

Applicant: Astral Pharma (Pty) Ltd

Product: Arrow Citalopram 20 & 40 mg

Dosage form and strength: Each tablet contains citalopram hydrobromide equivalent to 20 or 40 mg citalopram.

## PATIENT INFORMATION LEAFLET

### SCHEDULING STATUS:

**S5**

#### **ARROW CITALOPRAM 20mg Tablets**

Contains sugar (lactose 350 mesh 51.51 mg).

#### **ARROW CITALOPRAM 40mg Tablets**

Contains sugar (lactose 350 mesh 103.02 mg).

### **Read all of this leaflet carefully before you start taking ARROW CITALOPRAM.**

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

#### **1. What ARROW CITALOPRAM is and what it is used for**

ARROW CITALOPRAM is a Selective Serotonin Reuptake Inhibitors (SSRIs) and belongs to a group of medicines called antidepressants. These medicines help to correct certain imbalances in the brain that are causing the symptoms or your illness.

ARROW CITALOPRAM is used for the treatment of depression and when you feel better, to help prevent these symptoms recurring.

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Citalopram tablets is also used for long-term treatment to prevent the occurrence of new episodes of depression or if you have recurrent depression.

ARROW Citalopram Tablets are also used to relieve symptoms if you are suffering from panic attacks.

Obsessive-compulsive disorder

## **2. ~~2. INSTRUCCIONES BEFORE YOU TAKE THE MEDICINE~~ What you need to know before you take ARROW CITALOPRAM tablets**

Do not take ARROW CITALOPRAM Tablets and talk to your doctor:

- if you are allergic (hypersensitive) to citalopram or to any of the other ingredients of ARROW CITALOPRAM Tablets (see section 6).
- if you are also taking a medicine containing pimozide (Antipsychotic).
- if you are taking medicines known as monoamine oxidase inhibitors (MAOIs)
- MAOIs include medicines such as phenelzine, iproniazid, isocarboxazid, nialamide, tranylcypromine, moclobemide (used for the treatment of depression), selegiline (used in the treatment of Parkinson's disease) and linezolid (an antibiotic). Even if you have finished taking one of the following MAOIs: phenelzine, iproniazid, isocarboxazid, nialamide or tranylcypromine then you will need to wait 2 weeks before you start taking your Citalopram Tablets. One day must elapse after you have finished taking moclobemide. After stopping Citalopram Tablets you must allow 1 week before taking any MAOI.
- if you are born with or have had an episode of abnormal heart rhythm known as QT interval prolongation (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. Also refer to the section "Taking other medicines" below.
- If you have severely impaired kidney function
- If you are taking linezolid, an antibiotic.
- If you are pregnant or breastfeeding
- ARROW CITALOPRAM must not be used by children under the age of 18 years.

### **Warnings and precautions**

If you suffer or have suffered from heart problems or have recently had a heart attack.

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

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vomiting (being sick) or usage of diuretics (water tablets).

If you experience a fast or irregular heart beat, fainting, collapse or dizziness on standing up which may indicate abnormal functioning of the heart rate.

Medicines like Citalopram tablets (so called SSRIs/SNRIs) may cause symptoms of sexual dysfunction (see section 4). In some cases, these symptoms have continued after stopping treatment.

Please tell your doctor if you are suffering from

- Liver disease.
- Severe kidney disease.
- If you are an elderly person
- 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 or appearance of bruises or unusual bleeding or if you are taking any medicine that thins the blood.
- Mania or panic disorder.
- Low blood levels of sodium.
- Receiving ECT (electroconvulsive therapy).
- Problems with your eyes, such as certain kinds of glaucoma (increased pressure in the eye).
- 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).
- If you experience a fast or irregular heartbeat, fainting, collapse or dizziness on standing up which may indicate abnormal functioning of the heart rate.
- If you have suicidal thoughts. If you are depressed and/or have anxiety disorders you can sometimes experience increased anxiety symptoms or have thoughts of harming or killing yourselves. These may be increased when first starting antidepressants, including ARROW CITALOPRAM, since these medicines all take time to work, usually about two weeks but sometimes longer. If you have thoughts of harming or killing yourself at any time, contact your doctor or go to a hospital straight away.
- If you experience a combination of the below mentioned symptoms, ARROW CITALOPRAM should be stopped: Agitation,

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- confusion, disorientation, muscle spasms, hyper-reflexia, tremor, rigidity, incoordination, fever, sweating and diarrhoea.
- There has been a relation between a group of medicine called SSRI and SNRI and heavy bleeding following birth. ARROW CITALOPRAM belongs to the group of medicines called SSRIs. If you have bleeding disorders or are pregnant, your doctor will have to change your treatment to an alternative group of medicines.

