

Patient Information leaflet

Seroxat® 20mg/10ml Liquid (Paroxetine)

The name of your medicine is Seroxat 20mg/10ml Liquid, but will be referred to as Seroxat Liquid throughout the remainder of this leaflet.

Eight important things you need to know about Seroxat Liquid

Please read all of the leaflet. It includes a lot of additional important information about this medicine.

- **Seroxat Liquid treats depression and anxiety disorders.** Like all medicines it can have unwanted effects. It is therefore important that you and your doctor weigh up the benefits of treatment against the possible unwanted effects, before starting treatment.
- **Seroxat Liquid is not for use in children and adolescents under 18.** See section 6, *Children and adolescents under 18*, inside this leaflet.
- **Seroxat Liquid won't work straight away.** Some people taking antidepressants feel worse before feeling better. Your doctor should ask to see you again a couple of weeks after you first start treatment. Tell your doctor if you haven't started feeling better. See section 3, *How to take your medicine*, inside this leaflet.
- **Some people who are depressed or anxious think of harming or killing themselves.** If you start to feel worse, or think of harming or killing yourself, **see your doctor or go to a hospital straight away.** See *Thoughts of harming yourself*, inside this leaflet.
- **Don't stop taking Seroxat Liquid without talking to your doctor.** If you stop taking Seroxat Liquid suddenly or miss a dose, you may get withdrawal effects. See section 5, *Stopping Seroxat Liquid*, inside this leaflet.
- **If you feel restless and feel like you can't sit or stand still, tell your doctor.** Increasing the dose of Seroxat Liquid may make these feelings worse. See section 4, *Possible side-effects*, inside this leaflet.
- **Taking some other medicines with Seroxat Liquid can cause problems.** You may need to talk to your doctor. See *Other medicines and Seroxat Liquid*, inside this leaflet.
- **If you are pregnant or planning to get pregnant,** talk to your doctor. See *Pregnancy, breast-feeding and Seroxat Liquid*, inside this leaflet.

Read this leaflet. It includes a lot of important information about this medicine.

Keep this leaflet. You may need to read it again.

If you have more questions, ask your doctor or pharmacist (chemist). You may also find it helpful to contact a self-help group, or patient organisation, to find out more about your condition. Your doctor will be able to give you details.

1. What Seroxat Liquid is and what it is used for

Your medicine is available in bottles of 150ml. Each 5ml of the liquid contains 10mg of paroxetine. The liquid is an orange suspension with a smell of oranges and a sweet taste.

Seroxat Liquid is a treatment for adults with depression and/or anxiety disorders.

Seroxat Liquid is one of a group of medicines called SSRIs (*selective serotonin reuptake inhibitors*). Everyone has a substance called serotonin in their brain. People who are depressed or anxious have lower levels of serotonin than others. It is not fully understood how Seroxat Liquid and other SSRIs work but they may help by increasing the level of serotonin in the brain.

Other medicines or psychotherapy can also treat depression and anxiety. Treating depression or anxiety disorders properly is important to help you get better. If it's not treated, your condition may not go away and may become more serious and more difficult to treat.

You may find it helpful to tell a friend or relative that you are depressed or suffering from 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.

2. Before you take Seroxat Liquid

Do not take Seroxat Liquid...

- **If you are taking medicines called monoamine oxidase inhibitors** (MAOIs, including *moclobemide* and methylthionium 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 Liquid once you have stopped taking the MAOI
 - **If you are taking a tranquilliser** called *thioridazine*
 - **If you are taking an anti-psychotic** called *pimozide*
 - **If you have previously had an allergic reaction** to paroxetine or any of the other liquid ingredients listed. See section 8, *What Seroxat Liquid contains*, inside this leaflet.
- **If any of these apply to you,** tell your doctor without taking Seroxat Liquid.

Check with your doctor...

