PATIENT INFORMATION LEAFLET

Information for the Patient about

LEXAMIL 5 / 10 / 20

SCHEDULING STATUS

S5

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

LEXAMIL 5 containing **escitalopram** 5 mg (Tablets)

LEXAMIL 10 containing **escitalopram** 10 mg (Tablets)

LEXAMIL 20 containing **escitalopram** 20 mg (Tablets)

Read all of this leaflet carefully before you start taking LEXAMIL:

- Keep this leaflet, you may need to read it again.

- If you have further questions, please ask your doctor or your pharmacist.

- LEXAMIL 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 LEXAMIL CONTAINS

The active substance in **LEXAMIL** is escitalopram oxalate.

LEXAMIL 5: Each tablet contains escitalopram oxalate equivalent to 5 mg escitalopram.

LEXAMIL 10: Each tablet contains escitalopram oxalate equivalent to 10 mg escitalopram.

LEXAMIL 20: Each tablet contains escitalopram oxalate equivalent to 20 mg escitalopram.

Inactive ingredients include croscarmellose sodium, magnesium stearate, mannitol, microcrystalline cellulose, Opadry 04F58804 white, and starch.

Contains sugar (mannitol).

WHAT LEXAMIL IS USED FOR

LEXAMIL belongs to a group of medicines known as antidepressants. **LEXAMIL** is used to treat:

- Major depressive episodes.
- Panic disorder with or without agoraphobia (fear of open/public spaces).
- Social anxiety disorder (social phobia).
- Generalised anxiety disorder.
- Obsessive-compulsive disorder.

BEFORE YOU TAKE LEXAMIL

Do NOT take LEXAMIL:

- If you are allergic (hypersensitive) to escitalopram oxalate or to any of the inactive ingredients of **LEXAMIL**. Please discuss this with your doctor or pharmacist if you are unsure.
- If you are younger than 18 years of age, as safety and efficacy in children have not

been proven (see **"Take special care with LEXAMIL"**).

- If you are also taking **monoamine oxidase inhibitors** (MAOIs) for the treatment of depression or other mood disorders (see **"Taking LEXAMIL with other medicines"**). Please speak to your doctor or pharmacist if you are unsure.
- If you are taking linezolid, an antibiotic (see **"Taking LEXAMIL with other medicines"**).
- If you have been diagnosed with an abnormal heart rhythm or heart block or if you have previously been told that the medicines you are using may slow your heart rate (see **"Taking LEXAMIL with other medicines"**).

Take special care with LEXAMIL

Before you start treatment with **LEXAMIL**, tell your doctor if any of the following applies to you as you may then require a lower dose or special precautions:

- Previously been diagnosed with mania or manic episodes.
- Seizures (convulsions) or epilepsy.
- Diabetes mellitus.
- You think about suicide.
- Previously been diagnosed with a bleeding disorder, or if you are pregnant (see **“Pregnancy and breastfeeding”**. Please inform your doctor immediately if you develop bruising, blood in the urine, bleeding from the gums, or pinpoint red spots on the skin while taking **LEXAMIL**.
- You are scheduled to undergo electroconvulsive therapy (ECT).

- Your heart rate is very slow, you recently suffered a heart attack or if you are in heart failure. Please speak to your doctor if you are unsure.

  Since treatment with **LEXAMIL** may slow your heart rate, your doctor may perform an electrocardiogram (ECG) before you start treatment with **LEXAMIL**.
- Previously been diagnosed with heart disease.

Please inform your doctor if you experience increased anxiety while taking **LEXAMIL** for panic disorder.

Safety and efficacy of **LEXAMIL** in children under 18 years of age have not been established (see **"Do NOT take LEXAMIL"**). There have been increased reports of hostility and suicide-related adverse events, such as suicidal thoughts and self-harm. Please report any such thoughts or behaviour to your doctor as soon as possible.

If you take other medicines known as monoamine oxidase inhibitors (see **"Do NOT take LEXAMIL"**) or other medicines that increase serotonin levels, you may develop a condition known as the serotonin syndrome. Symptoms of this syndrome include confusion, agitation, hyperactivity, shivering, fever, tremors, eye movements, severe muscle spasms, incoordination of movements, and abnormal behaviour (see **"POSSIBLE SIDE-EFFECTS"**). Please report any of these symptoms to your doctor as a matter of urgency.

