

**PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE
PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986**

The medicine is dispensed with a doctor's prescription only

PAXXET 20, 30

Tablets

Composition:

Each **Paxxet 20** tablet contains: Paroxetine (as HCl) 20 mg

Each **Paxxet 30** tablet contains: Paroxetine (as HCl) 30 mg

For a list of inactive and allergenic ingredients in the preparation, please 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 your doctor or pharmacist.

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.

Antidepressants and anti-anxiety medicines increase the risk of suicidal behavior and thoughts in patients up to the age of 25. On starting treatment with the medicine, patients and their relatives should monitor changes such as worsening of depression, suicidal thoughts, aggression, and the like. If such changes should occur, refer immediately to the doctor.

1. WHAT IS THE MEDICINE INTENDED FOR?

Therapeutic group: Selective serotonin reuptake inhibitors (SSRIs).

Therapeutic activity: For the symptomatic treatment of different types of depression, including depression accompanied by anxiety, and prevention of relapse of mental disorders, treatment of symptoms and prevention of relapse of obsessive compulsive disorder (OCD) and of anxiety disorders with or without agoraphobia and for treatment of symptoms of social phobia.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- **You are sensitive (allergic)** to paroxetine, or to any of the additional ingredients contained in the medicine (for the list of inactive ingredients, see section 6 – “Further information”).
- **You are taking medicines called monoamine oxidase inhibitors** (MAOIs, including moclobemide and methylthionium chloride [methylene blue]) or if you have taken them at any time within the past two weeks. The doctor will advise you how you should begin taking **Paxxet** once you have stopped taking monoamine oxidase inhibitors.
- **You are taking an anti-psychotic** medicine called thioridazine or an anti-psychotic medicine called pimozide.

If any of these apply to you, tell the doctor without taking Paxxet.

Special warnings regarding use of the medicine

Before treatment with Paxxet, tell the doctor if:

- You are taking any other medicines (see in section 2 – “Drug interactions”).
- You are taking tamoxifen to treat breast cancer or fertility problems. **Paxxet** may make tamoxifen less effective, so your doctor may recommend that you take a different antidepressant.
- You have a kidney, liver or heart problem.
- After an electrocardiogram (ECG) test, an abnormality of your heart tracing known as prolonged QT interval was found.
- You have a family history of QT prolongation, heart disease such as heart failure, low heart rate, or low potassium levels or low magnesium levels.
- You have epilepsy or a history of fits or seizures.
- You have ever had episodes of mania (behavioral and mental overactivity).
- You are receiving electro-convulsive therapy (ECT).
- You have a history of bleeding, or you are taking other medicines that may increase the risk of bleeding (these are medicines used to thin the blood such as warfarin, anti-psychotics such as perphenazine or clozapine, tricyclic antidepressants, medicines used to treat pain and inflammation called non-steroidal anti-inflammatory drugs [NSAIDs] such as: acetylsalicylic acid, ibuprofen, celecoxib, etodolac, diclofenac, meloxicam).
- You have diabetes.
- You are on a low-sodium diet.
- You have glaucoma (intraocular pressure).
- You are pregnant or planning to become pregnant (see “Pregnancy, breastfeeding and fertility” section).
- You are under 18 years of age (see “Children and adolescents under the age of 18” section).

If any of these apply to you, and you have not yet consulted with your doctor, **go back to your doctor and ask what you should do about taking Paxxet.**

Children and adolescents under the age of 18

Do not use **Paxxet** in children and adolescents under the age of 18.

Paxxet is not intended for use, and should not be used, to treat children and adolescents, since clinical studies have found a link between **Paxxet** and an increased risk of suicidal and hostile behavior.

The use of **Paxxet** in children under 7 years of age has not been tested.

Suicidal thoughts and worsening of your depression or anxiety disorder

If you are depressed and/or have anxiety disorders, you may sometimes have thoughts of harming yourself or committing suicide. These may be increased when first starting to take antidepressants, since all these medicines take time to work, usually about two weeks but sometimes even longer.

You may be more likely to think like this:

- If you have previously had thoughts about harming yourself or committing suicide.
- If you are a **young adult**. Information from clinical trials has shown an increased risk of suicidal behavior in adults under 25 years of age with psychiatric conditions treated with antidepressants.