- Are you taking any other medicines (see *Other medicines and Seroxat Liquid*, inside this leaflet)?
- Are you taking tamoxifen to treat breast cancer or fertility problems? Seroxat Liquid may make tamoxifen less effective, so your doctor may recommend you take another antidepressant.
- Do you have eye, kidney, liver or heart trouble?
- Do you have epilepsy or have a history of fits?
- Do you have episodes of mania (overactive behaviour or thoughts)?
- Are you having electro-convulsive therapy (ECT)?
- Do you have a history of bleeding disorders?
- 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 Seroxat Liquid*, inside this leaflet)?
- Have you been told by your doctor that you have an intolerance to some sugars, as this medicine contains the sugar, sorbitol (E420)?

→ **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 Liquid.**

Certain non active ingredients of your medicine may cause unwanted effects:

- methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216) may cause allergic reactions (possibly delayed)
- propylene glycol may cause skin irritation
- Sunset yellow FCF (E110), may cause allergic reactions.

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 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.

Pregnancy, breast-feeding and Seroxat Liquid

Talk to your doctor as soon as possible if you're pregnant, if you might be pregnant, or if you're planning to become pregnant. In babies whose mothers took Seroxat Liquid 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 about 2 in 100 babies in mothers who took Seroxat Liquid. You and your doctor may decide that it is better for you to gradually stop taking Seroxat Liquid while you are pregnant. However, depending on your circumstances, your doctor may suggest that it is better for you to keep taking Seroxat Liquid.

Make sure your midwife or doctor knows you're taking Seroxat Liquid.

When taken during pregnancy, particularly late pregnancy, medicines like Seroxat Liquid 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 Liquid during the last 3 months of pregnancy, 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.

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 Liquid may get into breast milk in very small amounts.

If you are taking Seroxat Liquid, 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 Liquid.

Medicines like Seroxat Liquid may reduce the quality of your sperm. Although the impact of this on fertility is unknown, fertility may be affected in some men whilst taking Seroxat Liquid.

Other medicines and Seroxat Liquid

Some medicines can affect the way Seroxat Liquid works, or make it more likely that you'll have side effects. Seroxat Liquid can also affect the way some other medicines work.

These include:

- Medicines called **monoamine oxidase inhibitors** (MAOIs, including moclobemide and methylthionium chloride (methylene blue)) – see *Do not take Seroxat Liquid*, inside this leaflet
 - Thioridazine or pimozide, which are **anti-psychotics** – see *Do not take Seroxat Liquid*, inside this leaflet
 - Aspirin, ibuprofen or other medicines called NSAIDs (*non-steroidal anti-inflammatory drugs*) like celecoxib, etodolac and meloxicam, used for **pain and inflammation**
 - Tramadol and pethidine, **painkillers**
 - Medicines called *triptans*, such as sumatriptan, used to treat **migraine**
 - Other **antidepressants** including other SSRIs, tryptophan and tricyclic antidepressants like clomipramine, nortriptyline and desipramine
 - Medicines such as lithium, risperidone, perphenazine (called *anti-psychotics*) used to treat some **psychiatric 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 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**
 - Rifampicin, used to treat **tuberculosis (TB) and leprosy**
 - Linezolid, an **antibiotic**
 - Tamoxifen, which is used to **treat breast cancer or fertility problems**
 - Medicines such as cimetidine or omeprazole, which are used to **reduce the amount of acid in your stomach.**
- **If you are taking 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 to do.** The dose may need to be changed or you may need to be given another medicine.

If you are taking any other medicines, including ones you have bought yourself, check with your doctor or pharmacist before taking Seroxat Liquid. They will know if it is safe for you to do so.

Seroxat Liquid and alcohol

Do not drink alcohol while you are taking Seroxat Liquid. Alcohol may make your symptoms or side-effects worse.

Driving and using machinery

Possible side-effects with Seroxat Liquid include dizziness, confusion or changes in eyesight. If you do get these side-effects, do not drive or use machinery.

Important information about some of the ingredients of Seroxat Liquid

- This medicine contains the sugar, sorbitol (E420). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking Seroxat Liquid.
- Methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216) may cause allergic reactions (possible delayed).
- Sunset yellow FCF (E110) is used as a colouring agent, and may cause allergic reactions.

