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

PROFESSIONAL INFORMATION

SCHEDULING STATUS: S5

1. NAME OF THE MEDICINE

Arrow Citalopram 20 mg (TABLETS)

Arrow Citalopram 40 mg (TABLETS)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

ARROW CITALOPRAM 20 mg: Each tablet contains Citalopram hydrobromide equivalent to 20 mg citalopram.

Contains sugar (lactose monohydrate 51.51 mg)

ARROW CITALOPRAM 40 mg: Each tablet contains Citalopram hydrobromide equivalent to 40 mg citalopram.

Contains sugar (lactose monohydrate 103.02 mg)

For full list of excipients, see section 6.1.

3. IDENTIFICATION PHARMACEUTICAL FORM

ARROW CITALOPRAM 20 mg: White film-coated, oval, convex tablet embossed C/A on one side and ">" on the other side.
ARROW CITALOPRAM 40 mg: White film-coated, oval, convex tablet embossed C/40 on one side and ">" on the other side.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

ARROW CITALOPRAM is indicated for the treatment of:

- Depression and prevention of relapse.

- Panic disorder with or without agoraphobia.
- Obsessive-compulsive disorder (OCD).

4.2 Posology and method of administration

Posology

Depression:

20mg a day as a single dose. Dosage may be increased by 20mg a day at intervals of at least one

week to a maximum of 60 mg depending on the patient's response.

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.

If the decision is made to discontinue treatment with **ARROW CITALOPRAM**, it is recommended that the dose should be decreased gradually to prevent the possibility of withdrawal symptoms (see section 4.4).

Special populations:

Renal impairment:

Dose adjustment is not necessary in cases of mild or moderate renal

impairment.

The onset of action is seen within 2 to 4 weeks. Treatment should be continued for an appropriate

length of time (up to six months) after recovery in order to prevent relapse. The medicine should be gradually withdrawn during a couple of weeks when stopping therapy.

Method of administration

For oral use.

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

4.3 Contraindications

- Hypersensitivity to citalopram or any of the ingredients in the formulation.
- MAOIs (monoamine oxidase inhibitors):

Cases of serious and sometimes fatal reactions have been reported in patients receiving as SSRI in combination with a monoamine oxidase inhibitor (MAOI), including the selective MAO-B inhibitor selegiline and the reversible MAOI (RIMA), moclobemide and in patients who have recently discontinued as SSRI and have been started on a MAOI. Some cases presented with features resembling serotonin syndrome. ARROW CITALOPRAM must not be used in combination with MAOI, including selegiline in doses above 10 mg daily.

Concurrent use with a monoamine oxidase inhibitor (MAOI). At least 14 days should lapse between discontinuing the MAOI and initiating therapy with ARROW CITALOPRAM. MAOIs should not be introduced for 7 days after discontinuation of ARROW CITALOPRAM (see section 4.5).

- Severe renal impairment (creatinine clearance less than 20 ml/min).
- Safety and efficacy in pregnancy and lactation has not been established.
- Children under the age of 18 years (See section 4.4 and 4.8).
- Concomitant treatment with pimozide (See section 4.5).
- ARROW CITALOPRAM is contraindicated in combination with linezolid (See section 4.5).
- ARROW CITALOPRAM is contraindicated in patients with known QT interval prolongation or congenital long QT syndrome (See section 4.4, 4.8 and 5.1).

4.4 Special warnings and precautions for use

Warnings

ARROW CITALOPRAM should be used with caution in:

Use in children and adolescents under 18 years of age - Safety and efficacy in children under 18 years of age have not been established. In clinical trials in Major Depressive Disorder, there were increased reports of hostility (predominantly aggression, oppositional behaviour and anger) and suicide – related adverse events such as suicidal ideation and self-harm.

In addition, long-term safety data in children and adolescents concerning growth, maturation and concerning growth, maturation and cognitive and behavioural development are lacking.

Elderly patients - longer half-life and decreased clearance due to a reduced rate of metabolism. A lower dose is recommended in the elderly.

Hepatic impairment - clearance of ARROW CITALOPRAM is reduced. Cautious dosage titration and a lower maximum dose are recommended.

Renal impairment - elimination is decreased. If creatine clearance is less than 20 ml/min, ARROW CITALOPRAM should not be used. (See section 4.3).

