
1.3.1 Core Package Leaflet

Package leaflet: Information for the user

Meloxat 20 mg, film-coated tablets

Paroxetine (as mesilate)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- 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:

1. What Meloxat is and what it is used for
2. What you need to know before you take Meloxat
3. How to take Meloxat
4. Possible side effects
5. How to store Meloxat
6. Contents of the pack and other information

1. What Meloxat is and what it is used for

Paroxetine belongs to the group of medicines known as selective serotonin re-uptake inhibitors (SSRIs), which are antidepressants.

Meloxat is used for the treatment of:

- Depressive illness (major depressive episode)
- Obsessive compulsive disorder (obsessive compulsive thoughts or actions)
- Panic disorder with or without agoraphobia (e.g. strong fear of leaving the house, entering shops, or fear of public places)
- Social anxiety disorder/ social phobia (strong fear or avoidance of everyday social situations)
- Generalised anxiety disorder (generally feeling very anxious or nervous)
- Post-traumatic stress disorder (anxiety caused by a traumatic event)

2. What you need to know before you take Meloxat

Do not take Meloxat

- if you are **allergic to paroxetine or any of the other ingredients** of this medicine (listed in section 6, What Meloxat contains; also see section 2, Meloxat contains lactose).
- if you take certain medicines used for the treatment of depression or Parkinson's disease (so called **monoamine-oxidase inhibitors (MAOIs)**)
 - You may only start using paroxetine if it has been at least 14 days since you stopped using *irreversible* MAOIs (such as **isocarboxazid, tranylcypromine and phenelzine**).
 - If you use *reversible* MAOIs (like **moclobemide, linezolid, methylene blue** (methylthionium chloride)) you must wait for at least 24 hours before you can start taking paroxetine.
 - The other way around, you must wait for at least 7 days after you have stopped using paroxetine, before you can start taking MAOIs.
- if you take a certain medicine (**thioridazine**) used to treat serious mental illnesses, for instance psychoses (see also section 2, Taking other medicines).
- if you take a certain medicine used to treat psychoses (**pimozide**) (see section 2, Taking other medicines).

Warnings and precautions

Talk to your doctor or pharmacist before taking Meloxat.

- if you are **under 18 years old**. Paroxetine should normally not be used in children and adolescents under 18 years. 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 this class of medicines. Despite this, your doctor may prescribe paroxetine for patients under 18 because he/she decides that this is in their best interests. If your doctor has prescribed paroxetine for a patient under 18 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 patients under 18 are taking paroxetine. Also, the long-term safety effects concerning growth, maturation and cognitive behavioural development of paroxetine in this age group have not yet been demonstrated.

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 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

- if you feel **restless, hyperactive or can't sit or stand still** (akathisia). This is most likely to occur within the first few weeks of treatment. If you develop these symptoms, please contact your doctor. In such a case increasing the dose may be harmful.
- if you develop a certain syndrome (**serotonin syndrome**). This syndrome presents itself as a combination of some of the following symptoms: (extreme) restlessness, confusion, irritability, imagining things that are not really there (hallucinations), sweating, shaking or shivering, heightened reflexes, sudden muscle contractions (myoclonus), increased body temperature or stiffness (see section 2, Taking other medicines). When you recognize some of these symptoms together, you should contact your doctor immediately and treatment with paroxetine should be discontinued.
- if you have ever experienced (periods of) extreme elation or over-excitement, causing unusual behaviour (**mania**). If a manic phase occurs, the treatment with paroxetine may need to be discontinued.
- if you have **liver** problems or **serious** problems with your **kidneys**. The dosage may need to be adjusted by your doctor.
- if you have **diabetes**. The treatment with paroxetine may alter your blood sugar level, which therefore should be carefully monitored. Your dosage of insulin and/or oral antidiabetic medicines may need to be adjusted.
- if you suffer or have ever suffered from **epilepsy or fits**. Paroxetine can cause fits (seizures), so your doctor will need to pay extra attention to this. If you develop fits (seizures) you should contact your doctor immediately. The treatment with paroxetine may need to be discontinued.
- if you are being treated with **electroconvulsive therapy (ECT)**. Little experience has been gained so far with the use of paroxetine during ECT, so your doctor will need to pay extra attention to this.
- if you suffer or have ever suffered from **high pressure inside the eye** (glaucoma). Paroxetine can cause widening of the pupil (mydriasis), which can lead to increased eyeball pressure. Your doctor will need to pay extra attention to this.