3. How to take your medicine

Take Seroxat Liquid in the morning with food.

Shake the bottle before use.

It is important to take your medicine as instructed by your doctor. The label will tell you how much medicine to take and how often. If you are unsure, ask your doctor or pharmacist.

Your doctor will advise you what dose to take when you first start taking Seroxat Liquid. Most people start to feel better after a couple of weeks. If you don't start to feel better after this time, talk to your doctor, who will advise you. He or she may decide to increase the dose gradually, 5ml (10mg of paroxetine) at a time, up to a maximum daily dose.

The usual doses for different conditions are set out in the table below.

	Starting dose	Recommended daily dose	Maximum daily dose
Depression	10 ml	10 ml	25 ml
Obsessive Compulsive Disorder (obsessions and compulsions)	10 ml	20 ml	30 ml
Panic Disorder (panic attacks)	5 ml	20 ml	30 ml
Social Anxiety Disorder (fear or avoidance of social situations)	10 ml	10 ml	25 ml
Post Traumatic Stress Disorder	10 ml	10 ml	25 ml
Generalised Anxiety Disorder	10 ml	10 ml	25 ml

Remember, your doctor will advise you on the daily dose you should take.

Your doctor will talk to you about how long you will need to keep taking your medicine. This may be for many months or even longer.

Older people

The maximum dose for people over 65 is 20ml (40mg of paroxetine) per day.

Patients with liver or kidney disease

If you have trouble with your liver or kidneys your doctor may decide that you should have a lower dose of Seroxat Liquid than usual. If you have severe liver or kidney disease the maximum dose is 10ml (20mg of paroxetine) per day.

What if you miss a dose?

Take your medicine at the same time every day.

If you do forget a dose, and you remember before you go to bed, take it straight away. Carry on as usual the next day.

If you only remember during the night, or the next day, leave out the missed dose. You may possibly get withdrawal effects, but these should go away after you take your next dose at the usual time.

What if you take too much Seroxat Liquid?

Never take more medicine than your doctor recommends. If you take too much Seroxat Liquid (or someone else does), tell your doctor or a hospital straight away. Show them the bottle of medicine.

What to do if you're feeling no better

Seroxat Liquid will not relieve your symptoms straight away - all antidepressants take time to work. Some people will start to 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 doctor should ask to see you again a couple of weeks after you first start treatment. Tell your doctor if you haven't started to feel better.

4. Possible side-effects

As with other medicines Seroxat Liquid can cause side-effects, but not everybody gets them.

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 away.

Likely to affect up to 1 in every 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.**

Likely to affect up to 1 in every 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 Liquid 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 doctor.**

Likely to affect up to 1 in every 10,000 people:

- **Allergic reactions to Seroxat Liquid.**
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 or swallowing, **contact your doctor or go to a hospital straight away.**
- **If you have some or all of the following symptoms** you 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.**

Frequency unknown

Some people have had thoughts of harming or killing themselves while taking Seroxat Liquid or soon after stopping treatment (see section 2, *Before you take Seroxat Liquid*).

Other possible side effects during treatment

Likely to 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.

Likely to 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
- Abnormal dreams (including nightmares)
- Feeling dizzy or shaky (tremors)
- Headache
- Difficulty in concentrating
- Feeling agitated
- Blurred vision
- Yawning, dry mouth
- Diarrhoea or constipation
- Vomiting
- Weight gain
- Feeling weak
- Sweating.

Likely to affect up to 1 in every 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
- Feeling confused
- Having hallucinations (strange visions or sounds)
- An inability to urinate (urinary retention) or an uncontrollable, involuntary passing of urine (urinary incontinence).

Likely to affect up to 1 in every 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.

Likely to affect up to 1 in every 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-Johnson 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 yellow
- 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
- Unexpected bleeding e.g. bleeding gums, blood in the urine or in vomit, or the appearance of unexpected bruises or broken blood vessels (broken veins).

Some patients have developed buzzing, hissing, whistling, ringing or other persistent noise in the ears (tinnitus) when they take Seroxat Liquid.

