

Seroxat 20 mg Film-Coated Tablets Paroxetine

Package leaflet: Information for the patient Read all of this leaflet carefully before you start taking this medicine because it contains important information for

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:

What Seroxat is and what it is used for

What you need to know before you take Seroxat 3. How to take Seroxat

4. Possible side effects

How to store Seroxat 6. Contents of the pack and other information

1. What Seroxat is and what it is used for Seroxat is a treatment for adults with depression and/or anxiety disorders. The anxiety disorders that Seroxat is used to treat are: obsessive compulsive disorder (repetitive, obsessive thoughts with uncontrollable behaviour); panic disorder (panicattacks, including those caused by agoraphobia which is a fear of open spaces); social anxiety disorder (fear or avoidance of social situations); post-traumatic stress disorder (anxiety caused by a traumatic event); and generalised anxiety lisorder (generally feeling very anxious or nervous). Seroxat is one of a group of medicines called SSRIs (selective erotonin reuptake inhibitors). It is not fully understood how Seroxat and other SSRIs work but they may help by increasing the level of serotonin in the brain. Treating depression or

anxiety disorders properly is important to help you get better. 2. What you need to know before you take Seroxat Do not take Seroxat If you are taking medicines called monoamine oxidase

inhibitors (MAOIs, including moclobemide and methylthioninium chloride (methylene blue)) or have taken them at any time within the last two weeks. Your doctor will advise you how you should begin taking Seroxat once you have stopped taking the MAOI · If you are taking an anti-psychotic called thioridazine or an ti-psychotic called pimozide

· If you are allergic to paroxetine or any of the other

ingredients of this medicine (listed in section 6). →If any of these apply to you, tell your doctor without taking

Warnings and precautions Talk to your doctor or pharmacist before taking Seroxat • Are you taking any other medicines (see Other medicines and Seroxat, inside this leaflet)?

• Are you taking tamoxifen to treat breast cancer or fertility problems? Seroxat may make tamoxifen less effective, so your

doctor may recommend you take another antidepressant. • Do you have kidney, liver or heart trouble? Do you have epilepsy or have a history of fits or seizures?
Have you ever had episodes of mania (overactive behaviour or thoughts)? Are you having electro-convulsive therapy (ECT)?

 Do you have a history of bleeding disorders, or are you taking other medicines that may increase the risk of bleeding (these include medicines used to thin the blood, such as warfarin, anti- psychotics such as perphenazine or clozapine, inflammation called non-steroidal anti-inflammatory drugs or NSAIDs, such as acetylsalicylic acid, ibuprofen, celecoxib, etodolac, diclofenac, meloxicam)?

· Do you have diabetes? • Are you on a low sodium diet?

• Do you have glaucoma (pressure in the eye)?

• Are you pregnant or planning to get pregnant (see Pregnancy, breast-feeding and fertility, inside this leaflet)?
Are you under 18 years old (see Children and adolescents)

under 18, inside this leaflet)? →If you answer YES to any of these questions, and you have not already discussed them with your doctor, go back to your doctor and ask what to do about taking Seroxat.

Children and adolescents under 18 Seroxat should not be used for children and adolescents under 18 years. Also, patients under 18 have an increased risk of side effects such as suicide attempt, suicidal thoughts and hostility (predominantly aggression, oppositional behaviour and anger) when they take Seroxat. If your doctor has prescribed Seroxat for you (or your child) and you want to discuss this, please go back to your doctor. You should inform your doctor if any of the symptoms listed above develop or worsen when you (or your child) are taking Seroxat. Also, the long-term safety effects, concerning growth, maturation and cognitive and behavioural development, of Seroxat in this age group have not vet been demonstrated.