If you have thoughts about harming yourself or committing suicide at any time, **refer to your doctor or proceed to a hospital immediately.**

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 can ask them to tell you if they think your depression or anxiety is getting worse, or if they are worried about changes in your behavior.

Important side effects observed with Paxxet

Some patients who take **Paxxet** develop an effect called akathisia, where they **feel restless and feel like they cannot sit or stand still.** Other patients develop an effect called **serotonin syndrome, or neuroleptic malignant syndrome,** where they have all or some of the following symptoms: a strong feeling of nervousness or irritability, feeling confused, feeling restless, feeling hot, sweating, tremor, chills, hallucinations (strange visions or sounds), muscle stiffness, sudden spasms of the muscles or a fast heartbeat. It may worsen, leading to loss of consciousness. If you notice any of these symptoms, **refer to your doctor.** For further information on these or other side effects of **Paxxet,** see section 4 – “Side effects”.

Medicines such as **Paxxet** (called selective serotonin reuptake inhibitors, SSRIs) may cause symptoms of “sexual dysfunction” (see section 4 – “Side effects”). In some cases, these symptoms continued after treatment cessation.

Drug interactions

Some medicines can affect the way **Paxxet** works, or increase the likelihood that you will have side effects. **Paxxet** may also affect the way certain medicines work.

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. In particular, if you are taking:

- Medicines called **monoamine oxidase inhibitors** (MAOIs, including moclobemide and methylthioninium chloride [methylene blue]) – see in section 2 – “Do not use the medicine if”.
- Medicines known to increase the risk of changes in the electrical activity of the heart (e.g., the **anti-psychotic** medicines thioridazine or pimozide) – see in section 2 – “Do not use the medicine if”.
- Acetylsalicylic acid (aspirin), ibuprofen or other medicines called NSAIDs (non-steroidal anti-inflammatory drugs) such as celecoxib, etodolac, diclofenac and meloxicam, used for treatment of **pain and inflammation.**
- Tramadol, buprenorphine and pethidine, **painkillers.**
- Buprenorphine combined with naloxone, replacement treatment for **opioid addiction.**
- Medicines called triptans, such as sumatriptan, used to treat **migraine.**
- Other **antidepressants,** including other SSRIs, tryptophan and tricyclic antidepressants such as clomipramine, nortriptyline and desipramine.
- A **dietary supplement** called tryptophan.
- Mivacurium and suxamethonium (used in anesthesia).
- Medicines such as lithium, risperidone, perphenazine, clozapine (called anti-psychotics) used for treatment of certain **psychiatric conditions.**
- Fentanyl, used in **anesthesia** or for treatment of **chronic pain.**

- A combination of fosamprenavir and ritonavir, which is used to treat **human immunodeficiency virus (HIV) infection**.
- Hypericum (St. John's wort), a herbal remedy for **depression**.
- Phenobarbital, phenytoin, sodium valproate or carbamazepine, used for treatment of **fits or epilepsy**.
- Atomoxetine, used for treatment of **attention deficit hyperactivity disorder (ADHD)**.
- Procyclidine, used to relieve tremor, especially in **Parkinson's disease**.
- Warfarin or other medicines (called anticoagulants) used to **thin the blood**.
- Propafenone, flecainide and medicines used for treatment of an **irregular heartbeat**.
- Metoprolol, a beta-blocker used for treatment of **high blood pressure and heart problems**.
- Pravastatin, used for treatment of **high cholesterol**.
- Rifampicin, used for treatment of **tuberculosis (TB) and leprosy**.
- Linezolid, an **antibiotic**.
- Tamoxifen, which is used for treatment of **breast cancer or fertility problems**.

If you are taking, or have recently taken, any of the medicines in this list, and you have not yet consulted with your doctor about them, go back to your doctor and ask what to do. The dosage may need to be adjusted or you may need to receive a different medicine.

Antidepressants from the SSRI and SNRI group could cause serotonin syndrome (rare) (see in section 2 – “Important side effects seen with **Paxxet**” and section 4 – “Side effects”).

The syndrome may occur more frequently if you are concomitantly taking other medicines that affect the central nervous system (see above). Inform the doctor about any additional medicine that you are taking.

Use of the medicine and food

Taking **Paxxet** in the morning with food will reduce the likelihood of you feeling nauseous.