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

- ➔ If you have any concerns while you are taking Seroxat Liquid, talk to your doctor or pharmacist who will be able to advise you.

5. Stopping Seroxat Liquid

Do not stop taking Seroxat Liquid until your doctor tells you to.

When stopping Seroxat Liquid, your doctor will help you to reduce 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 Liquid you take by 5ml (10mg of paroxetine) a week. Most people find that any symptoms on stopping Seroxat Liquid 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 medicine your doctor may decide that you should come off it more slowly. If you get severe withdrawal effects when you stop taking Seroxat Liquid, please see your doctor. He or she may ask you to start taking your medicine again and come off it more slowly.

If you do get withdrawal effects, you will still be able to stop Seroxat Liquid.

Possible withdrawal effects when stopping treatment

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

Likely to 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 Liquid.
- Sleep disturbances (vivid dreams, nightmares, inability to sleep)
- Feeling anxious
- Headaches.

Likely to affect up to 1 in every 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
- Visual disturbances
- Fluttering or pounding heartbeat (palpitations).

- ➔ **Please see your doctor if you are worried about withdrawal effects when stopping Seroxat Liquid.**

6. Children and adolescents under 18

Seroxat Liquid should not be used for children and adolescents under 18 years because it has not been proven to be an effective medicine for this age group. Also, patients under 18 have an increased risk of side effects such as suicidal thoughts and harming themselves when they take Seroxat Liquid. If your doctor has prescribed Seroxat Liquid for you (or your child) and you want to discuss this, please go back to your doctor.

In studies of Seroxat Liquid in under 18s, common side effects that affected less than 1 in 10 children/adolescents were: an increase 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 Liquid, although these were seen less often.

Some patients in these studies of under 18s had withdrawal effects when they stopped taking Seroxat Liquid. These effects were mostly similar to those seen in adults after stopping Seroxat Liquid (see section 5, *Stopping Seroxat Liquid*, inside this leaflet). 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).

7. Looking after your medicine

- Keep your medicine in the original bottle. Do not store above 25°C.
- Keep your medicine out of the sight and reach of children.
- Do not take your medicine after the expiry date shown on the label.
- Your Seroxat Liquid keeps for one month after it is first opened. If you have any left this time please give it back to your pharmacist who will dispose of it safely. If you need any more Seroxat Liquid, please see your doctor for a new prescription.
- Never give this medicine to others, even if they have similar symptoms to yours.
- Finish all your medicine as the doctor tells you to.
- Keep this leaflet. You may need to read it again.
- If your medicine appears discoloured, or shows any other signs of deterioration, take it back to the pharmacist who will advise you.

8. What Seroxat Liquid contains

The active ingredient in Seroxat liquid is paroxetine (as Paroxetine hydrochloride hemihydrate).

The inactive ingredients are polacrillin potassium, dispersible cellulose (E460), propylene glycol, glycerol (E422), sorbitol (E420), methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), sodium citrate (E331), citric acid (E330), sodium saccharin (E954), natural orange flavour, natural lemon flavour, sunset yellow (E110), simethicone emulsion and purified water. Sodium content is 6.6mg per 10ml.

Manufactured by: Farmaclair, Herouville Saint Clair, France.

Procured from within the EU and repackaged by: Doncaster Pharmaceuticals Group Ltd., Kirk Sandall, Doncaster, DN3 1QR.

Product Licence holder: BR Lewis Pharmaceuticals Ltd., Kirk Sandall, Doncaster, DN3 1QR.

PL No: 08929/0089

POM

Other formats:

To listen to or request a copy of this leaflet in Braille, large print or audio please call 01302 365000 and ask for the Regulatory Department.

Please be ready to give the following information:

Product name: Seroxat 20mg/10ml Liquid

Reference number: 08929/0089

Leaflet revision and issue date (Ref): 04.09.12

Seroxat® is a registered trademark of the GlaxoSmithKline group of companies.

Patient Information leaflet

Paroxetine 20mg/10ml Liquid (Paroxetine)

The name of your medicine is Paroxetine 20mg/10ml Liquid, but will be referred to as Paroxetine Liquid throughout the remainder of this leaflet.