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- if you suffer from **cardiovascular disease**. The safety of paroxetine use has not been investigated in patients with this condition, so your doctor will need to take extra precautions.
 - if you are **older**, use **other medication** or have a problem with your **liver** (cirrhosis), as a result of which you are at a higher risk of having low blood sodium levels. Paroxetine can lower blood sodium levels, which can result in weakness and fatigue. If this happens you should contact your doctor.
 - if you have an increased **tendency to bleed** or you are taking medicines that can increase the risk of bleeding. Paroxetine can cause abnormal bleedings, so your doctor will need to pay extra attention to this (see section 2, Taking other medicines).
 - if you want to **stop taking paroxetine**. You may experience withdrawal effects, particularly if the treatment is halted abruptly (see section 3, If you stop taking Meloxat). Consult your doctor before stopping treatment with paroxetine.

Other medicines and Meloxat

Other medicines may be affected by paroxetine. They, in turn, may affect how well paroxetine works. Paroxetine can interact with:

- medicines used for the treatment of depression or Parkinson's disease (**MAOIs** such as **moclobemide** or **isocarboxazid**), a certain food supplement (**L-tryptophan**), certain medicines used to treat migraine (**triptans**, such as **sumatriptan**, **almotriptan**), certain painkillers (**tramadol**, **pethidine**), a certain medicine use to treat infections (**linezolid**), a preoperative visualising agent (**methylene blue**), other selective serotonin-reuptake inhibitors (**SSRIs**, such as **fluoxetine**, **sertraline**), certain medicines used to treat some psychiatric conditions (**lithium**, **risperidone**), a certain medicine used to treat chronic pain or in anaesthesia (**fentanyl**) and **St. John's Wort** (*Hypericum perforatum*), a herbal remedy for depression. Simultaneous use of these medicines can lead to *serotonin syndrome* (see section 2, Do not take Meloxat and section 2, Take special care with Meloxat).
- a certain medicine used to treat psychoses (**pimozide**). Studies investigating the concomitant use of paroxetine and pimozide showed that paroxetine can increase the amount of pimozide in the blood, when taken together. Since pimozide can cause serious side effects like irregular heart beat, you must not use paroxetine at the same time as pimozide (see section 2, Do not take Meloxat).
- **enzyme inhibitors**, such as certain medicines used to treat depression (**clomipramine**). Your doctor will likely prescribe a lower dosage than is usual. If you are going to use paroxetine together with enzyme inducers (like carbamazepine, rifampicin, phenobarbital and phenytoin) a lower starting

dose is usually not needed and your doctor will adjust the following dosages to the effect of the medicine.