Use of the medicine and alcohol consumption

Do not drink alcohol while you are taking **Paxxet**. Alcohol may make your symptoms or side effects worse.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to become pregnant, ask your doctor for advice before using this medicine. In babies whose mothers took **Paxxet** during the first months of pregnancy, there have been a number of reports that have shown an increased risk of birth defects, in particular those affecting the heart.

In the general population, about 1 in 100 babies is born with a heart defect. This increased up to 2 in 100 babies in mothers who took **Paxxet**. You and your doctor may decide that it would be better for you to switch to another treatment or to stop taking **Paxxet** gradually while you are pregnant. However, depending on your circumstances, your doctor may suggest that it is better for you to keep taking **Paxxet**.

Make sure that your doctor knows that you are taking Paxxet. If you are taking **Paxxet** close to the end of your pregnancy, there may be an increased

risk of heavy vaginal bleeding shortly after the delivery, especially if you have a history of bleeding disturbances. Your doctor or midwife should be aware that you are taking **Paxxet** so they can advise you. When medicines like **Paxxet** are taken during pregnancy, particularly in the late stages of pregnancy, they may increase the risk of a serious medical condition in babies, called persistent pulmonary hypertension of the newborn (PPHN). In PPHN, the blood pressure in the blood vessels between the baby's heart and the lungs is too high. If you take **Paxxet** during the last 3 months of pregnancy, your newborn baby might also have other medical conditions, which usually begin during the first 24 hours after birth. The symptoms include:

- breathing difficulties
- bluish skin or being too hot or too cold
- blue lips
- vomiting or feeding difficulties
- extreme tiredness, difficulty sleeping or crying a lot
- stiff or floppy muscles
- tremors, jitters or fits
- exaggerated reflexes
- low blood sugar level

If your baby experiences any of these symptoms at birth, or you are concerned about your baby's health, **refer to your doctor for advice.**

Breastfeeding

Paxxet may pass into breast milk in very small amounts. If you are taking **Paxxet**, go back and consult with your doctor before you start breastfeeding. You and your doctor may decide that you can breastfeed while you are taking **Paxxet**.

Fertility

Animal studies have shown that paroxetine reduces sperm quality. Theoretically, this could affect fertility, but an impact on human fertility has not yet been observed.

Driving and using machinery

Possible side effects of **Paxxet** include dizziness, confusion, feeling sleepy or blurred vision. If you develop these side effects, do not drive or use machinery.

Important information about some of the ingredients of the medicine

Paxxet contains sodium

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

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 about the dosage and treatment regimen of the preparation.

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

You may sometimes need to take more than one tablet or to take half a tablet.

Your doctor will advise you what dosage to take when you first start taking Paxxet. Most people start to feel better after two weeks. Tell the doctor if you

do not start to feel better after this time interval. He may decide to increase the dosage gradually, 10 mg at a time, up to the maximum daily dose.

Do not exceed the recommended dose.

Take your tablets in the morning with food. Swallow the tablets with water. If necessary, the tablet can be halved for immediate use. There is no information regarding crushing or chewing the tablet.

The doctor will instruct you as for how long you will need to keep taking the tablets. This may be for many months and even longer.

Older people

The maximum dosage for people over the age of 65 years is 40 mg per day.

Patients with liver or kidney disease

If you have liver or kidney problems, your doctor may decide that you should take a lower dosage of **Paxxet** than usual. If you have severe liver or kidney disease, the maximum dosage is 20 mg per day.

If you accidentally take a higher dosage

Never take more tablets than recommended by your doctor. If you took an overdose, or if a child has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room, and bring the package of the medicine with you.

Anyone who has taken an overdose of **Paxxet** may develop any of the symptoms listed in section 4 – “Side effects”, or the following symptoms: fever, uncontrolled muscle contraction.

If you forget to take the medicine

Take your medicine at the same time every day.

If you forgot a dose, and you remember before you go to bed, take it immediately. Carry on as usual the next day.

If you only remember during the night, or the next day, skip the forgotten dose. You may get withdrawal symptoms, but these should pass after you take your next dose at the usual time.

Do not take a double dose to compensate for a forgotten dose.

What to do if your feeling does not improve

Paxxet will not relieve your symptoms straight away – all antidepressants take time to work. Some people will start to feel better after two weeks, but for others, it may take a little longer. Some people taking antidepressants feel worse before feeling better. If you do not start to feel better after two weeks, go back to your doctor for advice. Your doctor will ask to see you again two weeks after you first start treatment. Tell your doctor if you have not started to feel better.

