

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986
The medicine is dispensed with a doctor's prescription only

RECITAL 20 Tablets

Composition:

Each **Recital 20** tablet contains: Citalopram (as HBr) 20 mg

Each **Recital 40** tablet contains: Citalopram (as HBr) 40 mg

For information on the inactive and allergenic ingredients in the preparation, see in section 2 "Important information about some of the ingredients of the medicine" and section 6 "Further information".

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

It is recommended to have a relative or another person close to you read this leaflet.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

Warning: Suicidal thoughts and behavior <p>Antidepressants and anti-anxiety medicines increase the risk of suicidal actions and thoughts in children, adolescents and young adults up to the age of 25. Following commencement of treatment with the medicine, patients of all ages, as well as their relatives, should monitor behavioral changes such as: worsening of depression, suicidal thoughts, aggression, etc. Refer to a doctor immediately if such changes occur.</p>
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1. WHAT IS THE MEDICINE INTENDED FOR?

Therapeutic activity: For treatment of depression and anxiety disorder.

Recital belongs to a group of antidepressants called selective serotonin reuptake inhibitors (SSRI). These medicines increase serotonin levels in the brain. Disturbances in the serotonin system in the brain are considered an important factor in the development of depression and related diseases.

Therapeutic group: selective serotonin reuptake inhibitors (SSRI).

2. BEFORE USING THE MEDICINE

Do not use Recital if:

- you are sensitive (allergic) to citalopram or to any of the additional ingredients contained in the medicine (see inactive ingredients in section 6 "Further information"). Consult the doctor if you think you may be sensitive.
- you are being concomitantly treated with monoamine oxidase inhibitors (MAOI), such as phenelzine, iproniazid, isocarboxazid, nialamide, tranlycypromine and moclobemide (used to treat depression); selegiline (to treat Parkinson's disease); linezolid (an antibiotic). Even if you have finished taking any of the following MAOIs: phenelzine, iproniazid, isocarboxazid, nialamide or tranlycypromine, wait two weeks before starting treatment with **Recital** tablets. Wait one day after discontinuing treatment with moclobemide. After discontinuing treatment with **Recital**, wait one week before taking any MAOI.

- you are born with or have had an episode of abnormal heart rhythm (seen at ECG; an examination to evaluate how the heart is functioning).
- you are taking medicines to treat heart rhythm disturbances or medicines that may have an effect on the heart rhythm (see in section 2 "Drug interactions" later in the leaflet).

Special warnings regarding use of the medicine:

Before treatment with Recital, tell the doctor if you have any medical problems, especially if:

- you have a history of bleeding disorders or if you suffered in the past from bleeding in the stomach or intestine, or if you are pregnant (see in section 2 "Pregnancy, breastfeeding and fertility").
- you have a liver disease.
- you have a kidney disease.
- you have diabetes (there may be a need to adjust the dosage of the medicines for diabetes).
- you have epilepsy or a history of fits or seizures.

- you have a mania or anxiety disturbance.
- you have low blood sodium levels.
- you are undergoing electroconvulsive treatment (ECT).
- you suffer, or have suffered in the past, from heart dysfunction or if you have recently had a heart attack.
- you have a low resting heart rate and/or you know that you may develop reduced blood salt levels as a result of prolonged severe diarrhea and vomiting or as a result of taking diuretics.
- you experienced a fast or irregular heartbeat, fainting, collapse or dizziness on standing up which may indicate abnormal functioning of the heart rate.
- you have, or have previously had, eye problems, such as certain kinds of glaucoma (increased intraocular pressure).

Please consult a doctor, even if you suffered in the past from the conditions listed above.

Attention

- Some patients with manic-depressive illness may enter into a manic phase. This phase is characterized by rapidly changing and abnormal ideas, inappropriate happiness and excessive physical activity. If you experienced these effects – refer to a doctor.
- Symptoms such as restlessness, difficulty in sitting or standing still may occur during the first weeks of the treatment. Refer to a doctor immediately if you experience these effects.
- Medicines like **Recital** (called SNRI/SSRI) may cause sexual dysfunction symptoms (see section 4). In certain cases, the symptoms persisted even after discontinuation of treatment.