- a combination of certain medicines to treat **Human Immunodeficiency Virus (HIV) infection (fosamprenavir and ritonavir)**
- a certain medicine used to treat Parkinson's disease (**procyclidine**). The effects and side effects of procyclidine can be enhanced. If you experience side effects such as a dry mouth, blurry vision, constipation and problems emptying the bladder (urinary retention), the dosage of procyclidine may need to be lowered, after consulting with your doctor.
- certain medicines used in the treatment of **epilepsy** (anticonvulsants, like **sodium valproate**). Although a direct effect has not been shown, your doctor will need to be extra careful when prescribing paroxetine to patients suffering from epilepsy.
- medicines that are broken down by the same liver enzymes as paroxetine. Examples of these are: certain medicines used to treat depression (**tricyclic antidepressants**, like **desipramine**), certain medicines used to treat severe mental illnesses, like psychoses (**perphenazine, thioridazine and risperidone**), a certain medicine used to treat children with ADHD (**atomoxetine**), certain medicines used to treat irregular heartbeat (like **flecainide and propafenone**), a certain medicine used to treat chest pain (angina pectoris) and elevated blood pressure (**metoprolol**), a certain medicine used to treat high cholesterol (**pravastatin**) and certain medicines to treat serious mental illnesses or nausea and vomiting (**phenothiazines**). The effects and side effects of these medicines can be enhanced. Paroxetine and thioridazine must not be used at the same time, because of the risk of serious side effects like irregular heartbeat (serious ventricular arrhythmia) and sudden death (see section 2, Do not take Meloxat).
- certain medicines that prevent blood clotting (**anticoagulants**, such as **acenocumarol, phenprocoumon**). The effects and side effects of these medicines can be enhanced and the risk of bleeding may increase (see section 2, Take special care with Meloxat).
- certain medicine used to treat breast cancer or fertility problems (**tamoxifen**).
- medicines that increase the risk of bleeding. Examples of these are: certain medicines used to treat serious mental illnesses or nausea and vomiting (**phenothiazines**, such as **chlorpromazine**), a certain medicine used to treat schizophrenia (**clozapine**), certain medicines used to treat depression (**tricyclic antidepressants**), acetylsalicylic acid, medicines used for pain and inflammation (NSAIDs, like **ibuprofen** or **COX-2 inhibitors**, such as **celecoxib**) (see section 2, Take special care with Meloxat).

Tell your doctor or pharmacist if you are taking, have recently taken or might take any of the medicines listed above or any other medicines.

Meloxat with food, drink and alcohol

The use of **alcohol** and paroxetine at the same time must be avoided.
The tablets should be taken in the morning with some food.

Pregnancy, breast-feeding and fertility

Talk to your doctor as soon as possible if you are pregnant, if you might be pregnant or if you are planning to become pregnant. This is because some studies have suggested a small increase in the risk of heart defects in babies whose mothers received paroxetine in the first few months of pregnancy. You and your doctor may decide that it is better for you to change to another treatment or to gradually stop taking paroxetine while you are pregnant. However, depending on your circumstances, your doctor may suggest that it is better for you to keep taking paroxetine.

Make sure your midwife and/or doctor know you are on paroxetine. When taken during pregnancy, particularly in the last 3 months of pregnancy, medicines like paroxetine may increase the risk of a serious condition in babies, called persistent pulmonary hypertension of the newborn (PPHN), making the baby breathe faster and appear bluish. These symptoms usually begin during the first 24 hours after the baby is born. If this happens to your baby you should contact your midwife and/or doctor immediately.

If you take paroxetine during the last 3 months of pregnancy, your newborn baby might also have other conditions, which also usually begin during the first 24 hours after birth. They include not being able to sleep or feed properly, trouble with breathing, a blue-ish skin or being too hot or cold, being sick, crying a lot, stiff or floppy muscles, lethargy, trembling, jitters or fits. If your baby has any of these symptoms when it is born and you are concerned, **contact your doctor who will be able to advise you.**

Paroxetine may get into breast milk in very small amounts. If you are taking paroxetine, 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're taking paroxetine.

Ask your doctor or pharmacist for advice before taking any medicine.

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 yet.

Driving and using machines

There is no evidence that paroxetine influences the ability to drive or use machines. However, this medicine may cause side effects (such as blurred

vision, feeling dizzy, sleepy, or confused). If you get these side effects, do not drive or operate machines or do anything else where you need to be alert and concentrate.

Important information about some of the ingredients of Meloxat

This medicinal product contains **lactose**. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Meloxat

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Paroxetine should preferably be taken in the morning with food. Swallow the tablets whole, without chewing them.

Avoid drinking **alcohol** while taking Meloxat.

The tablet can be divided into equal doses.