If you stop taking the medicine

Adhere to the treatment regimen as recommended by the doctor.

Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor.

When you stop taking Paxxet, your doctor will help you gradually reduce your dosage over a number of weeks or months – this should help reduce the chance of withdrawal symptoms. One way of doing this is to gradually reduce the

dosage of **Paxxet** you take by 10 mg each week. Most people find that any symptoms on stopping **Paxxet** are mild and pass on their own within two weeks. For some people, these symptoms may be more severe, or go on for longer.

If you develop withdrawal symptoms when you stop taking your tablets, your doctor may decide that stopping treatment should be done more slowly. If you develop severe withdrawal symptoms when you stop taking **Paxxet**, please refer to your doctor. Your doctor may ask you to start taking your tablets again and then to stop the treatment more slowly.

If you do develop withdrawal symptoms, you will still be able to stop taking Paxxet.

Possible withdrawal symptoms when stopping treatment:

Studies show that 3 in 10 patients notice one or more symptoms on stopping **Paxxet**. Some of the withdrawal symptoms on stopping treatment occur more frequently than others.

Common side effects (may occur in up to 1 user in 10):

- Feeling dizzy, unsteady or off-balance.
- Pins and needles sensation, burning sensations and (less common) sensations of electrical current, including in the head.
- Some patients have experienced buzzing, hissing, whistling, ringing or other persistent noise in the ears (tinnitus) when they took **Paxxet**.
- Sleep disturbances (vivid dreams, nightmares, inability to sleep).
- Feeling anxious.
- Headaches.

Uncommon side effects (may occur in up to 1 user in 100):

- Nausea.
- Sweating (including night sweats).
- Feeling restless or nervous.
- Tremor.
- Feeling confused or disorientated.
- Diarrhea (loose stools).
- Feeling emotional or irritable.
- Visual disturbances.
- Abnormal heart rate or palpitations.

Please refer to your doctor if you are concerned about the withdrawal symptoms when stopping **Paxxet**.

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 **Paxxet** 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.

Side effects are more likely to happen in the first few weeks of taking **Paxxet**.

Refer to the doctor if you experience any of the following side effects during treatment

You may need to contact your doctor or proceed to a hospital straight away.

Uncommon side effects (may occur in up to 1 user in 100):

- If you have unusual bruising or bleeding, including vomiting blood or bloody stools, contact your doctor or proceed to a hospital straight away.
- If you find that you are unable to urinate, contact your doctor or proceed to a hospital straight away.

Rare side effects (may occur in up to 1 user in 1,000):

- If you experience seizures (fits), contact your doctor or proceed to a hospital straight away.
- If you feel restless and feel that you cannot sit or stand still, you may have an effect called akathisia. Increasing your dosage of **Paxxet** may worsen these sensations. If you feel like this, **contact your doctor**.
- If you feel tired, weak or confused and have achy, stiff or uncoordinated muscles, this may be due to a low blood sodium level. If you experience these symptoms, **contact your doctor**.

Very rare side effects (may occur in up to 1 user in 10,000):

- **Allergic reactions to Paxxet, which may be severe.**
If you develop a red and lumpy skin rash, swelling of the eyelids, face, lips, mouth or tongue, start itching or it is difficult for you to breathe (shortness of breath) or swallow and you feel weakness or dizziness that causes you to collapse or lose consciousness, contact your doctor or go to the hospital immediately and feel weak or lightheaded resulting in collapse or loss of consciousness, **contact your doctor or go to a hospital straight away**.
- **If you have all or some of the following symptoms**, you may be suffering from an effect called **serotonin syndrome** or **neuroleptic malignant syndrome**. The symptoms include: a strong feeling of nervousness or irritability, feeling confused, feeling restless, feeling hot, sweating, tremors, chills, hallucinations (strange visions or sounds), muscle stiffness, sudden spasms of the muscles or a fast heartbeat. If you feel like this, **contact your doctor**.
- **Acute glaucoma.**
If your eyes hurt and you develop blurred vision, **contact your doctor**.