Special information relating to your disease

As with other medicines used to treat depression or related diseases, the improvement is not achieved immediately. After starting treatment with **Recital**, it may take several weeks before you experience any improvement. In the beginning of the treatment, some patients may experience increased anxiety, which will disappear during continued treatment. Therefore, it is very important that you follow exactly the doctor's orders and do not stop the treatment or change the dosage without consulting the doctor.

Suicidal thoughts or worsening of depression or anxiety disorder

If you are depressed and/or have anxiety disorders, you can sometimes have thoughts of harming or killing yourself.

These thoughts may be increased when first starting treatment with antidepressants, since time is required until the antidepressant effect of the medicine is apparent – usually two weeks, but sometimes longer.

There is a greater chance that you will have these thoughts if:

- you previously had thoughts about killing or harming yourself.
- you are a young adult. Information from clinical trials has shown an increased risk of suicidal behavior in young adults (below the age of 25) with a psychiatric disease who were treated with antidepressants.

If you have thoughts of killing or harming yourself at any time, **refer immediately to the attending doctor or proceed to the hospital.**

It is recommended that you tell a relative or close friend that you are suffering from depression or have an anxiety disorder, and ask them to read this leaflet.

Ask them to tell you if they think your depression or anxiety has worsened, or if they are concerned about changes in your behavior.

Children and adolescents under 18 years of age

Recital is not usually intended for use in children and adolescents under 18 years of age. You should be aware that patients under 18 years of age who took medicines from this group, have an increased risk of side effects such as: suicide attempt, suicidal thoughts and hostility (especially aggression, oppositional behavior and anger). Despite this, your doctor may prescribe this medicine for patients under 18 years of age if he thinks it is for their benefit.

If the doctor has prescribed the medicine for a patient under 18 years of age and you are interested in discussing it with him – refer to the doctor again.

When a patient under 18 years of age is taking **Recital**, inform your doctor if any of the side effects listed above occur or worsen.

In addition, the long-term safety effects of **Recital** concerning growth, maturation and cognitive-behavioral development in this age group have not been investigated.

Drug interactions

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, inform the doctor or pharmacist.

Medicines may affect the action of other medicines and this can sometimes cause

serious side effects. Tell your doctor or pharmacist if you are taking, have taken, or might take other medicines, including other medicines for depression (see in section 2: "**Do not use Recital if**").

- The herbal preparation St. John's wort (*Hypericum perforatum*) – **do not** take it concomitantly with **Recital**.
- Monoamine oxidase inhibitors (MAOIs) – do not take these medicines concomitantly with **Recital** (see in section 2: "Do not use **Recital** if").
- Tell the doctor if you are taking one of the following medicines:
 - Linezolid (an antibiotic).
 - Sumatriptan (to treat migraine) or tramadol (a painkiller). If you feel unwell when using these medicines with **Recital**, refer to a doctor.
 - Lithium (to prevent and treat mania) and tryptophan (medicines to treat depression).
 - Pimozide (a neuroleptic) – do not take it together with **Recital**.
 - Imipramine and desipramine (used to treat depression).
 - Medicines containing selegiline (medicines to treat Parkinson's disease).
 - Cimetidine, lansoprazole and omeprazole (to treat stomach ulcers), fluconazole (used to treat fungal infections), flvoxamine (to treat depression) and ticlopidine (used to reduce the risk of stroke). These medicines may cause increased blood levels of citalopram.

