

## **Package leaflet: Information for the patient**

### **Depreger 50 mg film-coated tablet Depreger 100 mg film-coated tablet sertraline hydrochloride**

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet**

1. What Depreger is and what it is used for.
2. What you need to know before you take Depreger.
3. How to take Depreger.
4. Possible side effects.
5. How to store Depreger.
6. Contents of the pack and other information.

#### **1. What Depreger is and what it is used for**

Depreger contains the active substance sertraline. Sertraline is one of a group of medicines called Selective Serotonin Re-uptake Inhibitors (SSRIs); these medicines are used to treat depression and or anxiety disorders.

#### **Depreger can be used to treat:**

- Depression and prevention of recurrence of depression (in adults).
- Social anxiety disorder (in adults).
- Post-traumatic stress disorder (PTSD) (in adults).
- Panic disorder (in adults).
- Obsessive compulsive disorder (OCD) (in adults and children and adolescents aged 6-17 years old).

Depression is a clinical illness with symptoms like feeling sad, unable to sleep properly or to enjoy life as you used to.

OCD and panic disorders are illnesses linked to anxiety with symptoms like being constantly troubled by persistent ideas (obsessions) that make you carry out repetitive rituals (compulsions).

PTSD is a condition that can occur after a very emotionally traumatic experience, and has some symptoms that are similar to depression and anxiety. Social anxiety disorder (social phobia) is an illness linked to anxiety. It is characterised by feelings of intense anxiety or distress in social situations (for example: talking to strangers, speaking in front of groups of people, eating or drinking in front of others or worrying that you might behave in an embarrassing manner).

Your doctor has decided that this medicine is suitable for treating your illness.

You should ask your doctor if you are unsure why you have been given Depreger.

You must talk to a doctor if you do not feel better or if you feel worse after taking Depreger.

## 2. What you need to know before you take Depreger

### Do not take Depreger:

- If you are allergic to sertraline or any of the other ingredients of this medicine (listed in section 6).
- If you are taking or have taken medicines called monoamine oxidase inhibitors (MAOIs such as selegiline, moclobemide) or MAOI like medicines (such as linezolid). If you stop treatment with sertraline, you must wait until at least one week before you start treatment with a MAOI. After stopping treatment with a MAOI, you must wait at least 2 weeks before you can start treatment with sertraline.
- If you are taking another medicine called pimozide (an antipsychotic medicine).
- If you have severe liver disease.

### Warnings and precautions

Talk to your doctor or pharmacist before taking Depreger.

Medicines are not always suitable for everyone. Tell your doctor before you take Depreger, if you suffer from or have suffered in the past from any of the following conditions:

- Serotonin Syndrome or Neuroleptic Malignant Syndrome. In rare cases these syndromes may occur when you are taking certain medicines at the same time as sertraline. (For symptoms, see section 4. "Possible side effects"). Your doctor will have told you whether you have suffered from this in the past.
- If you have low sodium level in your blood, since this can occur as a result of treatment with Depreger. You should also tell your doctor if you are taking certain medicines for high blood pressure (hypertension), since these medicines may also alter the sodium level in your blood.
- Take special care if you are elderly as you may be more at risk of having low sodium level in your blood (see above).
- Liver disease; your doctor may decide that you should have a lower dose of Depreger.
- Diabetes; your blood glucose levels may be altered due to Depreger and your diabetes medicines may need to be adjusted.
- Epilepsy or a history of seizures. If you have a fit (seizure), contact your doctor immediately.
- If you have suffered from manic depressive illness (bipolar disorder) or schizophrenia. If you have a manic episode, contact your doctor immediately.
- If you have or have previously had thoughts of harming or killing yourself (see below - "Thoughts of suicide and worsening of your depression or anxiety disorder").
- If you have suffered from bleeding disorders or have been taking medicines which thin the blood (e.g. acetylsalicylic acid (aspirin), or warfarin) or may increase the risk of bleeding.
- If you are a child or adolescent under 18 years old. Depreger should only be used to treat children and adolescents aged 6-17 years old, suffering from obsessive compulsive disorder. If you are being treated for this disorder, your doctor will want to monitor you closely (see "Children and adolescents" below).
- If you are having electro-convulsive therapy (ECT).
- If you have a history of glaucoma (increased pressure in the eye).
- If you have low potassium levels in the blood, have a family history of sudden death or heart problems, have other heart problems or are using medicines known to affect the rhythm of your heart beats. You are more at risk of having problems with how the heart beats (QT prolongation, Torsade de Pointes).

