1.3.2 Patient information leaflet.

SCHEDULING STATUS: S5

BIO CITALOPRAM 10 film-coated tablets

BIO CITALOPRAM 20 film-coated tablets

BIO CITALOPRAM 30 film-coated tablets

Citalopram Hydrobromide

Contains sugar (lactose monohydrate)

Read all of this leaflet carefully before you start taking BIO CITALOPRAM

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- BIO 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 BIO CITALOPRAM is and what it is used for

2. What you need to know before you take BIO CITALOPRAM

3. How to take BIO CITALOPRAM

4. Possible side effects

5. How to store BIO CITALOPRAM

6. Contents of the pack and other information

Bio Citalopram 10, 20, 30, film-coated tablets
(42/1.2/1009, 42/1.2/1010, 42/1.2/1067)
Each tablet contains citalopram hydrobromide equivalent
to 10, 20 or 20 mg citalopram respectively.

1. What BIO CITALOPRAM is and what it is used for

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

BIO CITALOPRAM is used for the treatment of:

- depression and prevention of relapse
- people suffering from panic attacks
- people suffering from obsessive-compulsive disorder (OCD).

2. What you need to know before you take BIO CITALOPRAM

Do not take BIO CITALOPRAM:

- If you are hypersensitive (allergic) to citalopram or any of the other ingredients of BIO CITALOPRAM (listed in section 6).
- If you are currently using a monoamine oxidase inhibitor (MAOI), for example, moclobemide, linezolid or selegiline. These are medicines used in the treatment of depression. At least 14 days should elapse between discontinuing the MAOI and initiating therapy with BIO CITALOPRAM. MAOIs should not be introduced for 7 days after discontinuation of BIO CITALOPRAM.
- If you are also taking a medicine containing antipsychotics (e.g. phenothiazine derivatives, pimozide, haloperidol), tricyclic antidepressants. Talk to your doctor.
- If you are under 18 years of age.
- If you are pregnant, trying for a baby or breastfeeding.
- If you suffer from severe kidney problems.
- If you have a condition where your heart rhythm is affected and or you are using medicines to regulate your heart rate (QT-interval prolongation medicines known as Class IA and III antidysrhythmics).

- If you are using certain antibiotic medicines to treat an infection (e.g. moxifloxacin, erythromycin, anti-malarial treatment particularly halofantrine).
- If you are using certain antihistamine medicines used to treat allergy (astemizole, mizolastine).
- If you are born with or have had an episode of abnormal heart rhythm (seen at ECG; an examination to evaluate how the heart is functioning).

Warnings and precautions

Special care should be taken with BIO CITALOPRAM:

- If you are under 18 years of age
- If you are an elderly patient
- If you suffer from liver or kidney problems.
- If you suffer from panic disorder
- If you suffer from low blood levels of sodium.
- If you suffer from Mania
- If you have seizures, a history thereof or are being treated with ECT (electroconvulsive therapy).
- Diabetes (you may need an adjustment of your antidiabetic therapy).
- If you suffer from epilepsy or a history of seizures or fits.
- If you suffer from eye problems, such as certain types of glaucoma.
- If you have a bleeding disorder or have ever suffered from bleeding in the stomach or intestine or if you are pregnant.
- Medicines like BIO 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.
- If you have ever had an allergic reaction to this or any other medicine.
- 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 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 are taking any other medicines, including those available to buy without a prescription, herbal and complementary medicines.
- If you are having any kind of surgery, including dental and emergency treatment, tell your doctor, dentist or surgeon you are taking BIO CITALOPRAM.
- If you are in the early phase of treatment. You should be carefully monitored for improvement of your depression because suicide is an inherent risk in depressed patients.

As with other medicines used to treat depression or related diseases, the improvement is not achieved immediately. After the start of BIO 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 with psychiatric conditions who were treated with an antidepressant.

Children and adolescents

BIO 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 BIO 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 BIO CITALOPRAM tablets. Also, the long-term safety effects concerning growth, maturation and cognitive and behavioural development of BIO CITALOPRAM in this age group have not yet been demonstrated.

Other medicines and BIO CITALOPRAM

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

- Monoamine oxidase inhibitors (MAOI), tricyclic anti-depressants, (medicine used for treatment of depression) such as selegiline, moclobemide, linezolid, amitriptyline or other antipsychotic medicine.
- Lithium (used to prevent and treat mania) and tryptophan (an anti-depressant)
- Tramadol (a pain killer)
- Sumatriptan (used to treat migraine)