Seizures or history thereof – there is an increased risk of seizures. ARROW CITALOPRAM should be discontinued in any patient who develops seizures.

ARROW CITALOPRAM should be used with caution in patients with controlled epilepsy and avoided in patients who are poorly controlled epileptics. ARROW CITALOPRAM should be discontinued if there is an increase in seizure frequency.

ECT (electroconvulsive therapy) - Care is advised in patients receiving electroconvulsive therapy.

Mania or history of mania – condition may be re-activated. ARROW CITALOPRAM should be discontinued if the patient enters the manic phase.

ARROW CITALOPRAM may cause a reduction in heart rate. Caution is advised in patients with pre-existing slow heart rates.

Diabetes mellitus – rare occurrences of hypoglycaemia have been reported. In patients with diabetes, treatment with an SSRI, including ARROW CITALOPRAM may alter glycaemic control. Insulin and/or oral hypoglycaemic dosage may need to be adjusted.

Use with other medicines - ARROW CITALOPRAM should not be used with monoamine oxidase inhibitors, imipramine, other serotonergic medicines, moclobemide, alcohol, warfarin, and cimetidine (see section 4.5).

Risk of serotonin syndrome, a rare but potentially hyperserotonergic state, if combined with other serotonin medicines (see section 4.5).

Suicide/suicidal thoughts or clinical worsening - Patients with major depressive disorder, both adults and children may experience worsening of their depression and or the emergence of suicidal ideation and behavior, whether or not they are taking antidepressant medicines. This risk may persist until significant remission occurs. A causal role, however, for antidepressant medicines in inducing such behavior has not been established. Patients being treated with ARROW CITALOPRAM should, nevertheless, be observed closely for clinical worsening and suicidality, especially at the beginning or a course of therapy, or at any time of dose changes, either increases or decreases.

Because of the possibility of co-morbidity between major depressive disorder and other psychiatric and non-psychiatric disorders, the same precautions observed when treating patients with major depressive disorder should be observed when treating patients with other psychiatric and non-psychiatric disorders.

The following symptoms have been reported in patients being treated with antidepressants for major depressive disorder as well as for other indications, both psychiatric and non-psychiatric: anxiety, agitation, panic attacks, insomnia, irritability, hostility, aggressiveness, impulsivity, akathisia, hypomania, and mania. Although a causal link between the emergence of such symptoms and either the worsening of depression and/or the emergence of suicidal impulses has not been established, consideration should be given to changing the therapeutic regimen, including possibly discontinuing ARROW CITALOPRAM, in patients for whom such symptoms are severe, abrupt in onset, or were not part of the patient's presenting symptoms.

If the decision is made to discontinue treatment with ARROW CITALOPRAM, it is recommended that the dose should be decreased gradually to prevent the possibility of withdrawal symptoms (see section 4.4 and 4.8)

Paradoxical anxiety- Some patients with panic disorder may experience intensified anxiety symptoms at the start of treatment with antidepressants. This paradoxical reaction usually subsides within the first two weeks of starting treatment. A low starting dose of ARROW CITALOPRAM is advised to reduce the likelihood of a paradoxical anxiogenic effect (see section 4.2).

Hyponatraemia - Hyponatraemia, probably due to inappropriate antidiuretic hormone secretion (SIADH), has been reported as an adverse reaction with the use of SSRIs and generally reverses on discontinuation of therapy. Elderly female patients seem to be at higher risk.

Akathisia/psychomotor restlessness - The use of SSRIs/SNRIs has been associated with the development of akathisia, characterised by a subjectively unpleasant or distressing restlessness and need to move often accompanied by an inability to sit or stand still. This is most likely to occur within the first few weeks of treatment. In patients who develop these symptoms, increasing the dose of ARROW CITALOPRAM may be detrimental.

Serotonin syndrome - Serotonin syndrome has been reported in patients using SSRIs. Serotonin syndrome is more likely to occur after an increase in dose. A combination of symptoms such as agitation, tremor, myoclonus, and hyperthermia may indicate the development of this condition. Treatment with ARROW CITALOPRAM should be discontinued immediately and symptomatic treatment initiated.

Serotonergic medicines – ARROW CITALOPRAM should not be used concomitantly with medicines with serotonergic effects such as sumatriptan or other triptans, tramadol, oxitriptan, and tryptophan (see section 4.5).

