PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S5

ZYTOMIL 5 mg, coated tablet

ZYTOMIL 10 mg, coated tablet

ZYTOMIL 15 mg, coated tablet

ZYTOMIL 20 mg, coated tablet

Escitalopram

ZYTOMIL is sugar-free

Read all of this leaflet carefully before you start taking ZYTOMIL

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

ZYTOMIL is an antidepressant which belongs to the SSRI group (selective serotonin reuptake inhibitors).

ZYTOMIL is used to treat:

- Major depression
- Panic disorder with or without agoraphobia (e.g. fear of leaving the house, entering shops, being in crowds and in public places)
- Social anxiety disorder (social phobia)
- Generalised anxiety disorder
- Obsessive-compulsive disorder.

2. What you need to know before you take ZYTOMIL

Do not take ZYTOMIL:

- if you are hypersensitive (allergic) to escitalopram, or to any of the ingredients of ZYTOMIL (see section 6)
- If you are under the age of 18 years (see Take special care with ZYTOMIL).
- If you are taking any other medicines for depression such as monoamine oxidase inhibitors (MAOI). At least 14 days should pass between stopping such medication and starting with ZYTOMIL (see Other medicines with ZYTOMIL).
- If you are taking other MAO inhibitors such as selegiline (used in the treatment of Parkinson's disease), moclobemide (used in the treatment of depression) and linezolid (an antibiotic).
- If you are taking the antibiotic linezolid, as your dosage may need to be adjusted.
- If you are taking pimozide (an antipsychotic medicine), as it may lead to heart

problems.

- If you were born with or have had an episode of abnormal heart rhythm (as determined by an ECG: a test performed to check for problems with your heart).
- If you take medicines for heart rhythm problems or that may affect the heart's rhythm (see Other medicines with ZYTOMIL).
- If you are pregnant or breastfeeding your baby (see Pregnancy and breastfeeding).
- If you have a condition called porphyria (a rare blood disorder with symptoms such as severe abdominal pain, pain in your chest, back or legs, vomiting or a rapid heartbeat).

Warnings and precautions

Take special care with ZYTOMIL:

- ZYTOMIL should not be used by children and adolescents under 18 years (see Do not take ZYTOMIL). Patients under 18 are more likely to experience side effects such as suicide attempt, suicidal thoughts and hostility (mainly aggression, oppositional behaviour and anger) when they take ZYTOMIL. The long-term safety effects concerning growth and development of ZYTOMIL in this age group have not yet been studied.
- 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 take time to work (usually about two weeks but sometimes longer).
- If you have previously had thoughts about killing or harming yourself.

- Your doctor will monitor your treatment and your progress carefully for the first few weeks. If you have any thoughts of harming or killing yourself at any time, contact your doctor immediately 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.
- If you suffer or have suffered from heart problems or have recently had a heart attack.
- If your treatment is to be discontinued. Do not stop taking ZYTOMIL without talking to your doctor. If you stop taking your ZYTOMIL tablets suddenly, you may experience withdrawal effects (see If you stop taking ZYTOMIL).
- If you are an elderly person (older than 65 years).
- If you have liver or kidney impairment.
- If you get seizures (epilepsy) during treatment with ZYTOMIL, or have a history of epilepsy and there is an increase in seizure frequency your treatment will need to be gradually discontinued.
- If you are receiving electroconvulsive treatment for your depression.
- If you have episodes of mania (overactive behaviour or thoughts).
- If you have pre-existing slow heart rate.
- If you are a diabetic (high blood sugar) as your dose of diabetic medicine may need to be adjusted.
- If your anxiety increases during treatment. Some patients with panic disorder may experience increased anxiety symptoms at the start of treatment with ZYTOMIL. This reaction usually disappears within two weeks of continued

treatment. Your doctor will start you on a lower dose in order to reduce the likelihood of increased anxiety attacks.