The recommended dose is:

major depressive episode

The recommended dose is 1 tablet (20 mg paroxetine) daily. You should usually start to feel better after one week, but it is possible that the effects will show later (as of the second week). If the effects are insufficient, your doctor may gradually increase the dosage in steps of ½ tablet (10 mg paroxetine), to a maximum of 2½ tablets (50 mg paroxetine) daily. Your doctor will tell you how long you will need to keep taking your tablets. This may be for more than 6 months.

obsessive-compulsive disorder

The recommended dose is 2 tablets (40 mg paroxetine) daily, with a starting dose of 1 tablet (20 mg paroxetine) daily. If the effects are insufficient, your doctor may gradually increase the dosage, in steps of ½ tablet (10 mg paroxetine). The maximum daily dose is 3 tablets (60 mg paroxetine). Your doctor will tell you how long you will need to keep taking your tablets. This may be a few months or even longer.

- panic disorder with or without agoraphobia
- The recommended dose is 2 tablets (40 mg paroxetine) daily, with a starting dose of ½ tablet (10 mg paroxetine) daily. If the effects are insufficient, your doctor may gradually increase the dosage, in steps of ½ tablet (10 mg paroxetine). The maximum daily dose is 3 tablets (60 mg

paroxetine). The starting dose is low to avoid worsening the symptoms of the panic disorder at the beginning of treatment. Your doctor will tell you how long you will need to keep taking your tablets. This may be a few months or even longer.

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- social anxiety disorder/social phobia
 - The recommended dose is 1 tablet (20 mg paroxetine) daily. If the effects are insufficient, your doctor may gradually increase the dosage, in steps of ½ tablet (10 mg paroxetine). The maximum daily dose is 2½ tablets (50 mg paroxetine). Your doctor will tell you how long you will need to keep taking your tablets. This may be for a long period of time, during which the treatment will be regularly evaluated.
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- generalized anxiety disorder
 - The recommended dose is 1 tablet (20 mg paroxetine) daily. If the effects are insufficient, your doctor may gradually increase the dosage, in steps of ½ tablet (10 mg paroxetine). The maximum daily dose is 2½ tablets (50 mg paroxetine). Your doctor will tell you how long you will need to keep taking your tablets. This may be for a long period of time, during which the treatment will be regularly evaluated.
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- posttraumatic stress-disorder
 - The recommended dose is 1 tablet (20 mg paroxetine) daily. If the effects are insufficient, your doctor may gradually increase the dosage, in steps of ½ tablet (10 mg paroxetine). The maximum daily dose is 2½ tablets (50 mg paroxetine). Your doctor will tell you how long you will need to keep taking your tablets. This may be for a long period of time, during which the treatment will be regularly evaluated.

Use in older people

The recommended starting dose for elderly patients is the same as the starting dose for other adults, but the maximum daily dose may not exceed 2 tablets (40 mg paroxetine).

Use in children and adolescents under 18 years

Paroxetine should not be used for the treatment of children and adolescents under the age of 18 (see section 2, Take special care with Meloxat).

Patients with a decreased liver or kidney function

If your liver or kidneys do not function that well, your doctor will need to adjust the dosage.

Duration of treatment

Depending on your condition you may need to take paroxetine for a long time.

You should continue taking paroxetine for a while, even after your symptoms are gone, to ensure these symptoms will not return. **Never stop treatment with paroxetine without talking to your doctor.** Abruptly stopping the treatment with paroxetine may cause withdrawal effects and therefore the dosage should be gradually decreased (see section 3, If you stop taking Meloxat).

If you take more Meloxat than you should

If you have taken more of your medication than prescribed, contact your doctor immediately or go to the nearest hospital immediately. Take this leaflet and the remaining tablets along with you to show your doctor. In addition to the known side effects (see section 4, Possible side effects) you may suffer from the following symptoms: vomiting, dilated pupils, headache, fever, blood pressure changes, agitation, anxiety, increased heartbeat (tachycardia) and uncontrollable trembling of the limbs (tremor).

If you forget to take Meloxat

Never take a double dose of paroxetine to make up for a forgotten dose. Skip the missed dose and take the next tablet at the usual time. When in doubt, always contact your doctor.

