PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS’ REGULATIONS (PREPARATIONS, 1986)

The dispensing of this medicine requires a doctor’s prescription. Read this package insert carefully in its entirety before using this medicine.

CIPRALEX® film coated Tablets 10mg, 20mg

Composition: Cipralex 10 mg: each film coated tablet contains escitalopram (as esalate) 10 mg
Cipralex 20 mg: each film coated tablet contains escitalopram (as esalate) 20 mg

Inactive Ingredients: Talc, Croscarmellose sodium, Microcrystalline Cellulose, Colloidal Anhydrous Silicon, Magnesium Stearate, Hypromellose, Magnesium 455, Titanium Dioxide.

Therapeutic Activity: Selective serotonin reuptake inhibitors (SSRIs) for:
- Treatment of Depression.
- Treatment of Panic Disorder.
- Treatment of Generalized Anxiety Disorder (GAD).
- Treatment of Social anxiety disorder (SAD) (Social Phobia).
- Treatment of Obsessive-Compulsive disorder.

When should the preparation not be used?
Do not take Cipralex if you are pregnant or breast-feeding unless you and your doctor have discussed the risks and benefits involved. The general condition of your newborn baby might be affected by the use of this group of medicines (antidepressants).

If you take Cipralex during the last 3 months of your pregnancy you should be aware that the following effects may be seen in your newborn: trouble with breathing, blue-tinted skin, body temperature changes, feeding difficulties, vomiting, low sugar, sleeplessness, irritability, sneezing, skin irritation, difficulty sleeping, rapid eye movement, sneezing, tremor, jitteriness, irritability, lethargy, constant crying, sleeplessness and difficulty sleeping. It is not known how long your baby can have symptoms, but you may contact your doctor immediately. If used during pregnancy Cipralex should never be abruptly stopped.

Cipralex is contraindicated in combination with MAO inhibitors such as phenelzine, iproniazid, selegiline, rasagiline, nortryptiline. Cipralex may be started 14 days after discontinuing treatment with MAO inhibitors and at least 7 days should elapse after discontinuing Cipralex treatment before starting MAO inhibitor treatment. Do not use this medicine if you are sensitive to any of its ingredients.

Do not use this medicine without consulting a doctor before starting treatment.

If you are pregnant or breast-feeding, or suffer from a past post partum impaired function. The liver, coronary heart disease, the kidney(urethra tract), the blood system (e.g. coagulation etc.), Diabetes, Epilepsy, or Manic Depression. If you have a decreased level of sodium in the body. If you have a tendency to develop dizziness or bruises. If you are receiving electroshock treatment.

How will this medicine affect your daily life?

Use of this medicine may impair alertness, and therefore caution should be exercised when engaging in activities such as driving a car, operating dangerous machinery, and any other activity requiring alertness. Children should be cautioned against engaging in activities such as bicycle riding or playing near the road, etc.

Use in children and adolescents under 18 years of age
Cipralex should normally not be used for children and adolescents under 18 years. Also, you should know that patients under 18 have an increased risk of side-effects such as suicide attempts, suicidal thoughts and hostility (premeditated aggression, oppositional behaviour and anger) when they take the class of medicines. Despite this, your doctor may prescribe Cipralex for patients under 18 because the doctor deems this to be in their best interest. If your doctor has prescribed Cipralex for a patient under 18 and you want to discuss this, please go back to your doctor. You should inform your doctor if any symptoms listed above develop or worsen when patients under 18 are taking Cipralex.

Please note!
As with other medicines used to treat depression or related diseases, the improvement is not achieved immediately. After the start of Cipralex treatment it may take several weeks before you experience any improvement. In the treatment of panic disorder it usually takes 4-6 weeks before any improvement is seen. In the beginning of the treatment certain patients may experience nervousness, which will disappear along the continued treatment. Therefore, it is very important that you follow exactly your doctor’s orders and do not stop the treatment or change the dose without consulting your doctor.

Occasionally, the symptoms of depression or panic disorder may include thoughts of suicide or self-harm. It is possible that these symptoms continue or get worse until the full antidepressant effect of the medicine becomes apparent. This is more likely to occur if you are a young adult, i.e. under 30 years of age and you have not used antidepressant medicines before. Some patients with manic-depressive illness may enter into a manic phase, This is characterized by unusual and rapid changing ideas, inappropriate happiness and excessive physical activity. If you experience this, contact your doctor.

Symptoms such as restlessness or difficulty to sit or stand still can also occur during the first weeks of the treatment. Tell your doctor if you experience these symptoms immediately. Sometimes you may be unaware of the above-mentioned symptoms and therefore you may find it helpful to ask a friend or a relative to help you to observe the possible changes in your behavior. Tell your doctor immediately or contact the nearest hospital if you have distressing thoughts or delusions or if any of the above-mentioned symptoms occur during the treatment.