- If you experience a feeling of restlessness, usually within the first few weeks of treatment (see Possible side effects).
- If you have a decreased level of sodium in the blood as a result of severe diarrhoea and vomiting or use of diuretics.
- If you are taking other similar medicines for a mental condition, anti-inflammatory drugs (NSAIDs) or aspirin and have a history of bleeding disorders as ZYTOMIL may increase the risk of bleeding.
- if you are pregnant and your doctor has prescribed ZYTOMIL for you in the month before your baby is due, there is a risk of excessive bleeding after childbirth
- If you are taking medicine to prevent the clotting of blood (e.g. warfarin) or are prone to bleed easily as ZYTOMIL may increase the risk of bleeding.
- If you take medicines to treat pain (e.g. tramadol), or migraine (e.g. sumatriptan) as you may be at risk of serotonin syndrome (a condition with symptoms such as agitation or restlessness, dilated pupils and heavy sweating).
- If you take medicines containing lithium or tryptophan as the effects of ZYTOMIL may be increased (see Other medicines with ZYTOMIL).
- If you suffer from glaucoma (an eye condition that can result in the damage of the optic nerve).
- ZYTOMIL should not be used with monoamine oxidase inhibitors, imipramine, other medicines that increase serotonin levels, moclobemide, alcohol, warfarin or cimetidine (see Other medicines with ZYTOMIL and ZYTOMIL with food and drink).

- If you are taking St. John's Wort (a herbal medicine) as this may result in unwanted side effects (see Other medicines with ZYTOMIL).
- If you are 50 years or older. An increased risk of bone fractures has been observed in patients aged 50 years or older taking ZYTOMIL.

Other medicines and ZYTOMIL

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

- Do not take any other medicines to treat depression (for example monoamine oxidase inhibitors, imipramine, other serotonergic medicines (a medicine that affects the release of serotonin, a type of hormone), linezolid and moclobemide) without consulting your doctor as they may interact with ZYTOMIL (see Do not take ZYTOMIL).
- Do not take ZYTOMIL if you take medicines that may affect the heart's rhythm such as pimozide (see Do not take ZYTOMIL).

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

- Selegiline (used to treat Parkinson's disease) increases the risk of side effects.
- Medicines that prolong or affect the heart rhythm (phenothiazide derivatives, pimozide, haloperidol), tricyclic antidepressants, certain antimicrobial medicines (sparfloxacin, moxifloxacin, erythromycin IV, pentamidine, antimalarial treatment particularly halofantrine), certain medicines to treat allergies (mizolastine), as they may affect the way ZYTOMIL works (see Do not take ZYTOMIL).
- Medicines used to treat heart burn or stomach ulcer such as cimetidine interact

with the breakdown of escitalopram, and the dose of ZYTOMIL may need to be changed.

- Sumatriptan and similar medicines (used to treat migraine) and tramadol (used against severe pain). These medicines may increase the risk of side effects (see Take special care with ZYTOMIL).
- Lithium (used in the treatment of manic-depressive disorder) and tryptophan (used by the body to generate serotonin which helps control your mood and sleep).
- Neuroleptics (medicines used to treat schizophrenia and other severe mental problems e.g. phenothiazines, thioxanthenes and butyrophenones), mefloquine (an antimalarial medicine), bupropion (an antidepressant medicine) and tramadol (medicine used to treat moderate to severe pain) and antidepressants (tricyclics, SSRIs) due to a possible risk of a lowered threshold for seizures.
- Flecainide, propafenone, and metoprolol (used in cardiovascular disease); desipramine, clomipramine, and nortriptyline (antidepressants); and risperidone, thioridazine, and haloperidol (antipsychotics). The dosage of ZYTOMIL may need to be adjusted.
- St. John's Wort (*Hypericum perforatum*) - a herbal remedy used for depression (see Take special care with ZYTOMIL).
- Do not use alcohol while taking ZYTOMIL.
- Medicines which lower potassium or magnesium levels in the blood as they may result in unwanted side effects.
- Pimozide, an antipsychotic medicine, as it may affect the heart's rhythm (see Do not take ZYTOMIL).

- Aspirin and non-steroidal anti-inflammatory drugs (medicines used for pain relief or to thin the blood) may increase the risk of bleeding.
- Warfarin (medicine used to thin the blood). Your doctor may check the coagulation time of your blood when starting and discontinuing ZYTOMIL in order to verify that your dose of anti-coagulant is still adequate.

ZYTOMIL with food and drink

ZYTOMIL can be taken with or without food.

Avoid consuming alcohol whilst taking ZYTOMIL (see Other medicines with ZYTOMIL).