If you stop taking Meloxat

Never stop treatment with Meloxat without consulting your doctor and never stop treatment abruptly, as this may cause withdrawal symptoms. Symptoms that may occur upon stopping treatment with paroxetine include: dizziness, sensory disturbances (pins and needles or burning sensations, or the sensation of feeling electric shocks), anxiety, tinnitus, sleep disturbances (including vivid dreams or nightmares) and headache. Less common effects include: agitation, nausea, tremor, confusion, sweating, emotional instability, visual disturbances, pounding or racing heartbeat sensations (palpitations), diarrhoea and irritability (see also section 4, Possible side effects).

These symptoms usually occur within the first few days after stopping treatment, but may also occur in patients who forget to take a dose. The withdrawal effects usually disappear within two weeks, but in some patients they may be more severe or present for a longer time (2-3 months or longer). If you and your doctor decide to stop treatment with paroxetine, the daily dosage should be tapered off slowly in a few weeks or months (starting with steps of 10 mg per week). You should always check with your doctor before reducing the dosage.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Meloxat can cause side effects, although not everybody gets them.

Side effects can be:

- Very common: may affect more than 1 in 10 people
- Common: may affect up to 1 in 10 people
- Uncommon: may affect up to 1 in 100 people
- Rare: may affect up to 1 in 1,000 people
- Very rare: may affect up to 1 in 10,000 people
- Not known: frequency cannot be estimated from the available data

Blood (blood and lymphatic system disorders)

Uncommon: abnormal bleeding, predominantly bruising of the skin (ecchymosis)

Very rare: reduction in blood platelets, which increases the risk of bleeding or bruising (thrombocytopenia)

Defense system (immune system disorders)

Very rare: allergic reactions, **which may be severe** to paroxetine, including a raised itchy and painful skin rash (urticaria) or a serious reaction which causes swelling of the skin, throat or tongue, difficulty breathing and/or itch (angioedema). 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.**

Hormones (endocrine disorders)

Very rare: fluid retention and low blood sodium levels as a result of a syndrome of inappropriate anti-diuretic hormone secretion (SIADH)

Food (metabolism and nutrition disorders)

Common: increase in the level of cholesterol in the blood, decreased appetite

Uncommon: if you are a diabetic patient you may notice a loss of control of your blood sugar levels whilst taking paroxetine. Please speak to your doctor about adjusting the dosage of your insulin or diabetes medications.

Rare: low blood sodium levels (hyponatraemia), predominantly in elderly patients

Mental (psychiatric disorders)

Common: sleepiness (somnolence), inability to sleep (insomnia), agitation, abnormal dreams (including nightmares).

Uncommon: confusion, imagining things that are not really there (hallucinations)

Rare: (periods of) feeling elated or over-excited, which causes unusual behaviour (mania, manic periods), anxiety, panic attacks, depersonalisation, feeling restless and hyperactive with an inability to sit or stand still (akathisia).

Frequency not known: cases of thoughts/behaviours of harming or killing yourself have been reported during paroxetine therapy or early after treatment has been stopped (see section 2 Take special care with).

These symptoms may however also be due to your disease.

Nerves (nervous system disorders)

Very common: inability to concentrate.

Common: dizziness, feeling shaky (tremors), headache.

Uncommon: uncontrolled movements of the body or face (extrapyramidal disorders)

Rare: fits, seizures (convulsions), irresistible urge to move the legs (Restless Legs Syndrome)

Very rare: so called serotonin syndrome (symptoms may include agitation, confusion, sweating, imagining things that are not really there (hallucinations), heightened reflexes, sudden muscle contractions (myoclonus), shivering, trembling, and an increased heartbeat (tachycardia))

Eyes (eye disorders)

Common: blurred vision

Uncommon: widening of the pupil (mydriasis)

Very rare: sudden elevation of pressure inside the eye (acute glaucoma)

Ear (ear and labyrinth disorders)

Frequency not known: buzzing, hissing, whistling, ringing or other persistent noise in the ears (tinnitus)

Heart (cardiac disorders)

Uncommon: fast heartbeat (sinus tachycardia)

Rare: slow heartbeat (bradycardia)

Blood vessels (vascular disorders)

Uncommon: transient increases or decreases in blood pressure

Airways (respiratory, thoracic and mediastinal disorders)

Common: yawning

Stomach and intestine (gastrointestinal disorders)