- Mefloquine (to treat malaria).
- Bupropion (to treat depression).
- Medicines known to affect the blood platelets (e.g., anticoagulant drugs used to treat or prevent blood clots; aspirin and non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen and diclofenac used as painkillers and some antipsychotic drugs and tricyclic antidepressants).
- Metoprolol, a beta blocker used to treat migraine, some heart conditions and high blood pressure. The effect of either drug could be increased, decreased or altered.
- Neuroleptics (to treat schizophrenia).
- **Do not take Recital** if you take medicines for heart rhythm disturbances or medicines that may affect the heart rhythm, such as Class IA and III antiarrhythmics, antipsychotics (e.g., phenothiazine derivatives, pimozide, haloperidol), tricyclic antidepressants, certain antimicrobial medicines (e.g., sparfloxacn, moxifloxacin, intravenous erythromycin, pentamidine, anti-malarial medicines, particularly halofantrine), certain antihistamines (astemizole, mizolastine). If you have any further questions about this, you should refer to a doctor.

Use of the medicine and food

The medicine can be taken with or without food.

Use of the medicine and consumption of alcohol

Despite the fact that an increased effect of alcohol was not observed as a result of use of **Recital**, as with all antidepressants, it is recommended to abstain from drinking alcohol during the course of treatment.

Pregnancy, breastfeeding and fertility

Pregnancy

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

Consult a doctor or pharmacist before taking any medicines. If you are pregnant, think you might be pregnant, or are trying to become pregnant, tell the doctor.

Do not take **Recital** if you are pregnant, unless you consulted with your doctor and discussed the risks and benefits involved with use of this medicine. Make sure your midwife and/or doctor know you are taking **Recital**.

Taking medicines such as **Recital** during pregnancy, particularly in the last three months of pregnancy, may increase the risk of a serious condition in babies, called persistent pulmonary hypertension of the newborn (PPHN), which causes the baby to breathe faster and appear bluish. These signs usually appear during the first 24 hours after the delivery. If you notice these symptoms in your baby, refer to a midwife and/or doctor immediately.

In addition, if you take **Recital** during the last three months of pregnancy until the delivery, you should be aware that the following effects may be seen in your newborn: fits (spasms), body temperature that is too high or too low, feeding difficulties, vomiting, low blood sugar level, stiff or floppy muscles, overactive reflexes, tremor, nervousness, irritability, lethargy, constant crying, sleepiness or sleeping difficulties. If your newborn baby shows these symptoms, refer to a doctor immediately.

Breastfeeding

Consult a doctor or pharmacist before taking any medicines. If you are breastfeeding,

consult a doctor. Do not breastfeed while taking the medicine, because small amounts of the medicine might pass into the breast milk.

Fertility

Animal studies have shown that citalopram, the active ingredient in **Recital**, reduces the quality of sperm. Theoretically, this could affect fertility, but an impact on human fertility has not been observed as yet.

Driving and operating machinery

Recital does not usually affect ability to perform daily activities; however, if you feel dizzy or sleepy at the beginning of treatment with the medicine, exercise caution when driving a car or operating dangerous machinery or when engaging in any activity that requires alertness, until these symptoms pass.

Important information about some of the ingredients of the medicine

Information on sodium content

This medicine contains less than 1 mmol sodium (23 mg) per tablet; therefore, it is considered sodium-free.

Recital contains lactose.

If you have been told by the doctor that you have an intolerance (sensitivity) to certain sugars, consult the doctor before taking the medicine.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the doctor's instructions.

Check with the doctor or pharmacist if you are uncertain regarding the dosage and treatment regimen of the preparation.

The dosage and treatment regimen will be determined by the doctor only.

The usual dosage is generally:

Depression: 20 mg per day. The doctor can increase the dosage to up to 40 mg per day. Anxiety disorder: Starting dosage of 10 mg per day in the first week of treatment and then an increase of the dosage to 20 mg per day. The doctor can increase the dosage to up to 40 mg per day.

Elderly (above 65 years of age): a reduction to half the recommended dosage is necessary: 10 to 20 mg per day. The maximal dosage is 20 mg per day.

Patients with impaired liver function: a reduced dosage is necessary: a maximal dosage of 20 mg per day.

Children and adolescents (below the age of 18): Do not give **Recital** to children and adolescents. For additional information, see in section 2 "Before using the medicine".

