Package leaflet: Information for the patient

Sertraline 25 mg Film-coated Tablets
Sertraline 100 mg Film-coated Tablets

(Sertraline hydrochloride)

Warning – Thoughts of self- harm and suicidal behaviour – see section 2

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

1. What Sertraline is and what it is used for

Sertraline Tablets contains the active substance sertraline. Sertraline is one of a group of medicines called Selective Serotonin Re-uptake Inhibitors (SSRIs); these medicines are used to treat depression and/or anxiety disorders.

Sertraline can be used to treat:

- Depression and prevention of recurrence of depression (in adults);
- Social anxiety disorder (in adults);
- Post traumatic stress disorder (PTSD) (in adults);
- Panic disorder (in adults);
- Obsessive compulsive disorder (OCD) (in adults and children and adolescents aged 6-17 years old).

Depression is a clinical illness with symptoms like feeling sad, unable to sleep properly or to enjoy life as you used to. OCD and Panic disorders are illnesses linked to anxiety with symptoms like being constantly troubled by persistent ideas (obsessions) that make you carry out repetitive rituals (compulsions).

PTSD is a condition that can occur after a very emotionally traumatic experience, and has some symptoms that are similar to depression and anxiety. Social anxiety disorder (social phobia) is an illness linked to anxiety. It is characterised by feelings of intense anxiety or distress in social situations (for example: talking to strangers, speaking in front of groups of people, eating or drinking in front of others or worrying that you might behave in an embarrassing manner).

Your doctor has decided that this medicine is suitable for treating your illness.

You should ask your doctor if you are unsure why you have been given Sertraline.

2. What you need to know before you take Sertraline

Do not take Sertraline:

- If you are allergic to sertraline or any of the other ingredients of this medicine (listed in section 6).
- If you are taking or have taken medicines called monoamine oxidase inhibitors (MAOIs such as selegiline, moclobemide) or MAOI like drugs (such as linezolid). If you stop treatment with sertraline, you must wait until at least one week before you start treatment with a MAOI. After stopping treatment with a MAOI, you must wait at least 2 weeks before you can start treatment with sertraline.
- If you are taking another medicine called pimozide (a medicine for mental disorders such as psychosis).

Warnings and precautions

Talk to your doctor or pharmacist before taking Sertraline.

Medicines are not always suitable for everyone. Tell your doctor before you take Sertraline, if you suffer from or have suffered in the past from any of the following conditions:

- If you have epilepsy (fit) or a history of seizures. If you have a fit (seizure), contact your doctor immediately.
- If you have suffered from manic depressive illness (bipolar disorder) or schizophrenia. If you have a manic episode, contact your doctor immediately.
- If you have or have previously had thoughts of harming or killing yourself (see below-Thoughts of suicide and worsening of your depression or anxiety disorder).
- If you have Serotonin Syndrome. In rare cases this syndrome may occur when you are taking certain medicines at the same time as sertraline. (For symptoms, see section 4. Possible Side Effects). Your doctor will have told you whether you have suffered from this in the past.
- If you have low sodium level in your blood, since this can occur as a result of treatment with Sertraline. You should also tell your doctor if you are taking certain medicines for hypertension, since these medicines may also alter the sodium level in your blood.
- If you are elderly as you may be more at risk of having low sodium level in your blood (see above).
- If you have liver disease; your doctor may decide that you should have a lower dose of Sertraline.
- If you have diabetes; your blood glucose levels may be altered due to Sertraline and your diabetes medicines may need to be adjusted.
- If you have suffered from bleeding disorders or have been taking medicines which thin the blood (e.g. acetylsalicyclic acid (aspirin), or warfarin) or may increase the risk of bleeding or if you are pregnant (see Pregnancy, breast-feeding and fertility).
- If you are a child or adolescent under 18 years old. Sertraline should only be used to treat children and adolescents aged 6-17 years old, suffering from obsessive compulsive disorder (OCD). If you are being treated for this disorder, your doctor will want to monitor you closely (see below-Children and adolescents).
- If you are having electro-convulsive therapy (ECT).
- If you have eye problems, such as certain kinds of glaucoma (increased pressure in the eye).
- If you have been told that you have an abnormality of your heart tracing after an electrocardiogram (ECG) known as prolonged QT interval.

The use of buprenorphine/ opioids together with sertraline can lead to serotonin syndrome, a potentially life-threatening condition (see Other medicines and Sertraline).

Medicines like Sertraline may cause symptoms of sexual dysfunction (see section 4). Rarely people can experience more persistent sexual side-effects after they have stopped taking SSRIs. The term 'post SSRI sexual dysfunction' (PSSD) has been used by some people to describe these symptoms. For these people, PSSD can have a significant and distressing impact on their lives. Research is needed to understand why this happens and how common it is. It is important that people experiencing ongoing sexual side-effects receive appropriate and timely support .

