AMENDED PROPOSED PATIENT INFORMATION LEAFLET (CLEAN COPY)

SCHEDULING STATUS

S5

ACCORD ESCITALOPRAM 10 (film-coated tablets)

ACCORD ESCITALOPRAM 20 (film-coated tablets)

Escitalopram (as oxalate)

Sugar free

Read all of this leaflet carefully before you start taking ACCORD ESCITALOPRAM

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

1. What ACCORD ESCITALOPRAM is and what it is used for

ACCORD ESCITALOPRAM is used to treat depression (major depressive episodes) and anxiety disorders (such as panic disorder with or without agoraphobia, social anxiety disorder, generalised anxiety disorder and obsessive-compulsive disorder).

2. What you need to know before you take ACCORD ESCITALOPRAM

Do not take ACCORD ESCITALOPRAM

- If you are allergic (hypersensitive) to escitalopram or any of the other ingredients of ACCORD ESCITALOPRAM (see WHAT ACCORD ESCITALOPRAM CONTAINS).
- If you take other medication that belongs to a group of medicines called Monoamine Oxidase Inhibitors (MAOI), e.g. selegiline (used in the treatment of Parkinson's disease), moclobemide (used in the treatment of depression) and linezolid (an antibiotic).
- If you are under the age of 18 years.

If you have taken any of these medicines you will need to wait 14 days before you start taking your ACCORD ESCITALOPRAM tablets. After stopping ACCORD ESCITALOPRAM, you must allow 7 days before taking any of these medicines.

- 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).
- If you take medicines for heart rhythm problems or that may affect the heart's rhythm (see section 2 'Other medicines and ACCORD ESCITALOPRAM')
- at the same time as taking linezolid.
- at the same time as taking pimozide.

Warnings and precautions

Take special care with ACCORD ESCITALOPRAM

Please inform your doctor if you have any other condition or illness, as your doctor may need to take this into consideration.

Please inform your doctor:

- If you have or ever had a condition known as mania (abnormally elevated or irritable mood). Some patients with manic-depressive illness may enter into a manic phase This is characterised by unusual and rapidly changing ideas, inappropriate happiness and excessive physical activity If you experience this, contact your doctor.
- If you experience increased anxiety or restlessness.
- if you suffer or have suffered from heart problems or have recently had a heart attack

- if you have a low resting heartrate and/or you know that you may have salt depletion as a result of prolonged severe diarrhoea and vomiting (being sick) or usage of diuretics (water tablets).
- if you have or have previously had eye problems, such as certain kinds of glaucoma (increased pressure in the eye).
- If you experience epileptic fits, if you have epilepsy or if you or notice an increase in frequency of epileptic fits after taking ACCORD ESCITALOPRAM.
- If you have diabetes mellitus, treatment with ACCORD ESCITALOPRAM may alter blood sugar control. Your diabetic medication dosage (insulin and/or oral medication) may need to be adjusted.
- If you have a bleeding disorder or if you experience bruising easily.
- If you are receiving electroconvulsive treatment.
- If you are feeling suicidal or feel like harming yourself. If you are depressed and/or have anxiety disorders you can sometimes have thoughts of harming or killing yourself. These feelings may be increased when first starting ACCORD ESCITALOPRAM, since ACCORD ESCITALOPRAM takes time to work, usually about two weeks but sometimes longer.
- If you experience a rapid change in mental state with confusion, agitation, hyperactivity, fast or irregular heartbeat**,** shivering, muscle twitches and high fever.
- If you have kidney or liver impairment.
- If you are older than 65 years of age.
- When stopping ACCORD ESCITALOPRAM, the dose should be gradually reduced over a period of one or two weeks as instructed by your doctor.

Other medicines and ACCORD ESCITALOPRAM

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

Please inform your doctor or pharmacist if you are taking any of the following medication:

- Cimetidine (used to treat stomach ulcers).
- Medication which belongs to a group of medicines called Monoamine Oxidase Inhibitors (MAOIs) e.g. selegiline (used in the treatment of Parkinson’s disease), moclobemide (used in

the treatment of depression) and linezolid (an antibiotic). If you have taken any of these medicines you will need to wait 14 days before you start taking ACCORD ESCITALOPRAM. After stopping ACCORD ESCITALOPRAM you must allow 7 days to elapse before taking any of these medicines.