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

- Some people have had thoughts of hurting themselves or committing suicide while taking **Paxxet** or right after stopping treatment (see section 2 – “Before using the medicine”).
- Some people have experienced aggression while taking **Paxxet**.
- Heavy vaginal bleeding shortly after delivery (postpartum bleeding), see further information in section 2 – “Pregnancy, breastfeeding and fertility”.

If you experience these side effects, contact your doctor.

Additional side effects

Very common side effects (may occur in more than 1 user in 10):

Nausea. Taking your medicine in the morning with food will reduce the chance of this happening; change in sexual drive or sexual function. For example, lack of orgasm and, in men, abnormal erection and ejaculation.

Common side effects (may occur in up to 1 in 10 users):

Increase in the level of cholesterol in the blood; lack of appetite; insomnia or sleepiness; abnormal dreams (including nightmares); feeling dizzy or unsteady

(tremors); headache; difficulty in concentrating; feeling restless; feeling unusually weak; blurred vision; yawning, dry mouth; diarrhea or constipation; vomiting; weight gain; sweating.

Uncommon side effects (may occur in up to 1 user in 100):

A brief increase or decrease in blood pressure, which may make you feel dizzy or faint when you stand up suddenly; a faster than normal heartbeat; lack of movement, stiffness, shaking or abnormal movements in the mouth and tongue; dilated pupils; skin rashes; itching; feeling confused; having hallucinations (strange visions or sounds); an inability to urinate (urinary retention) or an uncontrollable, involuntary passing of urine (urinary incontinence); If you have diabetes, you may notice a lack of control of your blood sugar levels while taking **Paxxet**. Please refer to your doctor about adjusting the dosage of your insulin or diabetes medications.

Rare side effects (may occur in up to 1 user in 1,000):

Abnormal production of breast milk in men and women; a slow heartbeat; effects on the liver seen on blood tests of your liver function; anxiety attacks; overexpression of behavior or thoughts (mania); feeling detached from yourself (depersonalization); feeling anxious; irresistible urge to move the legs (restless legs syndrome); pain in the joints or muscles; an increase in a hormone called prolactin in the blood; menstrual period disorders (including heavy or irregular periods, bleeding between periods and absence or delay of periods).

Very rare side effects (may occur in up to 1 user in 10,000):

Skin rash, which may form blisters, and look like small targets (central dark spots surrounded by a paler area, with a dark ring around the edge) called erythema multiforme; a widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (Stevens-Johnson syndrome); a widespread rash with blisters and peeling skin on extensive skin surfaces (toxic epidermal necrolysis); liver problems that cause yellowing of the skin or whites of the eyes; syndrome of inappropriate antidiuretic hormone production (SIADH) – this is a condition in which the body develops an excess of water and a decrease in sodium (salt) concentration, as a result of improper chemical signals. Patients with SIADH may become severely sick or may have no symptoms at all; fluid or water retention (which may cause swelling of the arms or legs); sensitivity to sunlight; painful erection of the penis that does not go away; low blood platelet count.

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

Inflammation of the intestine (causing diarrhea); teeth grinding.

Some patients experienced buzzing, hissing, whistling, ringing or other persistent noise in the ears (tinnitus) when they took **Paxxet**.

An increased risk of bone fractures has been observed in patients who took this type of medicine.

If a side effects occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in the leaflet, consult with 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, should 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 a 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.
- Store below 25°C and in a place protected from light.
- Do not discard medicines in the waste water or household waste bin. Consult a pharmacist about 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:

Dicalcium phosphate dihydrate, Sodium starch glycolate, Hydroxypropyl Methylcellulose, Magnesium stearate, Opadry coating.

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

Paxxet is packaged in trays (blisters), which is inserted into a carton package. Each pack contains 10, 15, 20, 28, 30, 50 or 60 tablets. Not all package sizes may be marketed.

Paxxet 20 tablets are film-coated, pinkish beige, round, biconvex, with a score line on one side.

Paxxet 30 tablets are film-coated, pale beige, round, biconvex, with a score line on one side.

Registration holder and address: Unipharm Ltd., P.O.Box 21429, Tel Aviv, 6121310.

Manufacturer and address: Unipharm Ltd., “Mevo Carmel” Industrial Park. Registration number of the medicine in the National Drug Registry of the Ministry of Health:

Paxxet 20: 117 10 29855 02

Paxxet 30: 143 53 29943 02

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