- The herbal remedy St John's Wort (Hypericum perforatum). This should not be taken at the same time as Citalopram.
- 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).
- Linezolid (an antibiotic).
- Imipramine and desipramine (medicine used for the treatment of depression or bed-wetting).
- Other serotonergic medicines or medicines with serotonergic activity.
- Warfarin (medicine used in the treatment of blood clotting).
- Cimetidine (medicine used for heartburn and stomach ulcers).
- CYP2C19 inhibitors (e.g. omeprazole, esomeprazole, fluconazole, fluvoxamine, lansoprazole, ticlopidine)
- Mefloquine (used to treat malaria).
- Bupropion (used to treat depression).
- Neuroleptics (thioxanthenes and butyrophenones) (used in the treatment of schizophrenia).
- Metoprolol, a beta blocker used to treat migraine, some heart conditions and high blood pressure. The effects of either drug could be increased, decreased or altered.
- Medicines for heart rhythm problems or medicines that may affect the heart's rhythm, e.g. such as:
- Class IA and III antiarrhythmics, antipsychotics (e.g. phenothiazine derivatives, fentiazine derivatives, pimozide, haloperidol),
- tricyclic antidepressants
- certain antimicrobial agents (e.g. sparfloxacin, moxifloxacin, erythromycin IV, pentamidine,
- anti-malarial treatment particularly halofantrine
- certain antihistamines (astemizole, mizolastine).

BIO CITALOPRAM with food or drink

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

The effects of alcohol might be increased by the concurrent use of BIO CITALOPRAM.

Pregnancy, breastfeeding and fertility:

If you are pregnant or breastfeeding, think you may be pregnant or planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Pregnancy

Safety and efficacy in pregnancy and breastfeeding has not been established.

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.

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.

If you take Citalopram Tablets 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.

Breastfeeding

BIO CITALOPRAM is excreted into the breast milk.

Fertility

Citalopram has been shown to reduce the quality of sperm in animal studies. Theoretically, this could affect fertility, but impact on human fertility has not been observed as yet.

Driving and using machines

BIO CITALOPRAM can cause drowsiness, dizziness and problems with eye-sight. Make sure your reactions are normal before driving, operating machinery or doing any other jobs which could be dangerous if you are not fully alert or able to see properly.

BIO CITALOPRAM contains lactose

BIO CITALOPRAM contains lactose. Patients with the rare hereditary conditions of lactose or galactose intolerance should not take BIO CITALOPRAM.

BIO CITALOPRAM contains lactose monohydrate and persons that are lactose intolerant (the inability to digest and metabolise lactose) can experience bloating, flatulence and abdominal pain when taking BIO CITALOPRAM tablets.

3. How to take BIO CITALOPRAM

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

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

The dose of BIO CITALOPRAM will be different for different patients, and ranges from 10 – 40 mg.

Your doctor will decide on the suitable dose and the duration of your treatment based on your specific needs and medical condition.

If you have the impression that the effect of BIO CITALOPRAM is too strong or too weak, talk to your doctor or pharmacist.

Elderly:

10 to 20 mg a day as a single dose. The recommended maximum daily dose for the elderly is 20 mg.

Liver failure:

Mild to moderate liver failure:

An initial dose of 10 mg a day as a single dose for two weeks is recommended. The doctor may increase the dose to a maximum of 20 mg daily depending on your response to BIO CITALOPRAM.

Severe liver failure:

Your doctor will be monitoring you closely while you are on BIO CITALOPRAM. The maximum recommended dose is 20 mg daily.

If you take more BIO 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.

Symptoms of overdosage may include:

- Nausea (feeling sick)
- Vomiting
- Sweating
- Drowsiness
- Seizures

- Unconsciousness
- Fatal heart beats
- Tremor
- Irregular heart beat
- Change in heart rhythm
- Change in blood pressure
- Serotonin syndrome
- Agitation
- Dizziness
- Enlarged eye pupils
- Bluish skin
- Breathing too quickly

If you forget to take BIO CITALOPRAM

Do not take a double dose to make up for the forgotten individual doses. Continue to take the next tablet at the usual time. If you have trouble remembering when to use your medicine, ask your pharmacist for advice.

If you stop taking BIO CITALOPRAM

Withdrawal reactions can occur.

Frequent symptoms include dizziness, paraesthesia (abnormal sensations of the skin such as burning or prickling), headache, anxiety, nausea, 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). Abrupt discontinuation of treatment with

BIO CITALOPRAM should be avoided. The majority of symptoms experienced on withdrawal of BIO CITALOPRAM are non-serious and self-limiting. If therapy with BIO CITALOPRAM is to be discontinued, it is recommended that the dose be decreased gradually in order to prevent the possibility of a withdrawal syndrome.

5. POSSIBLE SIDE EFFECTS

BIO CITALOPRAM can have side effects.