If you are taking Depreger, it may interfere with the urine screening test.

### Restlessness/Akathisia

The use of sertraline has been linked to akathisia (a distressing restlessness and need to move, often being unable to sit or stand still). This is most likely to occur during the first few weeks of treatment. Increasing the dose may be harmful to patients who develop such symptoms.

### **Withdrawal reactions**

Withdrawal reactions when treatment is stopped are common, particularly if the treatment is stopped suddenly (see section 3 “If you stop taking Depreger” and section 4 “Possible side effects”). The risk of withdrawal symptoms depends on the length of treatment, dosage, and the rate at which the dose is reduced. Generally, such symptoms are mild to moderate. However, they can be serious in some patients. They normally occur within the first few days after stopping treatment. In general, such symptoms disappear on their own and wear off within 2 weeks. In some patients they may last longer (2-3 months or more). When stopping treatment with Depreger it is recommended to reduce the dose gradually over a period of several weeks or months, and you should always discuss the best way of stopping treatment with 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.

If you have thoughts of harming or killing yourself at any time, contact your doctor 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.

### **Children and adolescents**

Depreger should not usually be used in children and adolescents less than 18 years old, except for patients with Obsessive Compulsive Disorder. Patients under 18 have an increased risk of undesirable effects, such as suicide attempt, suicidal thoughts and hostility (mainly aggressiveness, oppositional behaviour and anger) when they are treated with this class of medicines. Nevertheless, it is possible that your doctor decides to prescribe Depreger to a patient under 18 if it is in the patient's interest. If your doctor has prescribed Depreger to a patient less than 18 years old and you want to discuss this, please contact him/her. Furthermore, if any of the symptoms listed above appear or worsen when a patient under 18 is taking Depreger, you should inform your doctor. Also, the long-term safety of Depreger in regard to growth, maturation and cognitive and behavioural development in this age group has not yet been demonstrated.

### **Other medicines and Depreger**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Some medicines can affect the way Depreger works, or Depreger itself can reduce the effectiveness of other medicines taken at the same time.

### **Taking Depreger together with the following medicines may cause serious side effects:**

- Medicines called monoamine oxidase inhibitors (MAOIs), like moclobemide (to treat depression) and selegiline (to treat Parkinson's disease), the antibiotic linezolid methylene blue (to treat high levels of methaemoglobin in the blood). Do not use Depreger together with MAOIs.
- Medicines to treat mental disorders (pimozide). Do not use Depreger together with pimozide.

### **Talk to your doctor or pharmacist if you are taking the following medicines:**

- Medicines containing amphetamines (used to treat attention deficit hyperactivity disorder (ADHD), narcolepsy, and obesity).

- Herbal medicine containing St. John's wort (*Hypericum perforatum*). The effects of St. John's wort may last for 1-2 weeks.
- Products containing the amino acid tryptophan.
- Medicines to treat migraines (e.g. sumatriptan).
- Blood thinning medicines (e.g. warfarin, ticlopidine).
- Medicines to treat pain/arthritis (Non-steroidal anti-inflammatory drugs (NSAID) such as ibuprofen, acetylsalicylic acid (aspirin)).
- Diuretics.
- Medicines to treat epilepsy (phenytoin, phenobarbital, carbamazepine).
- Medicines to treat excessive stomach acid, ulcers and heartburn (cimetidine, omeprazole, lansoprazole, pantoprazole, rabeprazole).
- Medicines to treat mania and depression (lithium).
- Other medicines to treat depression (such as amitriptyline, nortriptyline, desipramine, nefazodone, fluoxetine, fluvoxamine).
- Medicines to treat schizophrenia and other mental disorders (such as perphenazine, levomepromazine and olanzapine).
- Medicines used in anaesthesia or to treat chronic, severe pain (mivacurium, suxamethonium and opiate' medicines such as fentanyl).
- Medicines used to treat high blood pressure, chest pain or regulate the rate and rhythm of the heart (such as flecainide, propafenone, verapamil and diltiazem).
- Medicines to treat HIV infection (such as ritonavir).
- Medicines to treat fungal infections (such as fluconazole, ketoconazole, itraconazole, posaconazole, voriconazole).
- Antibiotics (such as clarithromycin, erythromycin, telithromycin).
- Medicines to treat nausea and vomiting (such as aprepitant).
- Medicines to treat tuberculosis (rifampicin).
- Medicines known to affect the rhythm of your heart beats (such as levofloxacin, haloperidol, imipramine).