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before using ZYTOMIL.

If you take ZYTOMIL 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 ZYTOMIL so they can advise you.

You should not use ZYTOMIL if you are pregnant or breastfeeding (see Do not take ZYTOMIL).

Driving and using machines:

ZYTOMIL may impair your ability to drive and use machinery. Take care if you feel dizzy, tired or drowsy while using ZYTOMIL.

It is not always possible to predict to what extent ZYTOMIL may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which ZYTOMIL affects them.

3. How to take ZYTOMIL

Do not share medicines prescribed for you with any other person. Always use ZYTOMIL exactly as your doctor has instructed. You should check with your doctor or pharmacist if you are unsure.

Major depression:

The usual dose of ZYTOMIL is 10 mg taken as one daily dose. The dose can be increased by your doctor to a maximum of 20 mg per day, depending on your response to treatment.

Panic disorders, with or without agoraphobia:

The starting dose of ZYTOMIL is 5 mg as one daily dose for the first week before increasing the dose to 10 mg per day. The dose may be further increased by your doctor to a maximum of 20 mg per day, depending on your response to treatment.

Social anxiety disorder (social phobia):

The usual dose of ZYTOMIL is 10 mg taken as one daily dose. Depending on your response to the treatment, your doctor may increase the dose to a maximum of 20 mg daily.

Generalised anxiety disorder:

The usual dose of ZYTOMIL is 10 mg taken as one daily dose. The dose may be increased by your doctor to a maximum of 20 mg per day, depending on your response to treatment.

Obsessive-compulsive Disorder (OCD):

The usual dose of ZYTOMIL is 10 mg taken as one daily dose. The dose may be increased by your doctor to a maximum of 20 mg daily, depending on your response to treatment.

Children and adolescents (below 18 years of age):

ZYTOMIL should not be given to children and adolescents under the age of 18 (see Do not take ZYTOMIL).

Your doctor will tell you how long your treatment with ZYTOMIL will last. Do not stop treatment early because you may experience unwanted side effects.
If you have the impression that the effect of ZYTOMIL is too strong or too weak, tell your doctor or pharmacist.

If you take more ZYTOMIL 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.
Take this leaflet and any remaining tablets with you so that your doctor may know what you have taken. In the event of overdose, your doctor will treat the symptoms.

Symptoms of overdose may include:

- increasing tiredness, weakness, sedation, dizziness, tremor, nausea, sleepiness, drowsiness and increase heart rate.

If you forget to take ZYTOMIL:

Take the missed dose as soon as possible. However, if it is almost time for your next dose, continue to take the next tablet at the usual time. **Do not take a double dose to make up for forgotten individual doses.**

If you stop taking ZYTOMIL

Do not stop taking your medicine abruptly as this may result unwanted side effects. Your doctor will prescribe the gradual lowering of the dose.

The most common reported reactions are dizziness, tingling (pins and needles), numbness, sleep disturbances (including insomnia and nightmares), agitation or anxiety, nausea and/or vomiting, tremor (shaking), confusion, sweating, headache, diarrhoea, palpitations (rapid heartbeat), emotional instability, irritability and visual disturbances. These events are mild to moderate however, in some patients they may be severe.

4. Possible side effects

ZYTOMIL can have side effects.

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

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

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching

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

- Easy or excessive bruising, superficial bleeding or prolonged bleeding from cuts, nose, gums or blood in urine or stools
- Chronic pain and/or tremors
- Having the feeling of great excitement or euphoria, delusions, overactivity, hostility, suicidal thoughts (thinking of killing yourself) and suicidal behaviour, having hallucinations (strange visions or sounds)
- Seizures (fits), shivering, rapid or slow heartbeat, increased sweating, confusion, mood swings, fever, tremor, involuntary eye movements, spasmodic jerky contraction of groups of muscles, difficulty moving, abnormal coordination or balance (known as serotonin syndrome, due to too much serotonin in the brain)
- Fast, irregular heartbeat, fainting which could be symptoms of a life-threatening condition known as *torsades de pointes*, chest pain
- Gastrointestinal bleeding, symptoms which may include vomiting red blood, vomiting black blood, bloody stool or black stool
- Yellowing of the skin and the whites of the eyes (jaundice)
- Difficulty urinating, inability to completely empty the bladder.