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 (akathisia) can also occur during the first weeks of the treatment. Tell your doctor immediately if you experience these symptoms.

### **Special information relating to your disease**

As with other medicines used to treat depression or related diseases, the improvement is not achieved immediately. After the start of Citalopram 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 clinical trials has shown an increased risk of suicidal behaviour in adults aged less than 25 years

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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.

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.

### **Children and adolescents**

Citalopram tablets should normally not be used for children and adolescents under 18 years. Also, you should know that patients under 18 years 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 citalopram for patients under 18 years because he/she decides that this is in their best interests. If your doctor has prescribed Citalopram tablets for a patient under 18 years and if 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 years are taking Citalopram tablets. Also, the long-term safety effects concerning growth, maturation and cognitive and behavioural development of Citalopram in this age group have not yet been demonstrated.

### **Other medicines and Citalopram tablets**

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

Medicines may affect the action of other medicines and this can sometimes cause serious adverse reactions. Please tell your doctor if you are taking or have taken any other medicines (including those purchased without prescription) during the last 14 days.

- Do not take any other medicines to treat depression (for example monoamine oxidase inhibitors, imipramine, other serotonergic medicines, and moclobemide) without consulting your doctor as they may interact with ARROW CITALOPRAM'
- Do not use alcohol while using ARROW CITALOPRAM.
- Medicines used to treat blood clotting such as warfarin may interact with ARROW CITALOPRAM. Consult with your doctor if you are or have to use such medicines.
- Medicines used to treat heart burn or stomach ulcer such as cimetidine interacts with the breakdown of citalopram, and the dose of ARROW CITALOPRAM should be changed.

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

- Sumatriptan (used to treat migraine) or tramadol (a pain killer). If you feel unwell when using these medicines with Citalopram tablets then you should see your doctor.
- Lithium (used to prevent and treat mania) and tryptophan (an antidepressant).
- Medicines known to affect the blood platelets (e.g. anticoagulant drugs used to treat or prevent blood clots; aspirin and non-steroidal anti-inflammatory drugs(NSAIDs) such as ibuprofen and diclofenac used as painkillers and some antipsychotic drugs and tricyclic antidepressants).
- Metoprolol (beta-blocker used to treat angina (chest pain) and high blood pressure).
- Linezolid (an antibiotic).
- Imipramine and desipramine (used to treat depression).
- Medicines containing selegiline (used to treat Parkinson's disease)
- Fluconazole (used to treat fungal infections).
- Mefloquine (used to treat malaria) and Bupropion (used to treat depression) due to a possible risk of a lowered threshold for seizures.
- Neuroleptics (used in the treatment of schizophrenia, psychosis), due to a possible risk of a lowered threshold for seizures (fits), and antidepressants.
- St. John's Wort (herbal remedy for depression)
- DO NOT TAKE CITALOPRAM TABLETS if you take medicines for heart rhythm problems or medicines that may affect the heart's

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rhythm, e.g. such as Class IA and III antiarrhythmics, antipsychotics (e.g. phenothiazine derivatives, fentiazine derivatives, pimoziide, haloperidol), tricyclic antidepressants, certain antimicrobial agents (e.g. sparfloxacin, moxifloxacin, erythromycin IV, pentamidine, anti-malarial treatment particularly halofantrine), certain antihistamines (astemizole, mizolastine), because taking one or more of these medicines with ARROW CITALOPRAM may increase the risk of changes in the electrical activity of the heart. If you have any further questions about this you should speak to your doctor.

### **ARROW CITALOPRAM tablets with food and drink**

Citalopram tablets can be taken with or without food (see section 3 "How to take Citalopram tablets).

As with all antidepressants, it is sensible to avoid drinking alcohol whilst receiving treatment.

### **Pregnancy and breastfeeding and fertility**

#### **Pregnancy**

Safety in pregnancy has not been established.

If you are pregnant, think you might be pregnant or are planning to have a baby, tell your doctor. Do not take Citalopram tablets 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 Citalopram Tablets.

When taken during pregnancy, particularly in the last 3 months of pregnancy, medicines like Citalopram Tablets may increase the risk of a serious condition in babies, called persistent pulmonary hypertension of the new born (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.

Also, if you take Citalopram 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.

Ask your doctor or pharmacist for advice before taking any medicine.

#### **Breast-feeding**

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Safety in breastfeeding has not been established.

