), a herbal preparation
- medicines which may cause seizures "fits" such as: other medicines used for the treatment of depression such as tricyclic antidepressants or SSRIs and medicines used to treat epilepsy
- medicines which may also affect your heart rhythm such as: medicines which are used to make your heart beat normally (e.g. quinidine, amiodarone), medicines to treat psychosis (e.g. phenothiazine (fentiazine) derivatives, pimozide, haloperidol), medicines to treat depression (tricyclic antidepressants), certain medicines used to treat infections (e.g. sparfloxacin, moxifloxacin, erythromycin, pentamidine), anti-malarial treatment such as halofantrine, and certain antihistamines (e.g. astemizole, mizolastine).

**DEPRECITEL with food, drink and alcohol**

- DEPRECITEL may be taken with or without food in the morning or evening.
- It is not advisable to drink alcohol with DEPRECITEL.

**Pregnancy and breastfeeding**

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please contact your doctor, pharmacist or other health care professional for advice before taking DEPRECITEL.

If you take DEPRECITEL 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 DEPRECITEL so they can advise you.

DEPRECITEL passes into the breast milk; therefore, breastfeeding is not recommended while taking DEPRECITEL.

**Driving and using machines**

Do not drive or operate machinery if you are feeling dizzy or sleepy.

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

**DEPRECITEL contains lactose monohydrate.**

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

**3. How to take DEPRECITEL**

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

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

Your doctor will determine your dose.

The usual dose is:

**Adults**

*In the treatment of depression:*

The initial dose is 20 mg daily by mouth. Your doctor may after at least one week increase, the dose to 40 mg once daily.

*In the treatment of panic disorder:*

The initial dose is 10 mg daily by mouth. The doctor may increase it to 20 mg after 1 week. Your doctor may further increase the dose thereafter as required up to a maximum of 40 mg daily.

*In the treatment of obsessive-compulsive disorder (OCD)***:**

An initial dose of 20 mg is recommended. Your doctor may increase the dose in increments of 20 mg to 40 mg daily if necessary.

**Elderly (65 years of age and over)**

If you are elderly your doctor should decrease the dose to half of the recommended dose, e.g. 10 – 20 mg. The maximum daily dose that should be prescribed to you is 20 mg.

*Reduced hepatic function:*

If you suffer from liver problems your doctor will half the dose and will increase it to a maximum of 20 mg.

*Reduced renal function:*

If you suffer from kidney failure your doctor will not need to adjust the dose. Dosage adjustment is not necessary in cases of mild or moderate renal impairment.

Improvement of depressive symptoms may be seen within 2 to 4 weeks after starting treatment with DEPRECITEL. Treatment should be continued for at least 6 months after feeling better.

**Children up to the age of 18 years**

DEPRECITEL is not recommended as safety and efficacy has not been established (see special precautions and warnings).

**Duration of administration**

Your doctor will tell you how long your treatment with DEPRECITEL will last. Do not stop treatment early or abruptly.

If you have the impression that the effect of DEPRECITEL is too strong or too weak, tell your doctor or pharmacist.

**Method of administration**

DEPRECITEL may be taken with or without food in the morning or evening.

**If you take more DEPRECITEL than you should**

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

Symptoms and signs of overdosage may include tiredness, weakness, sleepiness, dizziness, nausea (feeling sick), increased heartbeat and shaking. Your doctor will treat your symptoms and will monitor you for at least 24 hours.

**If you forget to take a dose of DEPRECITEL**

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

**If you stop taking DEPRECITEL**

Stopping DEPRECITEL 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 DEPRECITEL is usually reduced gradually over a couple of weeks.

When you have completed the treatment, the dose of DEPRECITEL must be reduced gradually over a couple of weeks.

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

**4. Possible side effects**

DEPRECITEL can have side effects.

Not all side effects reported for DEPRECITEL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

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

- difficulty in breathing
- swelling of face, lips, tongue or throat that causes difficulty in swallowing or breathing
- severe burning or itching of the skin
- fast irregular heartbeat or fainting which could be symptoms of life-threatening condition known as torsade de pointes.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to DEPRECITEL. You may need urgent medical attention or hospitalization.

Tell your doctor immediately or go to the nearest casualty department at your nearest hospital if you notice any of the following:

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

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:*

- drowsiness, dizziness, inability to sleep, trembling
- paraesthesia (prickling sensation or “pins and needles”)
- nausea (feeling sick), constipation, diarrhoea (running stomach), vomiting, dry mouth
- pain in muscles and joints
- tiredness, yawning
- increased sweating, itchiness
- sexual dysfunction, problems with ejaculation and inability to ejaculate
- agitation, nervousness, decreased sexual desire, abnormal orgasm in females, abnormal dreams, aggression, hallucination (seeing things), mania (hyperexcitability, hyperactivity)
- decreased appetite, weight loss
- ringing in the ears (tinnitus).