Eight important things you need to know about Paroxetine Liquid

Please read all of the leaflet. It includes a lot of additional important information about this medicine.

- **Paroxetine Liquid treats depression and anxiety disorders.** Like all medicines it can have unwanted effects. It is therefore important that you and your doctor weigh up the benefits of treatment against the possible unwanted effects, before starting treatment.
- **Paroxetine Liquid is not for use in children and adolescents under 18.** See section 6, *Children and adolescents under 18*, inside this leaflet.
- **Paroxetine Liquid won't work straight away.** Some people taking antidepressants feel worse before feeling better. Your doctor should ask to see you again a couple of weeks after you first start treatment. Tell your doctor if you haven't started feeling better. See section 3, *How to take your medicine*, inside this leaflet.
- **Some people who are depressed or anxious think of harming or killing themselves.** If you start to feel worse, or think of harming or killing yourself, **see your doctor or go to a hospital straight away.** See *Thoughts of harming yourself*, inside this leaflet.
- **Don't stop taking Paroxetine Liquid without talking to your doctor.** If you stop taking Paroxetine Liquid suddenly or miss a dose, you may get withdrawal effects. See section 5, *Stopping Paroxetine Liquid*, inside this leaflet.
- **If you feel restless and feel like you can't sit or stand still, tell your doctor.** Increasing the dose of Paroxetine Liquid may make these feelings worse. See section 4, *Possible side-effects*, inside this leaflet.
- **Taking some other medicines with Paroxetine Liquid can cause problems.** You may need to talk to your doctor. See *Other medicines and Paroxetine Liquid*, inside this leaflet.
- **If you are pregnant or planning to get pregnant,** talk to your doctor. See *Pregnancy, breast-feeding and Paroxetine Liquid*, inside this leaflet.

Read this leaflet. It includes a lot of important information about this medicine.

Keep this leaflet. You may need to read it again.

If you have more questions, ask your doctor or pharmacist (chemist). You may also find it helpful to contact a self-help group, or patient organisation, to find out more about your condition. Your doctor will be able to give you details.

5. What Paroxetine Liquid is and what it is used for

Your medicine is available in bottles of 150ml. Each 5ml of the liquid contains 10mg of paroxetine. The liquid is an orange suspension with a smell of oranges and a sweet taste.

Paroxetine Liquid is a treatment for adults with depression and/or anxiety disorders.

Paroxetine Liquid is one of a group of medicines called SSRIs (*selective serotonin reuptake inhibitors*). Everyone has a substance called serotonin in their brain. People who are depressed or anxious have lower levels of serotonin than others. It is not fully understood how Paroxetine Liquid and other SSRIs work but they may help by increasing the level of serotonin in the brain.

Other medicines or psychotherapy can also treat depression and anxiety. Treating depression or anxiety disorders properly is important to help you get better. If it's not treated, your condition may not go away and may become more serious and more difficult to treat.

You may find it helpful to tell a friend or relative that you are depressed or suffering from 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.

6. Before you take Paroxetine Liquid

Do not take Paroxetine Liquid...

- **If you are taking medicines called monoamine oxidase inhibitors** (MAOIs, including *moclobemide* and methylthionium 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 Paroxetine Liquid once you have stopped taking the MAOI
- **If you are taking a tranquilliser** called *thioridazine*
- **If you are taking an anti-psychotic** called *pimozide*
- **If you have previously had an allergic reaction** to paroxetine or any of the other liquid ingredients listed. See section 8, *What Paroxetine Liquid contains*, inside this leaflet.

→ **If any of these apply to you,** tell your doctor without taking Paroxetine Liquid.

Check with your doctor...

- Are you taking any other medicines (see *Other medicines and Paroxetine Liquid*, inside this leaflet)?
- Are you taking tamoxifen to treat breast cancer or fertility problems? Paroxetine Liquid may make tamoxifen less effective, so your doctor may recommend you take another antidepressant.
- Do you have eye, kidney, liver or heart trouble?
- Do you have epilepsy or have a history of fits?
- Do you have episodes of mania (overactive behaviour or thoughts)?
- Are you having electro-convulsive therapy (ECT)?
- Do you have a history of bleeding disorders?
- 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 Paroxetine Liquid*, inside this leaflet)?
- Have you been told by your doctor that you have an intolerance to some sugars, as this medicine contains the sugar, sorbitol (E420)?