Do not exceed the recommended dose.

Instructions for use:

Take **Recital** once a day.

The medicine can be taken at any time of the day, with or without food.

Swallow the medicine with a little water.

Do not hold the medicine in your mouth for more than the time necessary to swallow it.

Recital 20 – If necessary, the tablet can be halved for immediate use. There is no information regarding crushing or chewing of the tablet.

Recital 40 – Do not halve the tablet. There is no information regarding crushing or chewing of the tablet.

If you accidentally took a higher dosage

Symptoms of overdose (some of which can be life-threatening): Irregular heart rate, seizures, changes in heart rhythm, sleepiness, loss of consciousness, vomiting, tremor, drop in blood pressure, increase in blood pressure, nausea, serotonin syndrome (see section 4 "Side effects"), restlessness, dizziness, dilated pupils, bluish skin, hyperventilation.

If you took an overdose or if a child has accidentally swallowed the medicine, immediately refer to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you, even if you do not experience the above symptoms.

Do not induce vomiting unless explicitly instructed to do so by the doctor!

Use this medicine at set intervals, as determined by the attending doctor.

If you forgot to take this medicine at the designated time, take a dose as soon as you remember, but never take two doses together.

Adhere to the treatment regimen as recommended by the doctor.

Duration of treatment

Like other medicines for depression and similar diseases, the improvement is not achieved immediately. After starting treatment with this medicine, a few weeks may pass (approximately 2-4 weeks) before you feel an improvement in your condition. At the beginning of treatment, certain patients may experience an increase in anxiety, which will disappear with continued treatment. It is therefore important to be sure to take the medicine according to the doctor's instructions and not to stop taking the medicine or change the dosage being taken without consulting the doctor.

If you stop taking the medicine

Sudden discontinuation of treatment with the medicine may lead to the following symptoms: dizziness, sensation of pins and needles, sleep disturbances (vivid dreams, nightmares, insomnia), feeling anxious, headache, nausea, vomiting, sweating, feeling agitated or restless, tremor, feeling confused or disoriented, emotional instability, diarrhea, visual disturbances, rapid and pounding heartbeat (palpitations).

The duration of treatment with the medicine varies from patient to patient and is generally at least 6 months. Patients with recurring depression may be treated with the medicine for longer periods and even for years.

Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor or pharmacist; your disease may recur. In case of discontinuation of treatment, do so gradually to avoid occurrence of side effects.

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

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of **Recital** may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them. Some of the side effects listed below may also be symptoms of your disease and they may pass after you start feeling an improvement.

Serious side effects

Stop using Recital and refer to the doctor immediately if the following symptoms appear:

- Difficulty breathing,
- Swelling of the face, lips, tongue or throat that may cause difficulty in swallowing or breathing.
- Severe itching of the skin (with raised lumps).
- Fast, irregular heart rate, fainting which could be symptoms of a life-threatening condition known as torsades de pointes.

If you notice any of the following symptoms, refer to a doctor immediately; your dosage may need to be reduced or treatment stopped:

- you have an epileptic fit for the first time or epileptic fits that you have suffered from in the past become more frequent.
- if your behavior changes and you feel elated or overexcited.
- if you experience high fever, nervousness, confusion, trembling or strong muscle contractions. These symptoms may be signs of serotonin syndrome (rare).
- tiredness, confusion and muscle twitching may be signs of a low blood sodium level (hyponatremia).

If you have thoughts of harming or killing yourself at any time, refer to a doctor or proceed to a hospital straight away.

Additional side effects

The following side effects are usually mild and pass after a few days of treatment.