Do not drink wines or alcoholic beverages while under treatment with this medicine.

Warnings:
Suicide risk associated with psychiatric disorders
Suicide risk is common in psychiatric disorders especially in patients suffering from depression. They will often persist until the antidepressant effect of the medicine becomes apparent. It is recommended that the patients and their families monitor for behavioral changes such as worsening of depression, suicidal thoughts and expressions of intent to hurt themselves and in case of such changes please contact your doctor immediately.

Let your family and caregivers know how you feel and tell your doctor if your depressive symptoms become worse. Contact your doctor immediately.

Some patients with manic-depressive illness may enter into a manic phase. This is characterized by a change in mood, pronounced and rapid changing ideas, exaggerated and excessive physical activity. In such cases, it is important to contact your doctor.

Panic disorder
Patients who are prone to panic attacks may actually experience a temporary period of heightened anxiety after starting treatment, which generally resolves during the first 1-2 weeks. Therefore, a low starting dose is recommended in panic disorder.

If you are sensitive to any food or medicine, inform your doctor before taking this medicine.

Drug Interactions:
If you are taking another drug concomitantly, or if you have just finished treatment with another medicine, inform the attending doctor in order to prevent hazards or lack of efficacy due to drug interactions. This is especially important regarding medicines in the following categories:


Side Effects:
In addition to the desired activity of the medicine, adverse reactions may occur during the course of the medicine such as: flushing, sweating, nose congeglion, nausea, sore throat, sweating increase, fatigue, appetite increase or decrease, weight gain, paraesthesia, dry mouth, dizziness, sleep disturbances, restlessness, anxiety, abnormal dreams, dizziness, feeling asleep, feeling sleepy, dizziness, yawning, tremors, pricking of the skin, pain in muscles and joints (arthralgia and myalgia), sexual disturbances (delayed ejaculation, problems with erection, decreased sexual drive and women may experience difficulties achieving orgasm), fever.

These side effects generally disappear within a short period following adaptation to the medicine.

Side Effects Requiring Special Attention:
Confusion, nervousness, sexual dysfunction (rare), continue treatment and consult your doctor immediately.

- Symptoms syndrome (including symptoms as e.g. agitation, hallucination, coma, tachycardia, increased sweating, impaired body movement) (rare), stop treatment and consult your doctor immediately.

- Difficulties urinating, yellowing of the skin and the white in the eyes are signs of liver function impairment (rare), high temperature, muscle contractions (cramps) (rare), consult your doctor immediately.

In the event that you experience side effects not mentioned in this leaflet, or if there is a change in your condition, consult your doctor immediately.

Recommended Dosage
Dosage is according to doctor’s instructions only.
Do not exceed the recommended dosage. This medicine is not usually intended for administration to children and infants. This medicine is to be taken at specified time intervals as determined by the attending doctor. If you forget to take medicine at the specified time, take the dose as soon as you remember, but never take a double dose to compensate for a missed dose.

It may take a couple of weeks before you start to feel better. Continue to take Cipralex even if it takes some time before you feel any improvement in your condition. Do not change the dose of the medicine without taking to your doctor first.

Directions for Use:
Do not chew! Swallow the medicine with a small amount of water. Take the medicine with the milk is possible to dilute the tablet. Do not crush the tablet.

How Can You Contribute to the Success of the Treatment?
Consult the attending doctor immediately in case of a treatment failure or in case of wrong or insufficient dosage. If there is an improvement in your health, do not discontinue use of this medicine before consulting the doctor.

Avoid Poleneing
This medicine and all other medicines must be stored in a safe place out of the reach of infants and children to avoid poisoning. If you have taken an overdose, or if a child has accidentally swallowed the medicine, proceed immediately to the hospital emergency room and bring the package of the medicine with you.
Do not induce vomiting unless instructed to do so by a doctor.

This medicine has been prescribed for the treatment of您的 ailment; in another patient it may cause harm. Do not give this medicine to your relatives, neighbours or acquaintances.

Do not take medicines in the past! Check the label and the dose time each you take your medicine. Wear glasses if you need them.

Storage: Below 30°C.
Even if kept in their original container and stored as recommended, medicines may be kept for a limited period only.
Please note the expiry date of the medicine. In case of doubt, consult the dispensing pharmacist. Do not store different medicines in the same package.

Medicine License Number:
Cipralex 15 mg film coated tablets 127.01.30558
Cipralex 20 mg film coated tablets 127.03.30590

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Importer: Lundbeck Ireland LTD
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The format of this leaflet was determined by the Ministry of Health and its content was checked and approved by the Ministry of Health in August 2008.

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لا يوجد نص يمكن قراءته بشكل طبيعي من الصورة المقدمة.