### **Depreger with drink and alcohol**

Alcohol should be avoided whilst taking Depreger.

Depreger should not be taken in combination with grapefruit juice, as this may increase the level of sertraline in your body.

### **Pregnancy, breast-feeding and fertility**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

The safety of sertraline has not fully been established in pregnant women. Sertraline should only be given to pregnant women if the doctor considers that the benefit for the mother exceeds any possible risk to the foetus. Women of childbearing potential should employ an adequate method of contraception if taking sertraline.

Make sure your midwife and/or doctor know you are on Depreger. When taken during pregnancy, particularly in the last 3 months of pregnancy, medicines like Depreger may increase the risk of a serious condition in babies, called persistent pulmonary hypertension of the newborn (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.

Your newborn baby might also have other conditions, which usually begin during the first 24 hours after birth. Symptoms include:

- trouble with breathing,
- a blueish skin or being too hot or cold,
- blue lips,
- vomiting or not feeding properly,

- being very tired, not able to sleep or crying a lot,
- stiff or floppy muscles,
- tremors, jitters or fits,
- increased reflex reactions,
- irritability,
- low blood sugar.

If your baby has any of these symptoms when it is born, or you are concerned about your baby's health, contact your doctor or midwife who will be able to advise you.

There is evidence that sertraline is excreted in human breast milk. Sertraline should only be used in breast-feeding women, if the doctor considers that the benefit for the mother exceeds any possible risk to the baby.

Some medicines like sertraline may 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**

Psychotropic medicines such as sertraline may influence your ability to drive or use machines. You should therefore not drive or operate machinery, until you know how this medication affects your ability to perform these activities.

**This medicine contains less than 1 mmol sodium (23 mg) per tablet**, that is to say essentially 'sodium-free'

## **3. How to take Depreger**

Always take this medicine exactly as your doctor or pharmacist has told you. Depreger may be taken with or without food.

Take your medication once daily either in the morning or evening. The tablets can be divided into equal doses.

Check with your doctor or pharmacist if you are not sure.

### **The recommended dose is:**

#### **Adults:**

#### **Depression and Obsessive Compulsive Disorder**

For depression and OCD, the recommended effective dose is 50 mg/day. The daily dose may be increased in 50 mg increments and at intervals of at least one week over a period of weeks. The maximum recommended dose is 200 mg/day.

#### **Panic disorder, Social anxiety disorder and Post-Traumatic Stress Disorder:**

For panic disorder, social anxiety disorder and post-traumatic stress disorder, treatment should be started at 25 mg/day, and increased to 50 mg/day after one week.

The daily dose then may be increased in 50 mg increments over a period of weeks. The maximum recommended dose is 200 mg/day.

#### **Use in children and adolescents:**

Depreger must only be used to treat children and adolescents suffering from OCD aged 6-17 years old.

#### **Obsessive Compulsive Disorder**

**Children aged 6 to 12:** the recommended starting dose is 25 mg daily.

After one week, your doctor may increase this to 50 mg daily. The maximum dose is 200 mg daily.

**Adolescents aged 13 to 17:** the recommended starting dose is 50 mg daily.

The maximum dose is 200 mg daily.

If you have liver or kidney problems, please tell your doctor and follow the doctor's instructions.

Your doctor will advise you on how long to take this medication for. This will depend on the nature of your illness and how well you are responding to the treatment. It may take several weeks before your symptoms begin to improve.

**If you take more Depreger than you should:**

If you accidentally take too much Depreger contact your doctor at once or go to the nearest hospital casualty department. Always take the labelled medicine package with you, whether there is any medication left or not.

Symptoms of overdose may include drowsiness, nausea and vomiting, rapid heart rate, shaking, agitation, dizziness and in rare cases unconsciousness.

**If you forget to take Depreger:**

If you forget to take a dose, do not take the missed dose. Just take the next dose at the right time. Do not take a double dose to make up for a forgotten dose.

**If you stop taking Depreger:**

Do not stop taking Depreger unless your doctor tells you to. Your doctor will want to gradually reduce your dose of Depreger over several weeks, before you finally stop taking this medicine. If you suddenly stop taking this medicine you may experience side effects such as dizziness, numbness, sleep disturbances, agitation or anxiety, headaches, feeling sick, being sick and shaking. If you experience any of these side effects, or any other side effects whilst stopping taking Depreger, please speak to your doctor.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

#### **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**Tell your doctor immediately:**

If you experience any of the following symptoms after taking this medicine, these symptoms can be serious.