If you are breast-feeding, ask your doctor for advice. You should not breastfeed your baby while taking Citalopram tablets because small amounts of the medicine can pass into the breast milk.

### **Fertility**

Theoretically, this could affect fertility, but impact on human fertility has not been observed as yet.

### **Driving and using machines**

Do not operate machinery or drive as ARROW CITALOPRAM may impair the performance of skilled tasks.

### **ARROW CITALOPRAM contains lactose**

ARROW CITALOPRAM contains lactose which may have an effect on the control of your blood sugar if you have diabetes mellitus. 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 ARROW CITALOPRAM tablets**

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

Always take ARROW CITALOPRAM exactly as your doctor or pharmacist has told you.

Check with your doctor or pharmacist if you are not sure.

### **The usual dose is:**

#### **Adults:**

#### **Depression**

The usual dose is 20 mg per day. This may be increased by your doctor to a maximum of 60 mg per day.

#### **Panic disorder**

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The starting dose is 10 mg per day for the first week before increasing the dose to 20mg per day. The dose may be increased by your doctor to a maximum of 60 mg per day.

**Obsessive Compulsive Disorder:**

20 mg a day as a single dose. This dose can be increased by 20 mg increments to a maximum of 60 mg a day depending on the patient's response.

**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):**

Citalopram tablets is not recommended for children or adolescents

**Patients with special risks**

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

**Reduced renal function**

Dose adjustment is not necessary in cases of mild or moderate renal impairment. The onset of action is seen within 2 to 4 weeks.

**How and when to take Citalopram tablets**

Citalopram tablets is taken every day as a single daily dose. Citalopram tablets can be taken any time of the day with or without food. Swallow the tablets with a drink of water. Do not chew them (they have a bitter taste).

**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 Citalopram tablets even if it takes some time before you feel any improvement in your condition.

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The duration of treatment is individual, usually at least 6 months. Continue to take Citalopram 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.

Your doctor will tell you how long your treatment with ARROW CITALOPRAM will last.

Do not stop treatment early, because your doctor needs to slowly decrease the dosage taken daily. If you have the impression that the effect of ARROW CITALOPRAM is too strong or too weak, tell your doctor or pharmacist.

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

#### **If you take more ARROW CITALOPRAM than you should**

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. Always take any tablets left over with you, also the box and leaflet as this will allow easier identification of the tablets.

#### **Symptoms of overdosage may include:**

- Nausea (feeling sick)
- Vomiting
- Sweating
- Drowsiness
- Seizures
- Unconsciousness
- Fast heart beats
- Tremor
- Irregular heart beat
- Changes in heart rhythm

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- Changes in blood pressure
- Serotonin syndrome (see Section 4)
- Agitation
- Dizziness
- Enlarged eye pupils
- Bluish skin
- Breathing too quickly
- Tiredness
- Weakness
- Somnolence

#### **If you forget to take ARROW CITALOPRAM Tablets**

If you forget to take a dose, take it as soon as you remember. If it is almost time for your next dose, do not take the missed dose and just carry on as before. Do not take a double dose to make up for a forgotten dose.

#### **If you stop taking ARROW CITALOPRAM Tablets**

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 symptoms are generally non-serious and disappear within a few days.

When you have completed your course of treatment, the dose of Citalopram is usually reduced gradually over a couple of weeks.

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

#### **4. Possible side effects**

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ARROW CITALOPRAM can have side effects.

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

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

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

- 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 heart beat, fainting which could be symptoms of a life threatening condition known as torsades de pointes.
- If you have thoughts of harming or killing yourself at any time.

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

If you notice any of the following symptoms you should stop taking Citalopram tablets and see your doctor immediately:

- if you start having fits for the first time or fits that you have suffered from in the past become more frequent.
- if your behaviour changes because you feel elated or over excited.
- If you feel restless and cannot sit or stand still, you may have akathisia (feeling of “inner restlessness”, a constant urge to be moving).
- if you experience high fever with faster breathing or heart rate, sweating, agitation or sleepiness, 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.
- Tiredness, loss of appetite, weight loss, with or without yellowing of the skin or whites of the eyes (symptoms of abnormal liver function or hepatitis).
- Prolonged and painful erection.
- Heavy vaginal bleeding shortly after birth (postpartum haemorrhage), see Pregnancy in section 2 for more information.
- Symptoms of high fever, confusion, rigid muscles, variable blood pressure, sweating and fast heart rate (Symptoms of Neuroleptic Malignant Syndrome).

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

The following side effects are often mild and usually disappear after a few days' treatment.