Haemorrhage - There have been reports of cutaneous bleeding time and/or bleeding abnormalities such as ecchymoses, gynaecological haemorrhages, gastrointestinal bleedings, and other cutaneous or mucous bleedings with SSRIs (see section 4.8). Caution is advised in patients taking ARROW CITALOPRAM, particularly with concomitant use of active substances known to affect platelet function or other active substances that can increase the risk of haemorrhage, as well as in patients with a history of bleeding disorders (see section 4.5).

Post-partum haemorrhage – There has been evidence of an association between antidepressants [particularly selective serotonin reuptake inhibitors (SSRIs) and serotonin non-selective reuptake inhibitors (SNRIs)] and post-partum haemorrhage (PPH). Observational data indicate an increased risk (less than 2 – fold) of postpartum haemorrhage PPH following SSRI/SNRI exposure within the month prior to birth. Healthcare professionals should be aware of the potential risk of PPH while making treatment decisions for prescribing SSRI/SNRI towards the end of pregnancy. Patients should be advised to inform their doctors before taking SSRI/SNRI if they have history of bleeding disorders, such as van Willebrand disease (VWD) or haemophilia or if they are pregnant.

St. John's Wort- Undesirable effects may be more common during concomitant use of ARROW CITALOPRAM and herbal preparations containing St John's wort *(Hypericum perforatum).* Therefore ARROW CITALOPRAM and St John's wort preparations should not be taken concomitantly (see section 4.5).

Psychosis - Treatment of psychotic patients with depressive episodes may increase psychotic symptoms.

QT interval prolongation – ARROW CITALOPRAM has been found to cause a dose- dependent prolongation of the QT interval. Cases of QT interval prolongation and ventricular dysrhythmia including torsade de pointes have been reported during the post-marketing period, predominantly in patients of female gender, with hypokalaemia, or with pre-existing QT prolongation or other cardiac diseases (see sections 4.3, 4.5, 4.8, 4.9 and 5.1).

Caution is advised in patients with significant bradycardia; or in patients with recent acute myocardial infarction or uncompensated heart failure.

Electrolyte disturbances such as hypokalaemia and hypomagnesaemia increase the risk for malignant dysrhythmias and should be corrected before treatment with ARROW CITALOPRAM is started.

If patients with stable cardiac disease are treated, an ECG review should be considered before treatment is started.

If signs of cardiac dysrhythmia occur during treatment with ARROW CITALOPRAM, the treatment should be withdrawn, and an ECG should be performed.

Withdrawal symptoms - After prolonged administration, abrupt cessation of ARROW CITALOPRAM may produce withdrawal symptoms such as dizziness, sensory disturbances (including paraesthesia), sleep disturbances (including insomnia and intense dreams), agitation or anxiety, nausea and/or vomiting, tremor, confusion, sweating, headache, diarrhoea, palpitations, emotional instability, irritability, and visual disturbances in some patients. These symptoms are not indicative of addiction.

It is recommended that withdrawal of treatment should proceed by gradually tapering off the dosage over a period of several weeks or months, according to the patient's needs to avoid occurrence of discontinuation symptoms.

Angle-Closure Glaucoma

SSRIs including citalopram may have an effect on pupil size resulting in mydriasis. This mydriatic effect has the potential to narrow the eye angle resulting in increased intraocular pressure and angle-closure glaucoma, especially in patients pre-disposed. Citalopram should therefore be used with caution in patients with angle-closure glaucoma or history of glaucoma.

Special precautions

Patients should be monitored during early therapy until improvement in depression is observed because suicide is an inherent risk in depressed patents.

Alcohol - Avoid alcohol (see section 4.5).

ARROW CITALOPRAM contains lactose which may have an effect on the glycaemic control of patients with diabetes mellitus. ARROW CITALOPRAM contains lactose. Patients with the rare hereditary conditions of

galactose intolerance e.g. galactosaemia, Lapp lactase deficiency, glucose-galactose malabsorption or fructose intolerance should not take ARROW CITALOPRAM.

4.5 Interaction with other medicines and other forms of interaction

- **Monoamine oxidase inhibitors (MOAI)** - concurrent use is contra-indicated. Serious and potentially fatal reactions have occurred in patients receiving an SSRI in combination with a monoamine oxidase inhibitor (MAOI), including the irreversible MAOI selegiline, the reversible MAOIs linezolid and moclobemide and in patients who have recently discontinued SSRI and have been started on a MAOI. Some cases presented with features resembling serotonin syndrome.