- If you have a fit (seizure).
- Allergic reaction or allergy, which may include symptoms such as an itchy, raised skin rash (hives), breathing problems, wheezing, or sudden swelling of the eyelids, face or lips.
- Inability to urinate (pass water).
- If you experience depressive symptoms with suicidal ideas and suicidal behaviours. These symptoms have been reported during sertraline therapy or early after treatment discontinuation (see section 2).
- If you have a heart attack.
- If you fall unconscious (into a coma).
- If you have severe stomach and abdominal pain, feel very bloated and have a high temperature. These could be signs of diverticulitis, where a bulge in the lining of the gut becomes swollen or infected.
- Passing blood in stools (poo) – the blood may be fresh or your stools may be black or sticky/tarry.
- Unexpected or unusual (e.g. very heavy) vaginal bleeding.
- Problems controlling blood sugar levels (diabetes).
- Glaucoma (raised pressure in the eye), which may cause intense eye pain, reddening of the eye or you may notice halos in your vision or a “clouding” of vision.

- Very slow breathing.
- If you develop a severe skin rash that causes blistering (this can affect the mouth, tongue and genitals). These may be signs of a condition known as Stevens Johnson Syndrome, or Toxic Epidermal Necrolysis (TEN). Your doctor will stop your treatment in these cases.
- If you experience agitation, confusion, diarrhoea, high temperature and blood pressure, excessive muscle stiffness or sweating and rapid heartbeat. These are symptoms of Serotonin Syndrome or Neuroleptic Malignant Syndrome. In rare cases these syndromes may occur when you are taking certain medicines at the same time as sertraline. Your doctor may wish to stop your treatment.
- If you develop severe muscle pain, weakness and swelling of muscle (due to breakdown of the muscle -rhabdomyolysis)
- If you experience a sudden severe headache (which may be a sign of a serious condition known as Reversible Cerebral Vasoconstriction Syndrome (RCVS) or Call-Fleming syndrome).
- If you develop serious problems with the lung. You may have a persistent cough which does not produce any phlegm or find that you are becoming more and more short of breath.
- If you develop yellowing of the skin and eyes which may be a sign of liver damage.
- If you have inflammation of the pancreas causing severe upper stomach pain often with feeling or being sick.
- If you start to get feelings of restlessness and are not able to sit or stand still after you start to take Depreger. You should tell your doctor if you start to feel restless.
- If you have a manic episode (see section 2 “Warnings and precautions”).
- If you have a decrease in white blood cells, which help fight infections (you may notice more infections e.g. sore throat, mouth ulcers and fever).
- If you have bleeding problems (such as stomach bleeding – if you are sick it may look like it contains coffee grounds).
- Changes to the rhythm of your heart beat which can be seen on an electrocardiogram (ECG) (a sign of serious condition called QT prolongation or Torsade de Pointes).

The following other side effects were seen in clinical trials and post-marketing in adults.

**Very common** (may affect more than 1 in 10 people):

- Insomnia (trouble sleeping), dizziness, sleepiness, headache, diarrhoea, feeling sick, dry mouth, ejaculation failure, fatigue.

**Common** (may affect up to 1 in 10 people):

- Chest cold, sore throat, runny nose,
- Decreased or increased appetite,
- Depression, feeling strange, nightmares, anxiety, agitation, nervousness, decreased sexual interest, teeth grinding,
- Numbness and tingling, shaking, muscular movement problems (such as tense muscles and difficulty walking), abnormally twisted neck, arms or trunk,
- Muscle tense, abnormal taste, lack of attention,
- Visual disturbance, ringing in ears,
- Palpitations, hot flush, yawning,
- Abdominal pain, vomiting, constipation, upset stomach, gas,
- Rash, increased sweating,
  - Back pain, muscle or joint pain,
  - Erectile dysfunction, menstrual irregularities,
  - Chest pain, malaise (general feeling of being unwell), fever, weakness
  - Weight increased
  - Injury