Tell your doctor if you notice any of the following:

The following side effects have been reported frequently:

- Feeling sick (Nausea)
  - Abnormal awareness of the beating of your heart
  - Unintentional muscle movements
  - Sleep disturbances
  - Headache
  - Restlessness
  - Drowsiness
  - Loss of body strength, weakness
  - Decreased sex drive
  - Pins and needles sensations
  - Dizziness
  - Diarrhoea
  - Constipation
  - Indigestion
  - Dry mouth
  - Sweating
  - Difficulties urinating
  - Tiredness
  - Weight loss or gain
- 
- Agitation
  - Confusion
  - Yawning
  - Impaired concentration
  - Extremely elevated mood

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- Energy and unusual thought patterns
- Stuffy nose
- Large pupils (the dark centre of the eye)
- Slow heart beat
- Rash
- Convulsions
- Muscle rigidity and fever
- Salivation
- Sexual dysfunction including ejaculation disorder
- Decreased libido
- Delayed ejaculation
- Hepatitis
- Feeling unwell (malaise)

The following side effects have been reported but the frequency is unknown:

- Thoughts of harming or killing themselves
- An increase in bleeding or bruising caused by a decrease in blood platelets
- Rash (hypersensitivity)
- Increased or decreased appetite
- Low potassium levels in the blood (hypokalaemia), which can cause muscle weakness, twitching or abnormal heart rhythms
- Low levels of sodium in the blood (hyponatremia)
- Aggression
- Agitation
- Anxiety
- Nervousness
- Abnormal orgasms in women
- Hallucinations
- Itching
- Loss of hair
- Sensitivity to sunlight
- Excessive menstrual bleeding
- Feeling detached from yourself, hallucinations, abnormally high mood, panic attacks, grinding teeth, restlessness.

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- Unexplained bleeding, low blood pressure that happens when standing up from sitting or lying down.
- Indigestion, vomiting, constipation, bleeding from the gut including the back passage
- Bruising of the skin, rapid swelling of the tissues around the neck, face, mouth and/or throat
- Muscle pain, joint pain
- Unusual muscle movements or stiffness
- Involuntary movements of the muscles (akathisia)
- Nosebleed, stuffy nose
- Bleeding disorders including skin and mucosal bleeding (ecchymosis)
- Excessive bleeding after child birth (postpartum haemorrhage)
- Ringing in the ears (tinnitus)
- Fainting
- Taste disturbances
- Fever
- 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)
- 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, very rarely, 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.

Also let your doctor know if you continue to have other symptoms associated with your depression. 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 Citalopram tablets, please tell your doctor.

If you notice any side effects not mentioned in this leaflet, please inform you doctor or pharmacist.

### **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 online under SAHPRA's publications:

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<https://sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of ARROW CITALOPRAM.

## 5. How to store ARROW CITALOPRAM tablets

STORE ALL MEDICINES OUT OF REACH OF CHILDREN

Store at or below 25°C

Store in the original package/container

Do not store in a bathroom

Do not use your tablets after the expiry date stated on the label or carton.

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 ARROW CITALOPRAM contains:**

- **The active substance is Citalopram hydrobromide**

**ARROW CITALOPRAM 20 mg:** each tablet contains citalopram hydrobromide equivalent to 20 mg citalopram.

**ARROW CITALOPRAM 40 mg:** each tablet contains citalopram hydrobromide equivalent to 40 mg citalopram.

- **The other ingredients are**

Crospovidone, lactose 350 mesh, magnesium stearate (vegetable grade), maize Starch, microcrystalline cellulose (ph 101), povidone K30, Opadry white OY-LS 28908

**What ARROW CITALOPRAM looks like and content of the pack**

Film-Coated Tablet

Arrow Citalopram 20mg: White film-coated, oval, convex tablet embossed C/A on one side and “>” on the other side.

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Arrow Citalopram 40mg: White film-coated, oval, convex tablet embossed C/A on one side and “>” on the other side.

Blister strips of clear transparent film with aluminium foil backing containing 10 tablets per strip, three strips per carton

White round HDPE bottle with white cap containing 100 or 1000 tablets.

Not all pack sizes may be marketed.

### **Holder of certificate of Registration**

Astral Pharma (Pty) Ltd

125 Meade Street

George

6529

South Africa

### **This leaflet was last revised in**

Date of registration: 12 June 2009

Date of revision of text: 24 January 2024

### **Registration number(s)**

ARROW CITALOPRAM 20 mg: 42/1.2/0719

ARROW CITALOPRAM 40 mg: 42/1.2/0718

### **Access to corresponding Professional Information**

Can be obtained on the SAHPRA website.

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