studies of Seroxat in under 18s, common side effects that affected less than 1 in 10 children/adolescents were: an ncrease in suicidal thoughts and suicide attempts; deliberately harming themselves; being hostile; aggressive or unfriendly;

lack of appetite; shaking; abnormal sweating; hyperactivity (having too much energy); agitation; changing emotions (including crying and changes in mood); and unusual bruising or bleeding (such as nose bleeds). These studies also showed that the same symptoms affected children and adolescents taking sugar pills (placebo)

instead of Seroxat, although these were seen less often some patients in these studies of under 18s had withdrawal effects when they stopped taking Seroxat. These effects were mostly similar to those seen in adults after stopping Seroxat (see section 3). In addition, patients under 18 also commonly affecting less than 1 in 10) experienced stomach ache, feeling nervous and changing emotions (including crying, changes in mood, trying to hurt themselves, thoughts of suicide and attempting suicide)

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

vourself • 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.

Important side effects seen with Seroxat Some patients who take Seroxat develop something called akathisia, where they feel restless and feel like they can't sit or stand still. Other patients develop something called serotonin syndrome, or neuroleptic malignant syndrome, where they have some or all of the following symptoms: feeling very agitated or irritable, feeling confused, feeling restless, feeling hot, sweating, shaking, shivering, hallucinations (strange visions or sounds), muscle stiffness, sudden jerks of the muscles or a fast heartbeat. The severity can increase, leading to loss of consciousness. If you notice any of these symptoms contact your doctor. For more information on these or other side effects of Seroxat, see section 4. Medicines like 'Seroxat' (so called SSRIs) may cause symptoms of sexual dysfunction (see section 4). In some cases, Other medicines and Seroxat Some medicines can affect the way Seroxat works or make it more likely that you will have side effects. Seroxat can also

these symptoms have continued after stopping treatment.

affect the way some other medicines work. These include Medicines called monoamine oxidase inhibitors (MAOIs, Seroxat with food, drink and alcohol including moclobemide and methylthioninium chloride (methylene blue)) - see Do not take Seroxat, inside this leaflet Do not drink alcohol while you are taking Seroxat. Alcohol may make your symptoms or side effects worse. Taking Seroxat in Thioridazine or pimozide, which are **anti-psychotics** - see Do the morning with food will reduce the likelihood of you feeling not take Seroxat, inside this leaflet sick (nausea).

Aspirin (acetylsalicylic acid), ibuprofen or other medicines called NSAIDs (non-steroidal anti- inflammatory drugs) like celecoxib, etodolac, diclofenac and meloxicam, used for pain and inflammation Tramadol, buprenorphine and pethidine, painkillers

Buprenorphine combined with naloxone, substitution treatment for opioid drug addiction Medicines called triptans, such as sumatriptan, used to treat

migraine • Other antidepressants including other SSRIs, tryptophan and tricyclic antidepressants like clomipramine, nortriptyline and desipramine

- A dietary supplement called tryptophan
- Mivacurium and suxamethonium (used in anaesthesia) Medicines such as lithium, risperidone, perphenazine clozapine (called anti-psychotics) used to treat some
 - osychiatric conditions Fentanyl, used in anaesthesia or to treat chronic pain A combination of fosamprenavir and ritonavir, which is used to treat **Human Immunodeficiency Virus (HIV) infection**
 - St John's Wort, a herbal remedy for depression Phenobarbital, phenytoin, sodium valproate or
 - carbamazepine, used to treat fits or epilepsy Atomoxetine which is used to treat 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 to treat an
 - irregular heartbeat Metoprolol, a beta-blocker used to treat high blood pressure and heart problems
 - Pravastatin, used to treat high cholesterol · Rifampicin, used to treat tuberculosis (TB) and leprosy Linezolid, an antibiotic
 - · Tamoxifen, which is used to treat breast cancer or fertility problems. \rightarrow If you are taking or have recently taken any of the

medicines in this list, and you have not already discussed these with your doctor, go back to your doctor and ask what

 Visual disturbances Fluttering or pounding heartbeat (palpitations) →Please see your doctor if you are worried about withdrawal effects when stopping Seroxat. If you have any further questions on the use of this medicineask

our doctor or pharmacist

4. Possible side effects Like all medicines, this medicine can cause side effects, although not everybody gets them. Side effects are more likely to happen in the first few weeks of taking Seroxat. See the doctor if you get any of the following side effects during treatment. You may need to contact your doctor or go to a hospital straight

Uncommon side effects

awav.