**Uncommon** (may affect up to 1 in 100 people):

- Gastroenteritis, ear infection
- Tumour

- Hypersensitivity, seasonal allergy
- Hallucination (seeing, hearing or feeling things that are not there), feeling too happy, lack of caring, thinking abnormal, aggression, psychotic disorder, paranoia
- Involuntary muscle contractions, abnormal coordination, moving a lot, amnesia (loss of memory), decreased feeling, speech disorder, dizziness while standing up, fainting, migraine,
- Ear pain,
- Fast heartbeat, heart problem, high blood pressure, flushing, blood in the urine,
- Shortness of breath, nose bleed, breathing difficulty, possible wheezing
- Oesophageal problem, difficulty swallowing, haemorrhoids, increased saliva, tongue disorder, tongue problem, tooth disorder, burping,
- Enlarged pupils
- Eye swelling, purple spots on skin, swelling of the face, hair loss, cold sweat, dry skin, dermatitis, hives, itching
- Osteoarthritis, muscular weakness, muscle cramps, muscle twitching,
- Night-time urination, increase in urination, increase in frequency of urination, problems urinating, urinary incontinence,
- Heavy and prolonged periods menstrual (menorrhagia) sexual dysfunction,
- Swelling in the arms and legs, chills, difficulty walking, thirst,
- Increase in liver enzyme levels, weight decreased,
- Low thyroid hormone levels.

**Rare** (may affect up to 1 in 1,000 people):

- Swollen lymph glands,
- High cholesterol, low blood sugar levels, low blood salt (sodium), increase in blood sugar levels (hyperglycaemia)
  - Decrease in clotting cells (you may bruise or bleed more easily), severe allergic reaction,
- Physical symptoms due to stress or emotions, terrifying abnormal dreams, drug dependence, sleep walking, premature ejaculation,
- Abnormal movements, difficulty moving, increased sensation, sensory disturbance,
- Tear problem, spots in front of eyes, double vision, light hurts eye, blood in the eye, vision abnormal, pupils unequal
- Slow heart beat,
- Poor circulation to the arms and legs,
- Closing up of throat, breathing fast, difficulty talking, hiccups,
- Sore mouth, tongue ulceration, mouth ulceration, problems with liver function,
- Skin problem with blisters, rash around the hair follicles, hair texture abnormal, skin odour abnormal, skin oedema, skin reaction to sun
  - An increased risk of bone fractures has been observed in patients taking this type of medicines, bone disorder
- Decreased urination, urinary hesitation,
- Endocrine problems,
- Increase in blood cholesterol levels, abnormal laboratory tests, semen abnormal, problems with clotting,
- Dry vaginal area, red painful penis and foreskin, genital discharge, prolonged erection, breast discharge, breast enlargement,
- Hernia, drug tolerance decreased, relaxation of blood vessels procedure.

**Not known** (frequency cannot be estimated from the available data):

- Trismus (also called lockjaw, is reduced opening of the jaws).

#### **Additional side effects in children and adolescents**

In clinical trials with children and adolescents, the side effects were generally similar to adults (see above). After marketing sertraline, bedwetting was also reported. The most common side effects in children and adolescents were headache, insomnia, diarrhoea and feeling sick.

### **Reporting of side effects**

If you get any 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 directly via HPRAs Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517; website: [www.hpra.ie](http://www.hpra.ie); e-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie).

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

### **5. How to store Depreger**

Store in the original package.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date, which is stated on the package after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

### **6. Contents of the pack and other information**

#### **What Depreger contains**

- The active substance is sertraline hydrochloride. Each tablet contains 50 mg or 100 mg of sertraline.
- The other ingredients are calcium hydrogen phosphate, microcrystalline cellulose, magnesium stearate, sodium starch glycolate (Type A), hypromellose (E464), titanium dioxide (E171), polydextrose (E1200), triacetin and macrogol.

#### **What Depreger looks like and contents of the pack**

Depreger 50 mg film-coated tablets:

White to off-white capsule shaped, film-coated tablet with 'ST/50' on one side and 'G' on the other.

Depreger 100 mg film-coated tablets:

White to off-white capsule shaped, film-coated tablet with 'ST/100' on one side and 'G' on the other.

Depreger 50 mg and 100 mg film-coated tablets are available in HDPE bottles and blisters with pack sizes of 14, 15, 20, 28, 30, 50, 60, 98, 100, 250, 300 and 500 tablets.

Not all pack sizes may be marketed.

#### **Marketing Authorisation Holder and Manufacturer**

McDermott Laboratories Ltd. t/a Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland.

#### **Manufacturer**

Generics [UK] Limited, Station Close, Potters Bar, Hertfordshire EN6 1TL, United Kingdom.

Mylan Hungary Kft., H-2900 Komárom, Mylan utca 1, Hungary.

#### **This medicinal product is authorised in the Member States of the EEA under the following names:**

Italy: Sertralina Mylan Generics

Ireland: Depreger 50 mg & 100 mg film-coated tablet

**This leaflet was last revised in September 2019.**