*Less frequent side effects*:

- slow heartbeat
- slow pulse rate
- loss of consciousness, grand-mal seizure, movement disorder, taste disturbance
- difficulty in urinating
- inflammation of liver (hepatitis)
- dilation of the pupil of the eye (mydriasis)
- itch and appearance of hives, loss of hair, rash, sensitivity to light
- abnormal heavy menstruation in women (menorrhagia)
- increased appetite, increased weight, low blood sodium levels
- bleeding
- swelling of arms and legs (oedema), fever.

*Side effects with frequency unknown:*

- heavy vaginal bleeding shortly after birth (postpartum haemorrhage), see Pregnancy in section 2 for more information
- QT prolongation, abnormal heart rhythm including torsade de pointes and heart palpitations
- fits, serotonin syndrome
- extrapyramidal syndrome such as involuntary movements, an inability to sit still
- black tarry stools, a symptom of bleeding of the digestive tract
- abnormal liver function tests
- visual disturbance
- nosebleed and nose congestion
- spot on the skin with bluish or purplish patch (ecchymosis), sudden swelling of skin or mucosa

- uterine bleeding in females, painful erection and flow of breast milk in men
- panic attack, grinding or clenching of teeth, restlessness, thoughts of harming or killing yourself
- low potassium levels in the blood
- hypersensitivity reactions, allergic reactions
- decrease in blood platelets
- orthostatic hypotension which is a sudden drop in blood pressure experienced from a seated to a standing position
- bleeding originating from the alimentary-/digestive tract, salivation (increased saliva in mouth), heartburn
- asthenia (weakness), headache, malaise (feeling unwell), neuroleptic malignant syndrome (causing fever, muscular rigidity, altered mental status, and autonomic dysfunction)

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 or pharmacist. 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 [PRODUCT NAME]**.**

**5. How to store DEPRECITEL**

Keep this medicine in a dry place at or below 25 °C. Protect from light.

Store in the original package until required for use.

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

Do not store your medicine in the bathroom.

Return all unused medicine to your pharmacist.

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

STORE ALL MEDICINES OUT OF THE REACH OF CHILDREN.

**6. Contents of the pack and other information**

**What DEPRECITEL contains**

The active ingredient is citalopram.

Each film-coated tablet contains citalopram hydrobromide equivalent to citalopram 10, 20 or 40 mg.

The other ingredients are croscarmellose sodium, hydroxypropyl methylcellulose, lactose - monohydrate, magnesium stearate, maize starch, microcrystalline cellulose (Avicel PH200), polyethylene glycol 400, purified talc, titanium dioxide.

**What DEPRECITEL looks like and contents of the pack**

DEPRECITEL 10 mg are white to off-white, round, plain, film-coated tablets.

DEPRECITEL 10 mg TABLETS are supplied in:

Blister pack (Clear PVDC coated PVC film and Aluminium foil) of 1x14, 2x14, 4x14 or 6x14 tablets or 3x10 tablets.

Bulk pack (White HDPE Jars) of 100, 250, 500 or 1000 tablets.

DEPRECITEL 20 mg are white to off-white, oval, biconvex, film-coated tablets with ‘BL’ embossed on one side, and ‘20’ on the other.

DEPRECITEL 20 mg TABLETS are supplied in:

Blister pack (Clear PVDC coated PVC film and Aluminium foil) of 1x14, 2x14, 4x14 or 6x14 tablets or 3x10 tablets.

Dezzo Trading 392 (Pty) Ltd, 570134-6, DEPRECITEL 10 mg, 20 mg, & 40 mg Film-coated tablets

Bulk pack (White HDPE Jars) of 100, 250, 500 or 1000 tablets.

DEPRECITEL 40 mg are white to off-white, oval, biconvex, film-coated tablets with ‘BL’ embossed on one side and ‘40’ on the other.

DEPRECITEL 40 mg TABLETS are supplied in:

Blister pack (Clear PVDC coated PVC film and Aluminium foil) of 1x14, 2x14, 4x14 or 6x14 tablets or 3x10 tablets.

Bulk pack (White HDPE Jars) of 100, 250, 500 or 1000 tablets.

Not all pack sizes may be marketed.

**Holder of Certificate of Registration**

Dezzo Trading 392 (Pty) Ltd.

Jespan Centre,

Corner Garrick & Flagtail Street, Extension 8,

LENASIA, 1821, South Africa

Tel: +27 87 405 9660

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