These may affect up to 1 in 100 people • If you have unusual bruising or bleeding, including vomiting blood or passing blood in your stools, contact your doctor or go to a hospital straight away. If you find that you are not able to pass water, contact your doctor or go to a hospital straight away.

Rare side effects

These may affect up to 1 in 1,000 people • If you experience seizures (fits), contact your doctor or go

to a hospital straight away. If you feel restless and feel like you can't sit or stand still you may have something called akathisia. Increasing your dose of Seroxat may make these feelings worse. 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 because your blood is low in sodium. If you have these symptoms, contact your

Very rare side effects

DESTINATION:

DIMENSIONS:

Date of Issue

Name

Signature

Date

Description

COLORS:

hese may affect up to 1 in 10,000 people

• Allergic reactions, which may be severe to Seroxat. If you develop a red and lumpy skin rash, swelling of the eyelids, face, lips, mouth or tongue, start to itch or have difficulty breathing (shortness of breath) or swallowing 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 some or all of the following symp may have something called serotonin syndrome. The symptoms include: feeling confused, feeling restless, sweating,

shaking, shivering, hallucinations (strange visions or sounds) sudden jerks of the muscles or a fast heartbeat. If you feel like this contact your doctor. Acute glaucoma.

If your eyes become painful and you develop blurred vision, contact your doctor.

LOCAL

BLACK

Regulatory (Local)

160 x 610 mm

Heavy vaginal bleeding shortly after birth (postpartum hage), see Pregnancy, breast- feeding and fertility in haemor section 2 for more information If you experience these side effects, contact your doctor. Other possible side effects during treatment Very common side effects hese may affect more than 1 in 10 people Feeling sick (nausea). Taking your medicine in the morning with food will reduce the chance of this happening. Change in sex drive or sexual function. For example, lack of orgasm and, in men, abnormal erection and ejaculation. Common side effects These may affect up to 1 in 10 people Increases in the level of cholesterol in the blood · Lack of appetite Not sleeping well (insomnia) or feeling sleepy

Frequency cannot be estimated from the available data

emselves while taking Seroxat or soon after stopping

treatment (see Thoughts of suicide and worsening of your

Some people have had thoughts of harming or killing

pression or anxiety disorder in section 2) Some people have experienced aggression while taking

 Abnormal dreams (including nightmares) Feeling dizzy or shaky (tremors) Headache

Difficulty in concentrating Feeling agitated

Not known

SEBOXAT

Feeling unusually weak

Blurred vision

Yawning, dry mouth Diarrhoea or constipation

Vomiting

Weight gain Sweating.

Uncommon side effects These may affect up to 1 in 100 people

· A brief increase in blood pressure, or a brief decrease that 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

20 - 09 - 2023

Quality Assurance

GSK Approval

SEROXAT PIL (160 X 610 mm)

Having hallucinations (strange visions or sounds) An inability to urinate (urinary retention) or an uncontrollable. involuntary passing of urine (urinary incontinence) • If you are a diabetic patient you may notice a loss of control of

your blood sugar levels whilst taking Seroxat. Please speak to your doctor about adjusting the dosage of you

lin or diabetes medications. **Rare side effects** These may affect up to 1 in 1.000 people Abnormal production of breast milk in men and women A slow heartbeat

Effects on the liver showing up in blood tests of your liver function Panic attacks

- Overactive behaviour or thoughts (mania) Feeling detached from yourself (depersonalisation)
- Feeling anxious Irresistible urge to move the legs (Restless Legs Syndrome) Pain in the joints or muscles
- 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

These may affect **up to 1 in 10,000 people** • Skin rash, which may blister, and looks 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-Johnsor syndrome) A widespread rash with blisters and skin peeling on much of the body surface (toxic epidermal necrolysis Liver problems that make the skin or whites of the eyes go

vellow Syndrome of inappropriate antidiuretic hormone production (SIADH) which 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 ill 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 won't go away

Low blood platelet count. Not known

Frequency cannot be estimated from the available data

PHARMALINE Approval

Regulatory

Inflammation of the colon (causing diarrhoea) Tooth grinding Some patients have developed buzzing, hissing, whistling ringing or other persistent noise in the ears (tinnitus) when they take Seroxat.

