MODULE 1.3.2: PROPOSED CLEAN PATIENT INFORMATION LEAFLET

Information for the Patient about

DEPRAMIL 10 / 20 / 40

SCHEDULING STATUS:

S5

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

DEPRAMIL 10 containing **citalopram** 10 mg (Tablets)

DEPRAMIL 20 containing **citalopram** 20 mg (Tablets)

DEPRAMIL 40 containing **citalopram** 40 mg (Tablets)

Read all of this leaflet carefully before you start taking DEPRAMIL.

- **Keep this leaflet; you may need to read it again.**
- **If you have further questions, please ask your doctor or your pharmacist.**
- **DEPRAMIL 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 DEPRAMIL CONTAINS:

The active substance in **DEPRAMIL** is citalopram hydrobromide.

DEPRAMIL 10: Each tablet contains citalopram hydrobromide equivalent to 10 mg citalopram.

DEPRAMIL 20: Each tablet contains citalopram hydrobromide equivalent to 20 mg citalopram.

DEPRAMIL 40: Each tablet contains citalopram hydrobromide equivalent to 40 mg citalopram.

Inactive ingredients include colloidal anhydrous silica, hypromellose, macrogol 6000, magnesium stearate, mannitol, microcrystalline cellulose, and titanium dioxide.

WHAT DEPRAMIL IS USED FOR:

DEPRAMIL belongs to a group of medicines known as antidepressants. **DEPRAMIL** is used to treat depression and prevent relapse of depression. It is also used in the treatment of panic disorders and obsessive-compulsive disorder (OCD).

BEFORE YOU TAKE DEPRAMIL:

Do NOT take DEPRAMIL:

- If you are allergic (hypersensitive) to citalopram or to any of the inactive ingredients in **DEPRAMIL**. Please discuss this with your doctor or pharmacist if you are unsure.
- If you are also taking monoamine oxidase inhibitors (MAOIs) for the treatment of depression or other mood disorders or if you recently stopped taking them (see

"Taking DEPRAMIL with other medicines"). Please speak to your doctor or pharmacist if you are unsure.

- If you are using linezolid (a type of antibiotic).
- If you have impairment of kidney function. Please speak to your doctor if you are unsure.
- If you are pregnant or breastfeeding your baby (see **"Pregnancy and breastfeeding"**).
- If you are younger than 18 years of age, as safety and efficacy in children have not been proven (see **"Take special care with DEPRAMIL"**).
- If you have been told by your doctor that you have an abnormal electrocardiogram (ECG) or if you have previously been told that the medicines you are using may affect the rhythm or rate of your heart (see **"Taking DEPRAMIL with other medicines"**).
- If you are using pimozide (a type of antipsychotic medicine).

Take special care with DEPRAMIL:

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

- You have been diagnosed with impaired liver function.
- You have kidney disease (see **"Do NOT take DEPRAMIL"**). Please speak to your doctor if you are unsure.
- Seizures (convulsions / fits) or epilepsy.

- You have previously been diagnosed with mania or manic episodes or previously suffered from a psychotic episode. Please speak to your doctor or pharmacist if you are unsure.
- You have raised pressure in your eyes (glaucoma).
- You have a slow heart rate.
- You recently suffered a heart attack or if you are in heart failure. Please speak to your doctor if you are unsure.
- Diabetes mellitus.
- 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 **DEPRAMIL**.
- Previously been diagnosed with heart disease.
- You think about suicide.

Since treatment with **DEPRAMIL** may slow your heart rate, your doctor may perform an electrocardiogram (ECG) before you start treatment with **DEPRAMIL**.

If you take other medicines known as monoamine oxidase inhibitors (see **"Do NOT take DEPRAMIL"**) 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 **DEPRAMIL** 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.

DEPRAMIL may lower your blood levels of sodium (see **"POSSIBLE SIDE-EFFECTS"**). The likelihood of this is greater in elderly female patients. 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 **DEPRAMIL** in combination with herbal remedies for depression, such as St. John’s Wort (see **"Taking DEPRAMIL with other medicines"**).

Safety and efficacy of **DEPRAMIL** in children under 18 years of age have not been established (see **"Do NOT take DEPRAMIL"**). 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.

Please inform your doctor if you experience anxiety while taking **DEPRAMIL**.

Do not stop taking **DEPRAMIL** without your doctor's guidance as to how to gradually decrease the dose (see **"Effects when treatment with DEPRAMIL is stopped"**).

Taking DEPRAMIL with food and drink:

DEPRAMIL can be taken with or without food in the morning or evening.