→ **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 Paroxetine Liquid.**

Certain non active ingredients of your medicine may cause unwanted effects:

- methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216) may cause allergic reactions (possibly delayed)
- propylene glycol may cause skin irritation
- Sunset yellow FCF (E110), may cause allergic reactions.

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 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.

Pregnancy, breast-feeding and Paroxetine Liquid

Talk to your doctor as soon as possible if you're pregnant, if you might be pregnant, or if you're planning to become pregnant. In babies whose mothers took Paroxetine Liquid 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 about 2 in 100 babies in mothers who took Paroxetine Liquid. You and your doctor may decide that it is better for you to gradually stop taking Paroxetine Liquid while you are pregnant. However, depending on your circumstances, your doctor may suggest that it is better for you to keep taking Paroxetine Liquid.

Make sure your midwife or doctor knows you're taking Paroxetine Liquid.

When taken during pregnancy, particularly late pregnancy, medicines like Paroxetine Liquid 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 Paroxetine Liquid during the last 3 months of pregnancy, 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.

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.**

Paroxetine Liquid may get into breast milk in very small amounts.

If you are taking Paroxetine Liquid, 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 Paroxetine Liquid.

Medicines like Paroxetine Liquid may reduce the quality of your sperm. Although the impact of this on fertility is unknown, fertility may be affected in some men whilst taking Paroxetine Liquid.

Other medicines and Paroxetine Liquid

Some medicines can affect the way Paroxetine Liquid works, or make it more likely that you'll have side effects. Paroxetine Liquid can also affect the way some other medicines work.

These include:

- Medicines called **monoamine oxidase inhibitors** (MAOIs, including moclobemide and methylthionium chloride (methylene blue)) – see *Do not take Paroxetine Liquid*, inside this leaflet
 - Thioridazine or pimozide, which are **anti-psychotics** – see *Do not take Paroxetine Liquid*, inside this leaflet
 - Aspirin, ibuprofen or other medicines called NSAIDs (*non-steroidal anti-inflammatory drugs*) like celecoxib, etodolac and meloxicam, used for **pain and inflammation**
 - Tramadol and pethidine, **painkillers**
 - Medicines called *triptans*, such as sumatriptan, used to treat **migraine**
 - Other **antidepressants** including other SSRIs, tryptophan and tricyclic antidepressants like clomipramine, nortriptyline and desipramine
 - Medicines such as lithium, risperidone, perphenazine (called *anti-psychotics*) used to treat some **psychiatric 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 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**
 - Rifampicin, used to treat **tuberculosis (TB) and leprosy**
 - Linezolid, an **antibiotic**
 - Tamoxifen, which is used to **treat breast cancer or fertility problems**
 - Medicines such as cimetidine or omeprazole, which are used to **reduce the amount of acid in your stomach.**
- **If you are taking 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 to do.** The dose may need to be changed or you may need to be given another medicine.

If you are taking any other medicines, including ones you have bought yourself, check with your doctor or pharmacist before taking Paroxetine Liquid. They will know if it is safe for you to do so.

Paroxetine Liquid and alcohol

Do not drink alcohol while you are taking Paroxetine Liquid. Alcohol may make your symptoms or side-effects worse.

Driving and using machinery

Possible side-effects with Paroxetine Liquid include dizziness, confusion or changes in eyesight. If you do get these side-effects, do not drive or use machinery.

Important information about some of the ingredients of Paroxetine Liquid

- This medicine contains the sugar, sorbitol (E420). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking Paroxetine Liquid.
- Methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216) may cause allergic reactions (possible delayed).
- Sunset yellow FCF (E110) is used as a colouring agent, and may cause allergic reactions.

7. How to take your medicine

Take Paroxetine Liquid in the morning with food.