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

Reporting of side effects

Quality Assurance

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this

with the use of GSK product/s, please contact us via: gulf.safety@gsk.com. By reporting side effects you can help provide more information on the safety of this medicine 5. How to store Seroxat Keep this medicine out of the sight and reach of children

To report Product Complaint/s or Adverse Event/s associated

 Do not use this medicine after the expiry date (EXP) which is stated on the blister and the carton. The expiry date refers to the last day of that month. • Do not store your tablets above 30°C.

Store in the original package in order to protect from light.
If you are using half tablets, be careful to keep them safely in

• 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 environm

6. Contents of the pack and other information

The active substance is paroxetine (20 mg), as the

What Seroxat looks like and contents of the pack

in the tablet core: dibasic calcium phosphate dihydrate

nagnesium stearate and sodium starch glycolate (Type A).

in the tablet coat: hypromellose, titanium dixoide, macrogol

Seroxat 20 mg film-coated tablets are white, oval-shaped

tablets, marked '20' on one side, and with a break bar on the

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other side. Each pack of Seroxat contains child-resistant

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What Seroxat contains

/drochloride hemihydrate

The other ingredients are

400 and polysorbate 80

blisters of 30 tablets

Packed by **Pharmaline** – Lebanon

to do. The dose may need to be changed or you may need to be given another medicine. Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

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. In babies whose mothers took Seroxat during the first few months of pregnancy, there have been some reports showing an increased risk of birth defects in particular those affecting the heart. In the general population, about 1 in 100 babies are born with a heart defect. This increased to up to 2 in 100 babies in mothers who took Seroxat. You and your doctor may decide that it is better for you to change to another treatment or to gradually stop taking Seroxat while you are pregnant. However depending on your circumstances, your doctor may suggest that it is better for you to keep taking Seroxat. Make sure your midwife or doctor knows you're taking Seroxat. If you take Seroxat 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 bleed disorders. Your doctor or midwife should be aware that you are taking Seroxat so they can advise you. When taken during pregnancy, particularly late pregnancy, medicines like Seroxat may increase the risk of a serious 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 Seroxat during the last 3 months of pregnancy, your newborn baby miaht also have other conditions, which usually begin during the

first 24 hours after birth. Symptoms include: trouble with breathing • a blue-ish 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

exaggerated reflexes

→ 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.

Seroxat may get into breast milk in very small amounts. If you are taking Seroxat, go back and talk to your doctor before you start breast-feeding. You and your doctor may decide that you can breast-feed while you are taking Seroxat. Paroxetine has been shown to reduce the quality of sperm in animal studies. Theoretically, this could affect fertility, but impact on human fertility has not been observed as vet

Driving and using machines Possible side effects of Seroxat include dizziness feeling sleepy or blurred vision. If you do get these do not drive or use machinery.

Seroxat contains sodium This medicine contains less than 1 mmol sodium (23 mg) pe

tablet, that is to say essentially 'sodium-free 3. How to take Seroxat Always take this medicine exactly as your doctor or

pharmacist has told you. Check with your doctor or pharmacist if you are not sure eroxat strength:

Depression

Obsessive Compulsive Disorde

obsessions and compulsions)

Panic Disorder (panic attacks)

Social Anxiety Disorder (fear or

avoidance of social situations)

Post-Traumatic Stress Disorder

Generalised Anxiety Disorder

maximum daily dose.

with a drink of water

Do not chew.