Very common: nausea

Common: constipation, diarrhoea, vomiting, dry mouth
Very rare: bleeding of the stomach or intestine

Liver (hepatobiliary disorders)

Rare: elevation of liver-related enzymes

Very rare: liver disorders, such as hepatitis, sometimes associated with jaundice and/or liver failure

Skin (skin and subcutaneous tissue disorders)

Common: sweating

Uncommon: skin rashes, itch (pruritus)

Very rare: severe cutaneous adverse reactions (including erythema multiforme, Stevens-Johnson syndrome and toxic epidermal necrolysis), sensitivity to (sun)light

Muscles (musculoskeletal and connective tissue disorders)

Rare: muscle pain (myalgia), joint pain (arthralgia)

Kidney (renal and urinary disorders)

Uncommon: problems emptying the bladder (urinary retention) and an uncontrollable, involuntary passing of urine (urinary incontinence)

Genitals and breast (reproductive system and breast disorders)

Very common: sexual problems, such as ejaculation problems, reduced sex drive, male impotence and inability to orgasm

Rare: high blood levels of the hormone prolactin (hyperprolactinaemia), which can cause abnormal production of breast milk (galactorrhoea) in both men and women

Very rare: painful erection (priapism)

General (general disorders and administration site conditions)

Common: weight gain, feeling of general weakness with loss of muscle strength (asthenia)

Very rare: swelling of the arms and/or legs (peripheral oedema)

Withdrawal symptoms seen on discontinuation of paroxetine treatment

Common: dizziness, sensory disturbances, sleep disturbances, anxiety and headache

Uncommon: agitation, nausea, sweating, tremor, confusion, emotional instability, visual disturbances, palpitations, diarrhoea and irritability

These symptoms are usually mild and self-limiting. Never stop paroxetine treatment without consulting your doctor and never stop treatment abruptly, since you may get withdrawal symptoms (see section 3, If you stop taking Meloxat).

When children and adolescents below the age of 18 years were given paroxetine, more than 1 in 100, but less than 1 in 10 children/adolescents experienced one of the following side effects: emotional changes (including crying and mood changes), self-harm, suicidal thoughts and suicide attempts, hostile or unfriendly behaviour, lack of appetite, shaking, abnormal sweating, hyperactivity, agitation, nausea, stomach ache and nervousness.

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

Reporting of side effects

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

You can also report side effects directly via HPRC Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Meloxat

Keep this medicine out of the sight and reach of children.

Do not use the medicine after the expiry date, which is stated on the blisters and the carton box after 'EXP'. The first two digits indicate the month and the last four digits indicate the year. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer require. These measures will help protect the environment.

6. Contents of the pack and further information

What Meloxat contains

- The active substance is paroxetine (as mesilate). One tablet contains paroxetine mesilate, equivalent to 20 mg paroxetine.
- The other ingredients are:
 - Core: calcium hydrogen phosphate anhydrous, sodium starch glycolate (type A), magnesium stearate.

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- Coating: lactose monohydrate, hypromellose, macrogol 4000, titanium dioxide (E171), iron oxide yellow (E172) and iron oxide red (E172).

(see section 2, Meloxat contains lactose)

What Meloxat looks like and contents of the pack

Meloxat tablets are round, yellow and film-coated. They have the inscription "POT 20" on one side and a score line on both sides.

Meloxat is available in boxes with 10, 12, 14, 20, 28, 30, 50, 56, 60 or 100 tablets in blisters.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing authorization holder:

Genthon BV
Microweg 22
6545 CM Nijmegen
The Netherlands

Manufacturers:

Synthon BV
Microweg 22
6545 CM Nijmegen
The Netherlands

Synthon Hispania S.L.
Castelló 1, Polígono Las Salinas
08830 Sant Boi de Llobregat
Spain

This medicinal product is authorised in the Member States of the EEA under the following names:

Denmark: Paroxetin Genthon 20 mg, filmovertrukne tabletter
Finland: Paroxetine Avansor 20 mg
Ireland: Meloxat 20 mg film-coated tablets

This leaflet was last revised in August 2014.