Shake the bottle before use.

It is important to take your medicine as instructed by your doctor. The label will tell you how much medicine to take and how often. If you are unsure, ask your doctor or pharmacist.

Your doctor will advise you what dose to take when you first start taking Paroxetine Liquid. Most people start to feel better after a couple of weeks. If you don't start to feel better after this time, talk to your doctor, who will advise you. He or she may decide to increase the dose gradually, 5ml (10mg of paroxetine) at a time, up to a maximum daily dose.

The usual doses for different conditions are set out in the table below.

	Starting dose	Recommended daily dose	Maximum daily dose
Depression	10 ml	10 ml	25 ml
Obsessive Compulsive Disorder (obsessions and compulsions)	10 ml	20 ml	30 ml
Panic Disorder (panic attacks)	5 ml	20 ml	30 ml
Social Anxiety Disorder (fear or avoidance of social situations)	10 ml	10 ml	25 ml
Post Traumatic Stress Disorder	10 ml	10 ml	25 ml
Generalised Anxiety Disorder	10 ml	10 ml	25 ml

Remember, your doctor will advise you on the daily dose you should take.

Your doctor will talk to you about how long you will need to keep taking your medicine. This may be for many months or even longer.

Older people

The maximum dose for people over 65 is 20ml (40mg of paroxetine) per day.

Patients with liver or kidney disease

If you have trouble with your liver or kidneys your doctor may decide that you should have a lower dose of Paroxetine Liquid than usual. If you have severe liver or kidney disease the maximum dose is 10ml (20mg of paroxetine) per day.

What if you miss a dose?

Take your medicine at the same time every day.

If you do forget a dose, and you remember before you go to bed, take it straight away. Carry on as usual the next day.

If you only remember during the night, or the next day, leave out the missed dose. You may possibly get withdrawal effects, but these should go away after you take your next dose at the usual time.

What if you take too much Paroxetine Liquid?

Never take more medicine than your doctor recommends. If you take too much Paroxetine Liquid (or someone else does), tell your doctor or a hospital straight away. Show them the bottle of medicine.

What to do if you're feeling no better

Paroxetine Liquid will not relieve your symptoms straight away - all antidepressants take time to work. Some people will start to 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 doctor should ask to see you again a couple of weeks after you first start treatment. Tell your doctor if you haven't started to feel better.

8. Possible side-effects

As with other medicines Paroxetine Liquid can cause side-effects, but not everybody gets them.

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 away.

Likely to affect up to 1 in every 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.**

Likely to affect up to 1 in every 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 Paroxetine Liquid 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 doctor.**

Likely to affect up to 1 in every 10,000 people:

- **Allergic reactions to Paroxetine Liquid.**
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 or swallowing, **contact your doctor or go to a hospital straight away.**
- **If you have some or all of the following symptoms** you 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**.

Frequency unknown

Some people have had thoughts of harming or killing themselves while taking Paroxetine Liquid or soon after stopping treatment (see section 2, *Before you take Paroxetine Liquid*).

Other possible side effects during treatment**Likely to 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.

Likely to 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
- Abnormal dreams (including nightmares)
- Feeling dizzy or shaky (tremors)
- Headache
- Difficulty in concentrating
- Feeling agitated
- Blurred vision
- Yawning, dry mouth
- Diarrhoea or constipation
- Vomiting
- Weight gain
- Feeling weak
- Sweating.

Likely to affect up to 1 in every 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
- Feeling confused
- Having hallucinations (strange visions or sounds)
- An inability to urinate (urinary retention) or an uncontrollable, involuntary passing of urine (urinary incontinence).

Likely to affect up to 1 in every 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.

Likely to affect up to 1 in every 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-Johnson 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 yellow
- 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
- Unexpected bleeding e.g. bleeding gums, blood in the urine or in vomit, or the appearance of unexpected bruises or broken blood vessels (broken veins).

Some patients have developed buzzing, hissing, whistling, ringing or other persistent noise in the ears (tinnitus) when they take Paroxetine Liquid.