Very common side effects – effects that occur in more than one in ten users

- Sleepiness
- Difficulty in sleeping
- Headache
- Changes in your sleeping pattern
- Reduced body strength, weakness
- Increased sweating
- Dry mouth (increases the risk of caries; therefore, you should brush your teeth more often than usual)
- Nausea

Common side effects – effects that occur in 1-10 in 100 users

Decreased appetite, restlessness, decreased sexual drive, anxiety, nervousness, confusion, abnormal dreams, reduced emotions, indifference (apathy), tremor, tingling or numbness in the hands or legs, dizziness, problems concentrating, migraines, loss of memory (amnesia), ringing in the ears (tinnitus), palpitations, yawning, runny or blocked nose, diarrhea, vomiting, constipation, stomach pains, flatulence, drooling, itching, muscle and joint pains, erection and ejaculation problems in men, difficulty achieving an orgasm in women, tiredness, pricking of the skin, weight loss.

Uncommon side effects – effects that occur in 1-10 in 1,000 users

Skin bleeding (bruising), increased appetite, aggression, hallucinations, mania, fainting, enlarged pupils, fast or slow heart rate, urticaria (a type of rash), hair

loss, rash, sensitivity to sunlight, difficulties urinating, excessive menstrual bleeding, swelling of the limbs, weight gain.

Rare side effects – effects that occur in 1-10 in 10,000 users

Increased sex drive, convulsions, involuntary movements, taste disturbance, bleeding, coughing, hepatitis, malaise.

Side effects of unknown frequency (effects whose frequency has not yet been determined)

Heavy vaginal bleeding shortly after birth; see "Pregnancy, breastfeeding and fertility" in section 2 of the leaflet.

Thoughts of killing or harming yourself (see section 2 "Before using the medicine"); reduction in blood platelets (thrombocytopenia) which increases risk of bleeding or bruising, hypersensitivity (rash), hypokalemia: low blood potassium levels which can cause muscle weakness, twitching or abnormal heart rhythm; panic attack, teeth grinding, restlessness, unusual muscle movements or muscle stiffness, akathisia (involuntary movements), low blood pressure, nosebleed, bleeding disorders including subcutaneous and mucosal membrane bleeding, sudden swelling of the skin or mucosa, in men – painful erection, milk discharge in men and women who are not nursing, irregular menstrual periods, abnormal liver function tests, an increased risk of bone fractures has been observed in patients taking this type of medicine, abnormal heart rhythm.

In rare cases, SSRI's can increase the risk of bleeding, including stomach or intestinal bleeding. Tell the doctor if you vomit blood or develop black or blood-stained stools. Also tell the doctor if you continue to have other depression symptoms. These might include hallucinations, anxiety, mania or confusion.

Side effects usually disappear after a few days. If the side effects do not pass or are troublesome, if any of the side effects gets worse, or if you suffer from any side effects not listed in the leaflet, consult the doctor

Reporting side effects

Side effects can be reported to the Ministry of Health by clicking on the link "[Report Side Effects of Drug Treatment](#)", found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: <https://sideeffects.health.gov.il>

Additionally, you can report to "Unipharm Ltd."

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine must be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- **Storage conditions:** Store at a temperature that does not exceed 25°C, in a place protected from light.
- Do not dispose of medicines in the household waste bin or wastewater. Consult the pharmacist as to how to dispose of medicines that are no longer needed. These measures will help protect the environment.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:

Microcrystalline cellulose, lactose, copovidone, pregelatinized starch, carmellose sodium LS, magnesium stearate, opadry Y-1-7000 (white).

Each **Recital 20** tablet contains 76 mg lactose.

Each **Recital 40** tablet contains 152 mg lactose.

What the medicine looks like and the contents of the package:

Recital is packaged in a tray (blisters) within a carton box. **Recital** comes in packs of 7, 10, 14, 28 or 30 tablets.

Not all package sizes may be marketed.

Recital 20 are film-coated, circular, biconvex white tablets with a break line on one side.

Recital 40 are film-coated, oblong, capsule shaped white tablets.

Registration holder and address: Unipharm Ltd., P.O. Box 21429, Tel Aviv, 6121301.

Manufacturer and address: Unipharm Ltd., "Mevo Carmel" Industrial Park.

Revised in May 2021 according to MOH guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:

Recital 20: 123 22 30309 01

Recital 40: 123 23 30310 01

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