- Sumatriptan (used to treat migraines) and tramadol (pain relieving medication), lithium (used to treat mania) or tryptophan (used to treat depression).
- Warfarin or other anticoagulant medicines used to thin the blood.
- St John's Wort (Hypericum perforatum - a herbal remedy used against low spirits); the risk of side effects may increase if you take Cipralex concomitantly with herbal remedies containing St John´s Wort
- Medicines that affect the clotting of your blood such as anti-inflammatory pain relievers.
- Medicines used to regulate the heart rhythm such as flecainide, propafenone and metoprolol (when used in cardiac failure), or if you take medicines for heart rhythm problems or medicines that may affect the heart’s rhythm.
- Antidepressant medicines such as desipramine, imipramine, clomipramine, nortriptyline and bupropion.
- Antipsychotic medicines such as risperidone, thioridazine and haloperidol.
- Anti-epileptic medication.
- Medicines used to treat malaria such as mefloquin.
- Medicines used to treat schizophrenia and psychosis such as phenothiazines, thioxanthenes and butyrophenones

ACCORD ESCITALOPRAM with food, drink and alcohol

ACCORD ESCITALOPRAM can be taken with or without food.

ACCORD ESCITALOPRAM has been shown not to increase the effects of alcohol. Nevertheless, it is recommended not to drink alcohol during treatment with ACCORD ESCITALOPRAM.

Pregnancy and Breastfeeding

Do not take ACCORD ESCITALOPRAM if you are pregnant or breastfeeding your baby. Inform your doctor immediately if you are pregnant or planning to become pregnant while you are taking

ACCORD ESCITALOPRAM.

If you are taking ACCORD ESCITALOPRAM during the last 3 months of your pregnancy, you should be aware that the following effects may be seen in your new born baby: trouble with breathing, bluish skin, epileptic fits, body temperature changes, feeding difficulties, vomiting, low blood sugar, stiff or floppy muscles, vivid reflexes, tremor, jitteriness, irritability, lethargy, constant crying, sleepiness and sleeping difficulties. If your new born baby has any of these symptoms which can occur less than 24 hours after delivery, please inform your doctor immediately. There may also be a higher risk of persistent pulmonary hypertension in the newborn.

If you take ACCORD ESCITALOPRAM 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 ACCORD ESCITALOPRAM so they can advise you.

Do not take ACCORD ESCITALOPRAM if you are breastfeeding.

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

Driving and using machines

ACCORD ESCITALOPRAM can make you feel dizzy, drowsy or sleepy. Do not drive or operate machinery until you know how ACCORD ESCITALOPRAM affects you.

3. How to take ACCORD ESCITALOPRAM

Always take ACCORD ESCITALOPRAM exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The usual dose is one 10 mg tablet a day. Your doctor may adjust your dose, depending on your response to treatment.

Try to take ACCORD ESCITALOPRAM at the same time each day to avoid missing any doses. It may take a few weeks before you start to feel better. Continue to take ACCORD ESCITALOPRAM even if it takes some time before you feel any improvement in your condition.

Do not share medicines prescribed for you with others.

Your doctor will tell you how long your treatment with ACCORD ESCITALOPRAM will last. If you have the impression that the effect of ACCORD ESCITALOPRAM is too strong or too weak, talk to your doctor or pharmacist.

If you take more ACCORD ESCITALOPRAM than you should

Do not take more ACCORD ESCITALOPRAM 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.

If you forget to take ACCORD ESCITALOPRAM

If you forget to take a dose, just take your next dose as normal.

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

Effects when treatment with ACCORD ESCITALOPRAM is stopped

Do not change or stop the dose of ACCORD ESCITALOPRAM without talking to your doctor first. Continue to take ACCORD ESCITALOPRAM for as long as your doctor recommends. Your doctor will reduce your dose gradually over a few weeks, as stopping ACCORD ESCITALOPRAM suddenly can cause adverse effects.