Moclobemide - serotonin syndrome has developed after taking overdoses of moclobemide and **ARROW CITALOPRAM**.

Symptoms of citalopram interaction with MAOI include: hyperthermia, rigidity, myoclonus, autonomic instability with rapid fluctuation of vital signs and mental status changes including extreme agitation progressing to delirium and coma (see section 4.3).

Serotonergic medicines

Lithium and tryptophan: However, there have been reports of enhanced effects when SSRIs have been given with lithium or tryptophan and therefore the concomitant use of ARROW CITALOPRAM with these medicines should be undertaken with cation. Routine monitoring of lithium levels should be continued as usual.

Co-administration with serotonergic medicines (e.g. tramadol, sumatriptan) may lead to enchancement of 5-HT associated effects. The simultaneous use of ARROW CITALOPRAM and 5-HT agonists, such as sumatriptan and other triptans, is not recommended (see section 4.4).

St. John's Wort – Pharmacodynamic interactions between SSRIs such as ARROW CITALOPRAM and herbal remedy St. John's wort (Hypericum perforatum) can occur, resulting in an increase in undesirable effects (see section 4.4).

Medicines lowering the seizure threshold

ARROW CITALOPRAM can lower the seizure threshold. Caution is advised when concomitantly using other medicines capable of lowering the seizure threshold (e.g. antidepressants [tricyclic, other SSRIs], neuroleptics [phenothiazines, thioxanthenes, and butyrophenones], mefloquine, bupropion and tramadol).

Imipramine – an increase in the concentration of desimipramine (the active metabolite of imipramine) may occur. It appears that ARROW CITALOPRAM does not cause a marked increase in plasma levels of some tricyclic antidepressants.

QT interval prolongation – An additive effect of ARROW CITALOPRAM and these medicines cannot be excluded. Therefore, co-administration of ARROW CITALOPRAM with medicines that prolong the QT interval, such as a Class IA and III antidysrhythmics, antipsychotic (e.g. phenothiazine derivatives, pimozide, haloperidol), tricyclic antidepressants, certain animalarial treatment particularly halofantrine), certain antihistamines (astemizole, mizolastine), should only be prescribed after careful consideration**.**

Other serotonergic medicines or medicines with serotonergic activity – increased risk of developing the serotonin syndrome, a rare but potentially fatal hyperserotonergic state.

Alcohol – the effects of alcohol may be increased.

Warfarin – the anticoagulant activity of warfarin may be increased. Simultaneous treatment with anticoagulants, medicines that affect the platelet function, such as non-steroidal anti-inflammatory medicines (NSAIDs), acetylsalicylic acid, dipyridamol, and ticlopidine or other medicines (e.g. atypical antipsychotics, phenothiazines, tricyclic antidepressants) can increase the risk of haemorrhage (see section 4.4).

Cimetidine - the AUC and the maximum plasma concentration of **ARROW CITALOPRAM** are increased when **ARROW CITALOPRAM** is administered concurrently with cimetidine.

4.6 Fetility,Pregnancy and lactation

PREGNANCY AND LACTATION:

Safety and efficacy in pregnancy and lactation has not been established. **ARROW CITALOPRAM** is excreted into the breast milk.

Pregnancy

Safety and efficacy in pregnancy has not been established.

The following symptoms may occur in neonates after maternal SSRI use in later stages of pregnancy: respiratory distress, cyanosis, apnoea, seizures, temperature instability, feeding difficulty, vomiting, hypoglycaemia, hypertonia, hypotonia, hyperreflexia, tremor, jitteriness, irritability, lethargy, constant crying, somnolence and difficulty sleeping. These symptoms could be due to either serotonergic effects or discontinuation symptoms. In a majority of instances the complications begin immediately or soon (< 24 hours) after delivery.

Epidemiological data have suggested that the use of SSRIs such as ARROW CITALOPRAM in pregnancy, particularly in late pregnancy, may increase the risk of persistent pulmonary hypertension in the newborn (PPHN).

Neonates should be observed if maternal use of ARROW CITALOPRAM continues into the later stages of pregnancy, particularly in the third trimester. Abrupt discontinuation should be avoided during pregnancy.