Treatment with **LEXAMIL** may also cause a condition known as akathisia (an unpleasant or distressing restlessness and a need to move often, or an inability to sit or stand still)

(see **"POSSIBLE SIDE-EFFECTS"**). This is most likely to occur during the first few weeks of treatment. If you develop any of these symptoms, please inform your doctor as soon as possible.

LEXAMIL may lower your blood levels of sodium (see **"POSSIBLE SIDE-EFFECTS"**). The likelihood of this is greater in elderly patients, patients with liver cirrhosis, or if you use other medicines that may lower your blood sodium levels, such as diuretics (water pills). Please inform your doctor if you develop nausea and vomiting, headache, confusion, loss of energy, fatigue, muscle weakness, muscle spasms or muscle cramps.

You should not use **LEXAMIL** in combination with herbal remedies for depression, such as St. John's Wort (see **"Taking LEXAMIL with other medicines"**).

If you are 50 years of age or older, there may be an increased risk of bone fractures if you are taking **LEXAMIL**.

Escitalopram, as in **LEXAMIL**, may cause increased pressure in the eye (also known as glaucoma), especially if you are prone to this condition. Inform your doctor if you currently have, or have previously had increased pressure in the eye (glaucoma).

Taking LEXAMIL with food and drink

LEXAMIL can be taken with or without food.

Pregnancy and breastfeeding

The use of **LEXAMIL** while you are pregnant or breastfeeding your baby is not recommended. The safe and effective use of **LEXAMIL** in pregnancy and while you are breastfeeding has not been established.

If you are pregnant and have been taking **LEXAMIL** while you are pregnant, please inform your doctor / gynaecologist, as your newborn baby may require special observation / treatment.

If you take **LEXAMIL** 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 **LEXAMIL** so they can advise you.

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

Driving or using machinery

It is unlikely that **LEXAMIL** will impair your ability to drive or use machines. However, if your alertness is impaired, or if you should experience side-effects such as dizziness, you should avoid driving a car or operating machinery. Patients who are depressed and require treatment may have an impaired ability to drive or operate machinery and may need to

avoid such tasks.

Taking LEXAMIL with other medicines

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

Please discuss the use of the following medicines or substances in combination with **LEXAMIL** with your doctor or pharmacist:

- Monoamine oxidase inhibitors for the treatment of depression. You should wait 14 days after stopping a monoamine oxidase inhibitor before you start **LEXAMIL** and at least 7 days should elapse after you stop **LEXAMIL** before you can start treatment with a monoamine oxidase inhibitor (see **"Do NOT take LEXAMIL"** and **"Take special care with LEXAMIL"**). Please discuss this with your doctor or pharmacist if you are unsure.
- Any medicines for the treatment of abnormal heart rhythms (see **"Do NOT take LEXAMIL"**).
- Other medicines that may slow your heart rate (see **"Do NOT take LEXAMIL"**), such as:
    - Certain antidepressants.
    - Certain medicines for the treatment of psychosis, such as haloperidol and pimozide. Please speak to your doctor or pharmacist if you are unsure.
    - Antibiotics, such as sparfloxacin, moxifloxacin, erythromycin (intravenous) or pentamidine.

- Malaria treatment, especially halofantrine.
- Certain antihistamines, e.g. mizolastine, to treat or prevent allergies.

- Medicines which may increase your risk of developing seizures (convulsions), such as:
  - Certain antidepressants (please speak to your doctor or pharmacist if you are unsure).
  - Phenothiazines (chlorpromazine, fluphenazine, trifluoperazine and prochlorperazine) for the treatment of schizophrenia, mania, psychological disorders or behaviour disturbances.
  - Thioxanthenes (flupenthixol and zuclopenthixol) for the treatment of depression.
  - Haloperidol for the treatment of psychotic disorders, schizophrenia and mania.
  - Mefloquine for the prevention of malaria.
  - Bupropion for the treatment of depression and to assist with stopping smoking.
- Cimetidine, omeprazole, esomeprazole or lansoprazole for the treatment of stomach ulcers, heartburn or reflux.
- Sumatriptan for the treatment of migraine (severe headaches).
- Tramadol for the treatment of moderate to severe pain.
- Linezolid, an antibiotic (see **"Do NOT take LEXAMIL"**).
- Lithium for the treatment of psychosis or manic depression (bipolar disorder).