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

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

- Difficulty in breathing.
- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which causes difficulty in swallowing or breathing.
- Severe itching of the skin (with raised lumps).
- Fast, irregular heartbeat, fainting which could be symptoms of a life-threatening condition known as Torsades de Pointes.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to BIO CITALOPRAM. 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:

- Deficiency of platelets in the blood (Thromocytopenia)
- Low levels of potassium in the bloodstream

- Low levels of sodium in the bloodstream
- Temporary loss of consciousness (syncope)
- Irregular heartbeat
- Rapid, strong or irregular heartbeat (Palpitations)
- Convulsions (grand mal)
- Escape of blood from a ruptured blood vessel (haemorrhage)
- Serotonin syndrome is a potentially life-threatening reaction to an elevation of serotonin in the body. Medicines that act to block the reuptake of serotonin, slow breakdown, or increase release are implicated in the development of symptoms. The syndrome may be caused by the misuse and/or combination of a variety of medications. if you experience high fever, agitation, confusion, trembling or abrupt contractions of muscles. These may be signs of a rare condition called serotonin syndrome.
- You can develop a rare and unpredictable reaction known as neuroleptic malignant syndrome (NMS). The syndrome is characterized by fever, muscular rigidity and altered mental status
- Hepatitis
- Suicidal ideation and self-harm have been reported in children.
- Producing less urine than is normal for you
- Slowness of your heart beat
- Mania, if your behaviour changes because you feel elated or over excited.
- Rash
- Tiredness, confusion and twitching of your muscles. These may be signs of a low blood level of sodium.
- Low blood pressure
- Bleeding in the gastrointestinal tract, from the mouth to the rectum

- Liver function test abnormal
- More bleeding than normal after birth of baby (postpartum haemorrhage)

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:

- Reduce desire to eat
- Loss of weight
- Decreased sex drive
- Anxiety
- Nervousness
- Confusion
- For females, failing to reach an orgasm
- Abnormal dreams
- Reduced emotions, indifference (apathy)
- Sleepiness
- Sleep disturbance
- Tremor
- Drowsiness
- Headache
- Dizziness
- Agitation
- Paraesthesia (abnormal sensations of the skin such as burning or prickling)
- Impaired concentration
- Migraine

- Loss of memory (amnesia)
- Ringing in the ears (tinnitus)
- Yawning
- rhinitis
- Nausea
- Constipation
- Diarrhoea
- Dry mouth
- Vomiting
- Upper abdominal pain or discomfort (Dyspepsia)
- Stomach pain
- Flatulence (wind)
- Salivation
- Asthenia (weakness or loss of energy)
- Sweating
- Itching of the skin
- Pain in muscles and joints
- For men, problems with ejaculation and erection
- Fatigue

Less frequent side effects:

- Increased appetite
- Weight increase
- Aggression
- Depersonalisation

- Hallucination
- Increased sex drive
- Panic attack
- Involuntary habitual grinding of the teeth, typical during sleep (bruxism)
- Restlessness
- Abnormality or impairment of voluntary movement (dyskinesia)
- Taste disturbance
- Mydriasis (a long continued or excessive dilation of the pupil)
- Coughing
- Loss of hair (alopecia)
- A rash of purple spots on the skin caused by internal bleeding from small blood vessels
- Sensitivity to sunlight
- Abnormal heavy bleeding at menstruation
- Oedema

Frequency unknown side effects

- Movement disorder, that makes it hard for you to stay still (akathisia)
- Eye-sight disturbances
- Bleeding from the nose (epistaxis)
- A discoloration of the skin resulting from bleeding underneath, typically caused by bruising (ecchymosis)
- Swelling around the eyes and lips (angioedemas)
- Abnormal bleeding that occurs between periods or that is not associated with menstruation (metrorrhagia)
- Persistent and painful erection of the penis (priapism)

- milky nipple discharge unrelated to the normal milk production of breast-feeding
- Temperature above the normal range due to increase in the body temperature (pyrexia)
- Malaise (a vague feeling of bodily discomfort)

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 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 BIO CITALOPRAM.

5. How to store BIO CITALOPRAM

- Store at or below 25 °C.
- KEEP ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use the tablets after the expiry date printed on the carton and blister.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What BIO CITALOPRAM contains

The active substance is citalopram hydrobromide

The other ingredients are maize starch, lactose monohydrate, croscarmellose sodium, glycerin, copolyyidone, magnesium stearate, microcrystalline cellulose and opdry white.

What BIO CITALOPRAM looks like and contents of the pack

BIO CITALOPRAM 10: Round, biconvex, white coloured film-coated tablets, diameter 5,5 mm, with marking 10 on one side.

BIO CITALOPRAM 20: Oval, biconvex, scored, white coloured film-coated tablets, dimensions 8 x 5,5 mm, with marking 20 on one side.

BIO CITALOPRAM 30: Oval, biconvex, scored, white coloured film-coated tablets, dimensions 12,25 x 6 mm, with marking 30 on one side.

BIO CITALOPRAM 10, 20 and 30 tablets are available in transparent PVC/PVdC/Aluminium blister packs of 30 tablets. Each blister strip contains 10 tablets and 3 blister strips are packed in an outer carton.

Holder of Certificate of Registration

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