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:

- Increased or decreased appetite, weight gain
- Feeling anxious, restlessness or need to keep moving, abnormal dreams, decrease in libido
- Sleep disturbance, sleepiness, dizziness, drowsiness, inability to sleep, sensations of tingling, burning, pricking (pins and needles), or numbness
- Sinusitis, yawning
- Nausea, constipation, diarrhoea, dry mouth, vomiting, indigestion
- Increased sweating
- Muscle or joint pain
- Sexual disturbances (delayed ejaculation, problem with erection, decreased sexual drive and women may experience difficulties achieving orgasm)
- Extreme tiredness, raised body temperature (fever).

Less frequent side effects:

- Weight loss
- Involuntary habitual grinding of the teeth (typically during sleeping), feeling agitated, nervousness, panic attacks, feeling confused, aggressiveness, disorientation, feeling in a state in which one's thoughts and feelings seem unreal or not to belong to oneself
- Taste disturbances, sleep disorder, fainting
- Dilation of the pupil of the eye
- Ringing or buzzing in the ears
- Heartbeat that is faster or slower than normal
- Nasal congestion (stuffy nose), hay fever, flu like symptoms, bleeding from the

nose

- Abdominal pain
- Loss of hair, discolouration of the skin resulting from bleeding underneath, typically caused by bruising, rash or red welts on the hands, feet, face or genitals, hives, itching of the skin
- Bleeding from the uterus (womb) that is not associated with menstruation, abnormally heavy or extended menstrual flow
- Fluid retention.

The following side effects have been reported but the frequency for them to occur is not known:

- Heavy vaginal bleeding shortly after birth (postpartum haemorrhage), see section 2 for more information
- Low levels of sodium in the blood (which may result in confusion, seizures, fatigue and low levels of consciousness), loss of appetite
- Headaches, difficulty concentrating, feeling of discomfort, illness or unease, difficulty controlling movement, twitching or abnormal uncontrolled movements
- Blurred or abnormal vision
- Low blood pressure (feeling lightheaded or dizzy when standing up)
- Salivation
- Inflammation of the liver
- Abnormal physical weakness or lack of energy
- Excessive or inappropriate production of milk, persistent and painful erection of the penis.

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

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. 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 Reporting Form**", found on SAHPRA's website: www.sahpra.org.za under "online services". By reporting side effects, you can help provide more information on the safety of ZYTOMIL.

5. How to store ZYTOMIL

Store all medicines out of reach of children.

Store at or below 25 °C. Protect from light.

Keep blisters in outer carton until required for use.

Keep bottles tightly closed.

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 ZYTOMIL contains

ZYTOMIL 5 mg: Each coated tablet contains escitalopram oxalate equivalent to 5 mg escitalopram.

ZYTOMIL 10 mg: Each coated tablet contains escitalopram oxalate equivalent to 10 mg escitalopram.

ZYTOMIL 15 mg: Each coated tablet contains escitalopram oxalate equivalent to 15 mg escitalopram.

ZYTOMIL 20 mg: Each coated tablet contains escitalopram oxalate equivalent to 20 mg escitalopram.

The other ingredients are:

Colloidal silicon dioxide, croscarmellose sodium, hydroxypropyl methyl-cellulose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, talc, titanium dioxide.

What ZYTOMIL looks like and contents of the pack

ZYTOMIL 5 mg: White, oval, coated tablet, debossed with “E” and “C” on one side and nothing on the other side.

ZYTOMIL 10 mg: White, oval, coated tablet, debossed with “E” and “C” divided by a score on one side and “10” on the other side.

ZYTOMIL 15 mg: White, oval, coated tablet, debossed with “E” and “C” on one side and nothing on the other side.

ZYTOMIL 20 mg: White, oval, coated tablet, debossed with “E” and “C” divided by a score on one side and “20” on the other side.

ZYTOMIL is packed into hard, silver-coloured aluminium foil / clear PVC/PVDC or PVC/PE/PVDC film blister strips of 3 x 10 tablets each inside an outer cardboard box. ZYTOMIL is also packed into white, HDPE bottles with a desiccant, polyester pharmcoil and a white PP screw cap with 30 tablets inside.

Holder of Certificate of Registration

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