- Tryptophan, a component of many alternative medicines to help treat sleeping disorders, anxiety, depression, bipolar disorder, premenstrual syndrome, attention deficit disorder, to stop smoking and for other conditions.
- St. John's Wort, a herbal remedy used for mild depression (see **"Take special care with LEXAMIL"**).
- Tricyclic antidepressants, e.g. imipramine for the treatment of depression, panic and anxiety.
- Metoprolol for the treatment of heart failure.
- Selegiline for the treatment of Parkinson's disease.
- Warfarin, a blood thinner, used for the treatment of blood clotting disorders.
- Non-steroidal anti-inflammatory drugs (NSAIDs), such as diclofenac or ibuprofen.
- Alcohol.

HOW TO TAKE LEXAMIL

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

Depending on your diagnosis and your individual response to treatment, your doctor will decide on the dosage of **LEXAMIL** and how long treatment will last. The usual dose in adults is a single, once daily dose of 5 mg, 10 mg or 20 mg as determined by your doctor. Usually 2 to 4 weeks or longer are needed before **LEXAMIL** will make you feel better if you have

been diagnosed with major depressive episodes or social anxiety disorder; at least 3 months of treatment are needed for panic disorder and several months or even longer for obsessive compulsive disorder. When stopping **LEXAMIL** therapy, the doctor may consider decreasing the dose gradually before stopping treatment.

LEXAMIL can be taken with or without food.

If you have the impression that the effect of **LEXAMIL** is too strong or too weak, please discuss this with your doctor or pharmacist.

If you take more LEXAMIL than you should

In the event of an overdosage, or if someone else has taken your medicine by mistake, you, or this other person, may experience side-effects such as those listed below.

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 LEXAMIL

Always take **LEXAMIL** as prescribed. If you miss a dose, take it as soon as you remember. If you do not remember the missed dose until the next dose is due, skip the missed dose and go back to your regular dosing schedule of one tablet once daily. Do not take a double dose to make up for forgotten individual doses.

Effects when treatment with LEXAMIL is stopped

After using **LEXAMIL** for a long period, abruptly stopping your treatment may cause withdrawal symptoms. There have even been reports of withdrawal symptoms in patients who have accidentally missed a dose.

Withdrawal symptoms usually start within the first few days of stopping **LEXAMIL** treatment and usually disappear within 2 weeks.

LEXAMIL withdrawal symptoms may include dizziness, pins and needles and electric shock sensations, sleep disturbances (including sleeplessness and intense dreams), agitation or anxiety, nausea and/or vomiting, tremor, confusion, sweating, headache, diarrhoea (runny stomach), palpitations, emotional instability, irritability, and visual disturbances. Generally these symptoms are mild to moderate and self-limiting; however, in some patients they may be severe and/or prolonged. Always follow your doctor's instructions carefully when treatment with **LEXAMIL** is stopped. Do NOT stop treatment without your doctor's consent.

POSSIBLE SIDE-EFFECTS

LEXAMIL can have side-effects.

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

The side-effects of **LEXAMIL** are most frequent during the first 1 or 2 weeks of treatment and may decrease in intensity and frequency with continued treatment.

After using **LEXAMIL** for a long period, abruptly stopping your treatment may cause withdrawal symptoms (see **"Effects when treatment with LEXAMIL is stopped"**).