Pregnancy and breastfeeding:

Do not take **DEPRAMIL** while you are pregnant or breastfeeding your baby, as it may harm your baby (see **"Do NOT take DEPRAMIL"**). The safe and effective use of **DEPRAMIL** in pregnancy and while you are breastfeeding your baby has not been established.

If you take **DEPRAMIL** 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 **DEPRAMIL** 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 DEPRAMIL.

Driving or using machinery:

There is likelihood that **DEPRAMIL** will impair your ability to drive or use machines. If your alertness is impaired, or if you should experience side-effects such as dizziness, you should avoid driving a car or operating machinery.

Taking DEPRAMIL with other medicines:

Always tell your healthcare professional if you are taking any other medicine.

Please discuss the use of the following medicines or substances in combination with **DEPRAMIL** 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 **DEPRAMIL** and at least 7 days should elapse after you stop **DEPRAMIL** before you can start treatment with a monoamine oxidase inhibitor (see **"Do NOT take DEPRAMIL"** and **"Take special care with DEPRAMIL"**). Please discuss this with your doctor or pharmacist if you are unsure.
- Linezolid, an antibiotic (see **"Do NOT take DEPRAMIL"**).
- Other antidepressants, such as imipramine.
- Other medicines that may increase your risk of developing serotonin syndrome (see **"Take special care with DEPRAMIL"**) including:
    - Tramadol for the treatment of moderate to severe pain.

    - Sumatriptan for the treatment of migraine (severe headaches).
    - Moclobemide for the treatment of depression.
- Lithium for the treatment of psychosis or manic depression (bipolar disorder).
- Tryptophan, a component of many alternative (complementary) medicines to help treat sleeping disorders, anxiety, depression, bipolar disorder, premenstrual syndrome, attention deficit disorder, to stop smoking and for other conditions.
- Alcohol, since **DEPRAMIL** may enhance the effects of alcohol.
- Warfarin, a blood thinner, used for the treatment of blood clotting disorders.
- Cimetidine, omeprazole, esomeprazole or lansoprazole for the treatment of stomach ulcers, heartburn or reflux.
- Other medicines that may influence your heart rate or increase your risk of developing heart block (see **"Do NOT take DEPRAMIL"**), such as:
    - Any medicines for the treatment of abnormal heart rhythms.
    - Certain antidepressants.
    - Certain medicines for the treatment of psychosis, such as haloperidol and pimozide (see **"Do NOT take DEPRAMIL"**). Please speak to your doctor or pharmacist if you are unsure.
    - Antibiotics, such as sparfloxacin, moxifloxacin, erythromycin or pentamidine.
    - Malaria treatment, especially halofantrine.
    - Certain antihistamines, e.g. astemizole or mizolastine, to treat or prevent allergies.

- St. John's Wort, a herbal remedy used for mild depression (see **"Take special care with DEPRAMIL"**).
- Non-steroidal anti-inflammatory agents (NSAIDs), such as diclofenac or ibuprofen.
- Any medicines to prevent blood clots.
- Medicines which may increase your risk of developing seizures (convulsions), such as:
    - Antidepressants (please speak to your doctor or pharmacist if you are unsure).
    - Phenothiazines (e.g. 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.
    - Mefloquine for the prevention of malaria.
    - Bupropion for the treatment of depression and to assist with stopping smoking.
- Metoprolol for the treatment of heart failure.

HOW TO TAKE DEPRAMIL:

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

Always take DEPRAMIL 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 **DEPRAMIL** and how long treatment will last. For depression, the usual starting dose is 20 mg once daily. For panic disorder, the usual starting dose is 10 mg per day as a single dose. For obsessive-compulsive disorder, the usual starting dose is 20 mg per day as a single dose. The maximum daily dose is 40 mg.

Usually 2 to 4 weeks are needed before **DEPRAMIL** will make you feel better. When stopping **DEPRAMIL** therapy, the doctor will decrease your dose gradually to prevent discontinuation symptoms developing (see **"Effects when treatment with DEPRAMIL is stopped"**).

DEPRAMIL can be taken with or without food in the mornings or evenings.

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

If you take more DEPRAMIL 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 tiredness, weakness, sleepiness, dizziness,

tremor, nausea, and palpitations. **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 DEPRAMIL:

Always take **DEPRAMIL** 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 DEPRAMIL is stopped:

After using **DEPRAMIL** for a long period, abruptly stopping your treatment may cause withdrawal symptoms. **DEPRAMIL** withdrawal symptoms may include depressed mood or feelings of discontent, irritability, agitation, dizziness, pins and needles or electric shock sensations, anxiety, confusion, headache, tiredness and weakness, emotional lability, sleeplessness, elevated mood and nausea. Generally these symptoms are self-limiting; however, in some patients they may be severe and/or prolonged. Always follow your doctor's instructions carefully when treatment with **DEPRAMIL** is stopped. Do NOT stop treatment without your doctor's consent.