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

- ➔ If you have any concerns while you are taking Paroxetine Liquid, talk to your doctor or pharmacist who will be able to advise you.

8. Stopping Paroxetine Liquid

Do not stop taking Paroxetine Liquid until your doctor tells you to.

When stopping Paroxetine Liquid, your doctor will help you to reduce 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 Paroxetine Liquid you take by 5ml (10mg of paroxetine) a week. Most people find that any symptoms on stopping Paroxetine Liquid 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 medicine your doctor may decide that you should come off it more slowly. If you get severe withdrawal effects when you stop taking Paroxetine Liquid, please see your doctor. He or she may ask you to start taking your medicine again and come off it more slowly.

If you do get withdrawal effects, you will still be able to stop Paroxetine Liquid.

Possible withdrawal effects when stopping treatment

Studies show that 3 in 10 patients notice one or more symptoms on stopping Paroxetine Liquid. Some withdrawal effects on stopping occur more frequently than others.

Likely to 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 Paroxetine Liquid.
- Sleep disturbances (vivid dreams, nightmares, inability to sleep)
- Feeling anxious
- Headaches.

Likely to affect up to 1 in every 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
- Visual disturbances
- Fluttering or pounding heartbeat (palpitations).

- ➔ **Please see your doctor if you are worried about withdrawal effects when stopping Paroxetine Liquid.**

9. Children and adolescents under 18

Paroxetine Liquid should not be used for children and adolescents under 18 years because it has not been proven to be an effective medicine for this age group. Also, patients under 18 have an increased risk of side effects such as suicidal thoughts and harming themselves when they take Paroxetine Liquid. If your doctor has prescribed Paroxetine Liquid for you (or your child) and you want to discuss this, please go back to your doctor.

In studies of Paroxetine Liquid in under 18s, common side effects that affected less than 1 in 10 children/adolescents were: an increase 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 Paroxetine Liquid, although these were seen less often.

Some patients in these studies of under 18s had withdrawal effects when they stopped taking Paroxetine Liquid. These effects were mostly similar to those seen in adults after stopping Paroxetine Liquid (see section 5, *Stopping Paroxetine Liquid*, inside this leaflet). 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).

7. Looking after your medicine

- Keep your medicine in the original bottle. Do not store above 25°C.
- Keep your medicine out of the sight and reach of children.
- Do not take your medicine after the expiry date shown on the label.
- Your Paroxetine Liquid keeps for one month after it is first opened. If you have any left this time please give it back to your pharmacist who will dispose of it safely. If you need any more Paroxetine Liquid, please see your doctor for a new prescription.
- Never give this medicine to others, even if they have similar symptoms to yours.
- Finish all your medicine as the doctor tells you to.
- Keep this leaflet. You may need to read it again.
- If your medicine appears discoloured, or shows any other signs of deterioration, take it back to the pharmacist who will advise you.

8. What Paroxetine Liquid contains

The active ingredient in Paroxetine Liquid is paroxetine (as Paroxetine hydrochloride hemihydrate).

The inactive ingredients are polacrillin potassium, dispersible cellulose (E460), propylene glycol, glycerol (E422), sorbitol (E420), methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), sodium citrate (E331), citric acid (E330), sodium saccharin (E954), natural orange flavour, natural lemon flavour, sunset yellow (E110), simethicone emulsion and purified water. Sodium content is 6.6mg per 10ml.

Manufactured by: Farmaclair, Herouville Saint Clair, France.

Procured from within the EU and repackaged by: Doncaster Pharmaceuticals Group Ltd., Kirk Sandall, Doncaster, DN3 1QR.

Product Licence holder: BR Lewis Pharmaceuticals Ltd., Kirk Sandall, Doncaster, DN3 1QR.

PL No: 08929/0089

POM

Other formats:

To listen to or request a copy of this leaflet in Braille, large print or audio please call 01302 365000 and ask for the Regulatory Department.

Please be ready to give the following information:

Product name: Paroxetine 20mg/10ml Liquid

Reference number: 08929/0089

Leaflet revision and issue date (Ref): 04.09.12