Serious side-effects that you, or a family member, should report to your doctor as a matter of urgency include:

- Those that occur less frequently:
    - Severe allergic reactions presenting with shortness of breath, hives or itching, swelling of the face, tongue, or whole body, tightness of the chest, nausea, vomiting or fever.
    - Any combination of the following: rapidly developing changes in consciousness or alertness with confusion, elevated mood, agitation, hyperactive behaviour, shivering, fever, tremor, abnormal eye movements, severe muscle spasms, and inability to co-ordinate movements. These symptoms may be due to serotonin syndrome (see **"Take special care with LEXAMIL"**).
    - Vomiting of blood or a substance that resembles coffee-grounds, or passing blood per rectum or passing black, tarry, foul-smelling stools.
    - Confusion, aggression, personality changes or hallucinations (seeing or hearing things that are not real).
    - Slow heart rate or palpitations.
- Those for which the frequency is not known:

    - Convulsions (seizures).
    - Yellow discolouration of the skin or whites of the eyes accompanied by loss of appetite, nausea and/or vomiting with or without pain over the liver area.
    - Pinpoint red spots on the skin, easy bruising, bleeding from the gums or blood in the urine, since any combination of these symptoms may be due to low platelet counts.
    - Extremely elevated mood with inappropriate behaviour.
    - Inability to pass urine.
    - Persistent painful erection.

Other side-effects that you should report to your doctor as soon as possible include:

- Those that occur frequently:
    - Pins and needles.
    - Fever.
- Those that occur less frequently:
    - Visual disturbances.
    - Nose bleeds.
    - Hives, skin rash or itching.
    - Panic attacks.
    - Fainting spells.
    - Rapid heart rate.
    - Swelling of the legs or feet.
- Those for which the frequency is not known:

- Nausea and vomiting, confusion, loss of energy, fatigue, muscle weakness, muscle spasms or muscle cramps, since a combination of these symptoms may be due to low blood sodium levels (see **"Take special care with LEXAMIL"**).
- Abnormal movements over which you do not have control.
- Thoughts about suicide.
- Akathisia (see **"Take special care with LEXAMIL"**).
- Feeling faint or dizzy after standing up.
- Milky secretion from the breasts.
- Heavy vaginal bleeding shortly after birth (postpartum haemorrhage), see **“Pregnancy and breastfeeding”** for more information.

Please report the following side-effects to your doctor or pharmacist if they continue or become bothersome:

- Those that occur frequently:
  - Decreased or increased appetite, weight gain.
  - Anxiety, restlessness, abnormal dreams, decreased libido or inability to reach orgasm.
  - Headache.
  - Inability to sleep or excessive sleepiness, dizziness, or tremor.
  - Pain over the sinuses with blocked or runny nose.
  - Nausea, runny stomach, constipation, vomiting or dry mouth.
  - Muscle or joint pain.

    - Ejaculation disorder or impotence.
    - Yawning.
    - Increased sweating.
    - Fatigue.
- Those that occur less frequently:
    - Heavy menstruation or more frequent menstruation.
    - Weight loss.
    - Grinding of the teeth or clenching of the jaw, agitation, nervousness.
    - Taste disturbances.
    - Dilation of the pupil.
    - Ringing in the ears.
    - Hair loss.
- Those for which the frequency is not known:
    - Loss of appetite.

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

STORING AND DISPOSING OF LEXAMIL

Store at or below 30 ºC.

Keep the blisters in the outer carton until required for use.

Do not take the medicine after the expiry date stated on the package.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

PRESENTATION OF LEXAMIL

LEXAMIL 5:	Aluminium foil blister strips of 10 tablets packed in 30's.
LEXAMIL 10:	Aluminium foil blister strips of 10 tablets packed in 30's.
LEXAMIL 20:	Aluminium foil blister strips of 10 tablets packed in 30's.

IDENTIFICATION OF LEXAMIL

LEXAMIL 5:	White, round, biconvex, film-coated tablets plain on both sides.
LEXAMIL 10:	White, round, biconvex, film-coated tablets plain on both sides.
LEXAMIL 20:	White, round, biconvex, film-coated tablets plain on both sides.

REGISTRATION NUMBERS

LEXAMIL 5: 41/1.2/0394

LEXAMIL 10: 41/1.2/0395

LEXAMIL 20: 41/1.2/0396

NAME AND BUSINESS ADDRESS OF REGISTRATION HOLDER

CIPLA MEDPRO (PTY) LTD

Building 9

Parc du Cap

Mispel Street

Bellville

7530, RSA

DATE OF PUBLICATION

18 April 2008

Revised: 28 February 2019