Breastfeeding

Safety and efficacy in lactation has not been established. ARROW CITALOPRAM is excreted into the breast milk.

Fertility

Animal data have shown that citalopram may affect sperm quality. Human case reports with some SSRIs have shown that an effect on sperm quality is reversible. Impact on human fertility has not been observed so far.

4.7 Effects on the ability to drive and use machines

ARROW CITALOPRAM may impair performance of skilled tasks. If affected these patients should not operate machinery or drive.

4.8 Undesirable effects

a. Summary of the safety profile

Adverse events observed with ARROW CITALOPRAM are most frequent during the first one or two weeks of treatment, and usually decrease in intensity and frequency as the depressive state improves.

For the following reactions a dose-response was discovered: Sweating increased, dry mouth, insomnia, somnolence, diarrhoea, nausea and fatigue.

b. Tabulated list of adverse reactions

Body system	**Undesirable effect**		
	Frequent	Less frequent	Frequency not known
Blood and lymphatic system disorders:			Thrombocytopenia
Immune system disorders			Hypersensitivity Anaphylactic reaction
Cardiovascular system:	Palpitations Tremor	Bradycardia	Tachycardia Electrocardiogram QT prolonged Ventricular Dysrythmia including torsade de pointes
Central nervous system	Sleep disturbances Paraethesia Restlessness Somnolence Headache Dizziness Fatigue	Agitation Confusion Impaired concentration Malaise Mania Convulsions Serotonin syndrome Neuroleptic malignant syndrome	Disturbance in attention Syncope Dyskinesia Taste disturbance Extrapyramidal disorder Akathisia Movement disorder

Endocrine/ Metabolism and nutrition disorders	Weight changes		Appetite decreased Increased appetite Hyponatraemia Hypokalaemia
Psychiatric Disorders:	Female and Male: Libido decreased		Agitation Anxiety Nervousness Confusional state Abnormal orgasm (female) Aggression Depersonalization Hallucination Panic attack Bruxism Restlessness Suicidal ideation Suicidal behaviour
Vascular Disorders			Haemorrhage Orthostatic hypotension
Gastro-intestinal	Nausea Constipation Diarrhoea Dyspepsia Dry mouth	Salivation	Vomiting Gastrointestinal haemorrhage (including rectal haemorrhage)
Renal and urinary disorders	Micturition disorders	Sexual dysfunction including ejaculation disorder Decreased libido Anorgasmia	

Hepatobilliary disorders		Hepatitis	
Musculoskeletal, connective tissue and bone disorders	Asthenia		Myalgia Arthralgia
Eye disorders	Accommodation disturbances	Mydriasis	
Ear and labyrinth disorders			Tinnitus
Respiratory, thoracic and mediastinal disorders:		Nasal congestion	Epistaxis
Skin and subcutaneous tissue disorders:	Sweating	Rash	Pruritis Urticaria Alopecia Purpura Photosensitivity Ecchymosis Angioedema
Reproductive system and breast disorders	Male: Ejaculation disorder		Female: Menorrhagia Male: Priapism Galactorrhoea Female: Metrorrhagia Postpartum haemorrhage
Other General disorders and administrative site conditions		Yawning	Oedema Pyrexia

Investigations			Liver function test abnormal

c. Description of selected adverse reactions

Suicide/suicidal thoughts or clinical worsening

Cases of suicidal ideation and suicidal behaviour have been reported during citalopram therapy or early after treatment discontinuation (see section 4.4).

Bone fractures

Epidemiological studies, mainly conducted in patients 50 years of age and older, show an increased risk of bone fractures in patients receiving SSRI and TCAs. The mechanism leading to the risk is unknown.

QT interval prolongation

Cases of QT prolongation and ventricular dysrhythmia including torsade de pointes have been reported during the post-marketing period, predominantly in patients of female gender with hypokalaemia, or with pre-existing QT inverval prolongation of other cardiac diseases (see section 4.3, 4.4, 4.5, 4.9 and 5.1).

Withdrawal symptoms seen on discontinuation of citalopram treatments

Discontinuation of citalopram commonly leads to withdrawal symptoms. Dizziness, sensory disturbances (including paraesthesia), sleep disturbances (including insomnia and intense dreams), asthenia, agitation or anxiety, nausea and/or vomiting, tremor and headache are the most commonly reported reactions. Generally these events are mild to moderate and are self-limiting, however, in some patients they may be severe and/or prolonged (see section 4.). It is therefore advised that when ARROW CITALOPRAM treatment is no longer required, gradual discontinuation by dose tapering should be carried out (see sections 4.2 and 4.4).