20 mg: White tablets, marked with "20" he usual doses for different conditions are set out in the table below

four doctor will advise you what dose to take when you

first start taking Seroxat. Most people start to feel better after

a couple of weeks. If you don't start to feel better after this time,

decide to increase the dose gradually, 10 mg at a time, up to a

Take your tablets in the morning with food. Swallow them

taking your tablets. This may be for many months or even

Your doctor will talk to you about how long you will need to keep

talk to your doctor, who will advise you. He or she may

s, confusion, se side effects,	Never take more tablets than your doctor recommends. If you take too many Seroxat tablets (or someone else does), tell your doctor or a hospital straight away. Show them the pack of tablets.
	tablets. Someone who has taken an overdose of Seroxat may have any

Patients with liver or kidney disease

If you take more Seroxat than you should

lder people)

20 mg per day.

20 mg

40 mg

40 mg

20 mg

20 mg

20 mg

If you forget to take Seroxat

Take your medicine at the same time every day.

What to do if you're feeling no better

If you do forget a dose, and you remember before you go

If you only remember during the night, or the next day leave out

these should go away after you take your next dose at the usual

the missed dose. You may possibly get withdrawal effects, but

to bed, take it straight away. Carry on as usual the next day.

Do not take a double dose to make up for a forgotten dose

Seroxat will not relieve your symptoms straight away - all

ressants take time to work. Some people will start to

usual

Starting dose

20 mg

20 mg

10 mg

20 mg

20 mg

20 mg

one of the symptoms listed in section 4, Possible side effects or the following symptoms: fever; uncontrollable tightening of the muscles

The maximum dose for people over 65 is 40 mg per day.

If you have trouble with your liver or kidneys your doctor may

If you have severe liver or kidney disease the maximum dose is

decide that you should have a lower dose of Seroxat than

η the pack of

Recommended daily dose Maximum daily dose

may have any

50 mg

60 mg

60 mg

50 mg

50 mg

50 mg

Your doctor should ask to see you again a couple of weeks after ou first start treatment. Tell your doctor if you haven't started to feel better. If you stop taking Seroxat Do not stop taking Seroxat until your doctor tells you to. When stopping Seroxat, your doctor will help you to reduce

feel better within a couple of weeks, but for others it may take a

little longer. Some people taking antidepressants feel worse before feeling better. If you don't start to feel better after a

couple of weeks, go back to your doctor who will advise you.

your dose slowly over a number of weeks or months - this should help reduce the chance of withdrawal effects. One way of doing this is to gradually reduce the dose of Seroxat you take by 10 mg a week. Most people find that any symptoms on stopping Seroxat are mild and go away on their own within two weeks. For some people, these symptoms may be more severe, or go on for longer. If you get withdrawal effects when you are coming off your

tablets your doctor may decide that you should come off them more slowly. If you get severe withdrawal effects when you stop taking Seroxat, please see your doctor. He or she may ask you to start taking your tablets again and come off them more If you do get withdrawal effects, you will still be able to

Possible withdrawal effects when stopping treatment Studies show that 3 in 10 patients notice one or more symptoms on stopping Seroxat. Some withdrawal effects on stopping occur more frequently than others.

Common side effects These may affect up to 1 in 10 people

 Feeling dizzy, unsteady or off-balance • Feelings like pins and needles, burning sensations and (less commonly) electric shock sensations, including in the head

 Some patients have developed buzzing, hissing, whistling, ringing or other persistent noise in the ears (tinnitus) when they take Seroxat · Sleep disturbances (vivid dreams, nightmares, inability to

Feeling anxious

 Headaches. Uncommon side effects

These may affect up to 1 in 100 people Feeling sick (nausea)

 Sweating (including night sweats) Feeling restless or agitated

 Tremor (shakiness) · Feeling confused or disorientated

Diarrhoea (loose stools)

· Feeling emotional or irritable

This is a Medicament Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you. - Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the nedicament. The doctor and the pharmacist are the experts in medicines, their benefits and risks. Do not by yourself interrupt the period of treatment prescribed for you. Do not repeat the same prescription without consulting your doctor Keep all medicaments out of reach of children.

Council of Arab Health Ministers Union of Arab Pharmacists

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