If you get severe discontinuation symptoms when you stop taking ACCORD ESCITALOPRAM , please contact your doctor. He or she may ask you to start taking your tablets again and come off them more slowly.

You can have the following symptoms when stopping the medicine: Feeling dizzy, feelings like pins and needles, burning sensations and (less commonly) electric shock sensations, including in the head, sleep disturbances (vivid dreams, nightmares, inability to sleep), feeling anxious, headaches, feeling sick (nausea), sweating (including night sweats), feeling restless or agitated, tremor (shakiness), feeling confused or disorientated, feeling emotional or irritable, diarrhoea, visual disturbances, fluttering or rapid heartbeat (palpitations).

4. Possible side effects

ACCORD ESCITALOPRAM can have side effects.

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

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

- Skin rash or hives, difficulty breathing, swelling of your face, lips, tongue or throat.
- Hepatitis characterised by nausea, vomiting, diarrhoea or loss of appetite.
- Epileptic fits
- Serotonin syndrome characterised by a rapid change in mental state with confusion, agitation, hyperactivity, shivering, muscle twitches and high fever
- Thoughts of harming or killing yourself.

These are all very serious side effects. If you have them, you may have had a serious reaction to ACCORD ESCITALOPRAM. 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:

- Gastrointestinal or unusual bleeding.
- Changes in the way your heart beats.
- Difficulty breathing.
- Difficulty urinating.

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

Tell your doctor if you notice any of the following:

Frequent side-effects

- Increased or decreased appetite, increased weight.

- Difficulty falling asleep, anxiety, restlessness, abnormal dreams, confusion, agitation, teeth grinding, nervousness, panic attack, aggression, abnormal dreams.
- Feeling sleepy, dizziness, tremor or shaking.
- Blocked or runny nose, yawning.
- Nausea, vomiting, diarrhoea, constipation, dry mouth, heartburn.
- Increased sweating.
- Muscle and joint pain.
- Decreased sex drive, delayed ejaculation in males, difficulty in erection, difficulties achieving orgasm, in females.
- Fatigue.
- Fever.

Less-frequent side-effects

- Rash, itching, hives or swelling under the skin, bruising, hair loss, sensitivity to light.
- Swelling in the arms or legs.
- Decreased weight.
- Headache.
- Abnormal or blurred vision.
- Gastrointestinal bleeding, taste disturbance.
- Vaginal bleeding.

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. 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: https://www.sahpra.org.za/Publications/Index/8.

By reporting side effects, you can help provide more information on the safety of ACCORD ESCITALOPRAM.

5. How to store ACCORD ESCITALOPRAM

Store in a cool, dry place at or below 25 °C.

STORE ALL MEDICINE OUT OF REACH OF CHILDREN.

Keep the blisters in the carton until required for use.

Do not use after the expiry date stated on the 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 ACCORD ESCITALOPRAM contains:

- The active substance is escitalopram.
- The other ingredients are croscarmellose sodium, purified talc, colloidal anhydrous silica, magnesium stearate, microcrystalline cellulose, hypromellose E5, hypromellose (E-15), macrogol 400 and titanium dioxide.

What ACCORD ESCITALOPRAM looks like and contents of the pack:

ACCORD ESCITALOPRAM 10: White to off-white, oval, biconvex, film-coated tablets with an inscription of ‘1’ and ‘0’ on either side of the break-line and plain on the other side.
ACCORD ESCITALOPRAM 20: White to off-white, oval, biconvex, film-coated tablets with a break-line on one side and plain on the other side.

ACCORD ESCITALOPRAM 10: Film-coated tablets are packed in either PVC/PE/PVdC-Alu, and/or Alu-Alu blister strips of 7 tablets per strip. 4 strips are packed in a unit carton as a pack size of 28.
ACCORD ESCITALOPRAM 20: Film-coated tablets are packed in either PVC/PE/PVdC-Alu, and/or Alu-Alu blister strips of 7 tablets per strip. 4 strips are packed in a unit carton as a pack size of 28.

Holder of certificate of registration

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