Children and adolescents under 18 years of age

Hostility, suicidal ideation and self-harm have been reported in children under 18 years of age (see section 4.3).

*This event has been reported for the therapeutic class of SSRIs/SNRIs (see section 4.4 and 4.6).

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare ~~professionals~~ providers are asked to report any suspected adverse reactions 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

4.9 KNOWN SYMPTOMS OF OVERDOSAGE PARTICULARS OF ITS TREATMENT <u>Overdose</u>

Symptoms of overdose:

Tiredness. weakness, sedation, dizziness, tremor, nausea, somnolence and sinus tachycardia, sedation, convulsion, QT interval prolongation, coma, vomiting, tremor, hypotension, cardiac arrest, nausea, serotonin syndrome, agitation, bradycardia, bundle branch block, QRS prolongation, hypertension, and mydriasis, torsade de pointes, stupor, sweating, cyanosis, hyperventilation, and atrial- and ventricular dysrhythmia.

Treatment of overdose:

Treatment is symptomatic and supportive.

There is no specific antidote to ARROW CITALOPRAM.

Monitoring of cardiac and vital signs is necessary and medical surveillance is advisable for about 24 hours.

5 PHARMACOLOGICAL ACTION PROPERTIES

5.1 Pharmacodynamic properties

Category and class: A.1.2 Psychoanaleptics (antidepressants)

Citalopram is a bicyclic pthalane derivative with antidepressant effect. Its effect is linked to the selective inhibition of specific serotonin (5-HT) re-uptake. Citalopram, primarily through its (S)-enantiomer, blocks 5-HT re-uptake, leading to potentiation of serotonergic activity in the central nervous system (CNS). Neither citalopram nor its metabolites have an effect on noradrenaline,dopamine and GABA reuptake. Citalopram has little or no antidopaminergic, antiadrenergic, antiserotonergic, antihistaminergic or anticholinergic properties.

Pharmacokinetic properties:

Absorption

Oral bioavailability is about 80% with maximum plasma levels being reached in 4 hours (range

1 to 6 hours).

Distribution

Volume of distribution is about 14 liters/kg (range I to 17 liters/kg). Time to reach steady state concentration is 1 to 2 weeks. Protein binding is about 80%.

Metabolism

Citalopram undergoes hepatic metabolism primarily involving the

cytochrome P450 (CYP3A4) and 2C19 (CYP2C19) isoenzymes and to a small extent cytochrome P450 2D6 (CYP2D6) isoenzymes. The metabolites inhibit the reuptake of serotonin, but are less potent than the parent molecule. Citalopram is excreted mainly via the liver with the remainder via the kidneys (approximately 20% of which 12% is unchanged medicine).

Elimination

Elimination half-life is 36 hours (range 28-42 hours).

Elderly patients

Longer half-lives and decreased clearance due to a reduced rate of metabolism has been demonstrated in the elderly.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Core

Crospovidone

Lactose 350 mesh

Magnesium stearate (vegetable grade)

Maize Starch

Microcrystalline cellulose ph 101

Povidone K30

Purified water

Coating

Opadry white OY-LS 28908

6.2 Incompatibilities

Not applicable

6.3 Shelf life

2 years/24months

6.4 **Special precautions for storage**

Store at room temperature or below 25^0C.

KEEP OUT OF REACH OF CHILDREN

Store in original package/container.

6.5 Nature and contents of container

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

three strips per carton.

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

6.6 Special precautions for disposal of a used medicine or waste materials derived from such medicine and other handling of the product.

No special requirements.

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

7 NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

Astral Pharma (Pty) Ltd

125 Meade Street

George

6529

South Africa

8 **REGISTRATION NUMBERS**:

ARROW CITALOPRAM 20 mg: 42/1.2/0719

ARROW CITALOPRAM 40 mg: 42/1.2/0718

9 DATE OF PUBLICATION OF THE PACKAGE INSERT FIRST AUTHORISATION

Registration date for Arrow Citalopram 20 mg: 12 June 2009

Registration date for Arrow Citalopram 40 mg: 12 June 2009

10 DATE OF REVISION OF THE TEXT

24 January 2024