POSSIBLE SIDE-EFFECTS:

DEPRAMIL can have side-effects.

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

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

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

- Severe allergic reactions presenting with shortness of breath, hives or itching, severe swelling of the face, lips, tongue, or whole body, tightness of the chest, or fever.
- Those that occur frequently:
    - Confusion.
    - Palpitations.
- Those that occur less frequently:
    - Any combination of the following: rapidly developing changes in consciousness or alertness with confusion, elevated mood, agitation, hyperactive behaviour, shivering, fever or chills, tremor, abnormal eye movements, severe muscle spasms, extreme muscle stiffness, and inability to co-ordinate movements. These symptoms may be due to

serotonin syndrome (see **"Take special care with DEPRAMIL"**) or a condition known as neuroleptic malignant syndrome and may be life-threatening.

- Convulsions (seizures).
- Inappropriate behaviour or personality changes.
- Seeing or hearing things that are not real (hallucinations).
- Slow or rapid heart rate.
- Any bleeding.
- 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 as these symptoms may be due to inflammation of the liver.
- Inability to pass urine with severe pain over the bladder area.

- Those for which the frequency is not known:
  - 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.
  - Vomiting of blood or a substance that resembles coffee-grounds, or passing blood per rectum or passing black, tarry, foul-smelling stools.
  - 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.
- Migraine.
- Abnormal vision or other visual disturbances.
- Struggling to pass urine.

- Those that occur less frequently:
  - Aggression, hostility, thoughts about suicide or self-harm (see **"Take special care with DEPRAMIL"**).
  - Abnormal movements over which you do not have control.
  - Fainting spells.
  - Abnormal and prolonged dilation of the pupil.
  - Skin rash resembling sun-burn reaction on areas exposed to the sun.
  - Fever.
  - Swelling of the feet or legs.
- Those for which the frequency is not known:
  - Panic attacks.
  - Akathisia (see **"Take special care with DEPRAMIL"**).
  - Struggling to initiate movement.
  - 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:
    - Weight changes and decreased appetite.
    - Agitation, anxiety, nervousness, abnormal dreams, apathy, and restlessness.
    - Decreased libido or inability to reach orgasm.
    - Loss of memory or disturbances in attention, sleep disturbances including excessive sleepiness or inability to fall asleep.
    - Taste disturbances.
    - Ringing in the ears.
    - Yawning or runny nose.
    - Runny stomach, constipation, dry mouth, poor digestion, stomach pain, passing wind or increased salivation (production of sputum).
    - Increased sweating.
    - Severe tiredness or weakness.
    - Ejaculation disorder or impotence.
- Those that occur less frequently:
    - Increased appetite.
    - Increased libido.
    - Coughing or blocked nose.
    - Hair loss.

- Heavy menstruation or more frequent menstruation.
- Generally feeling unwell.

- Those for which the frequency is not known:
  - Grinding of the teeth or clenching of the jaw.

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

STORAGE AND DISPOSING OF DEPRAMIL:

Store in a cool, dry place at or below 25 ºC. Protect from light.

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).

KEEP ALL MEDICINES OUT OF REACH OF CHILDREN.

PRESENTATION OF DEPRAMIL:

DEPRAMIL 10: Blister strips of 10 tablets, packed in 28’s or 30’s.

DEPRAMIL 20: Blister strips of 10 tablets, packed in 28’s or 30’s.

DEPRAMIL 40: Blister strips of 10 tablets, packed in 28’s or 30’s.

IDENTIFICATION OF DEPRAMIL:

DEPRAMIL 10: White coloured, circular, biconvex, film-coated tablets, plain on both sides. Diameter approximately 6 mm.

DEPRAMIL 20: White coloured, circular, biconvex, film-coated tablets with scoreline on one side and plain on the other side. Diameter approximately 8 mm.

DEPRAMIL 40: White coloured, circular, biconvex, film-coated tablets with crosswise score on one side and plain on the other side. Diameter approximately 10 mm.

REGISTRATION NUMBERS:

DEPRAMIL 10: A38/1.2/0488

DEPRAMIL 20: A38/1.2/0489

DEPRAMIL 40: A38/1.2/0490

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATES OF REGISTRATION:

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