Restlessness/Akathisia
The use of sertraline has been linked to a distressing restlessness and need to move, often being unable to sit or stand still (akathisia). This is most likely to occur during the first few weeks of treatment. Increasing the dose may be harmful so if you develop such symptoms you should talk to your doctor.

Withdrawal reactions
Side effects relating to stopping treatment (withdrawal reactions) are common, particularly if the treatment is stopped suddenly (see section 3 If you stop taking Sertraline and section 4 Possible side effects). The risk of withdrawal symptoms depends on the length of treatment, dosage, and the rate at which the dose is reduced. Generally, such symptoms are mild to moderate. However, they can be serious in some patients. They normally occur within the first few days after stopping treatment. In general, such symptoms disappear on their own and wear off within 2 weeks. In some patients they may last longer (2-3 months or more). When stopping treatment with sertraline it is recommended to reduce the dose gradually over a period of several weeks or months, and you should always discuss the best way of stopping treatment with your doctor.

Thoughts of suicide and worsening of your depression or anxiety disorder
This medicine may be associated with thoughts of self-harm and suicidal behaviour in some people. Tell someone you trust, who can help you in an emergency, that you are taking this medicine and ask that they read this leaflet.
Talk to your trusted person, prescriber or go to a hospital straight away, if after starting this medicine, you have new or worse:

- Feelings of anxiety or irritability
- Feelings of restlessness and agitation
- Extreme increases in activity and difficulty sleeping
- Thoughts of acting on dangerous impulses to harm yourself
- Thoughts about suicide or dying
- Changes in behaviour or mood you, or someone you trust, notices and is worried about

In some people, thoughts of self-harm and suicidal behaviour may be increased when first starting antidepressants. Antidepressants take time to work; and sometimes side effects occur before you or others notice improvements in your mood.
Never stop taking an antidepressant suddenly without first talking to a healthcare professional. Stopping an antidepressant medicine suddenly can cause other symptoms related to withdrawal to occur.
Information from clinical trials has shown the highest risk of thoughts of self harm and suicidal behaviour, is in adults aged less than 25 years who were treated with an antidepressant but the risk applies to people of all ages treated with these medicines.
Call NHS 111 who can offer you support, until you can be with someone who can help you in person.

Children and adolescents
Sertraline should not usually be used in children and adolescents less than 18 years old, except for patients with Obsessive Compulsive Disorder (OCD). Patients under 18 have an increased risk of undesirable effects, such as suicide attempt, thoughts of harming or killing themselves (suicidal

thoughts) and hostility (mainly aggressiveness, oppositional behaviour and anger) when they are treated with this class of medicines. Nevertheless, it is possible that your doctor decides to prescribe Sertraline to a patient under 18 if it is in the patient's interest. If your doctor has prescribed Sertraline to you and you are less than 18 years old and you want to discuss this, please contact him/her. Furthermore, if any of the symptoms listed above appear or worsen while you are taking Sertraline, you should inform your doctor. Also, the long-term safety of Sertraline in regard to growth, maturation and learning (cognitive) and behavioural development in this age group has not yet been demonstrated.

Other medicines and Sertraline
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Some medicines can affect the way Sertraline works, or Sertraline itself can reduce the effectiveness of other medicines taken at the same time.

Taking Sertraline together with the following medicines may cause serious side effects:
- Medicines called monoamine oxidase inhibitors (MAOIs), like moclobemide (to treat depression) and selegiline (to treat Parkinson's disease), the antibiotic linezolid and methylene blue (to treat high levels of methaemoglobin in the blood). Do not use Sertraline together with these medicines.
- Medicines to treat mental disorders such as psychosis (pimozide). Do not use Sertraline together with pimozide.

Talk to your doctor if you are taking the following medicines:
- Medicines containing amphetamines (used to treat attention deficit hyperactivity disorder (ADHD), narcolepsy, and obesity).
- Herbal medicine containing St. John's Wort (Hypericum perforatum). The effects of St. John's Wort may last for 1–2 weeks.
- Products containing the amino acid tryptophan.
- Medicines to treat severe pain (e.g. tramadol).
- Medicines used in anaesthesia or to treat chronic pain (e.g. fentanyl, mivacurium and suxamethonium).
- Medicines to treat migraines (e.g. sumatriptan).
- Blood thinning medicine (warfarin).
- Medicines to treat pain/arthritis (Non-steroidal anti-inflammatory drug (NSAID) such as ibuprofen, acetylsalicylic acid (aspirin)).
- Sedatives (diazepam).
- Diuretics (also called 'water' tablets).
- Medicines to treat epilepsy (phenytoin, phenobarbital, carbamazepine).
- Medicines to treat diabetes (tolbutamide).
- Medicines to treat excessive stomach acid, ulcers and heartburn (cimetidine, omeprazole, lanzoprazole, pantoprazole, rabeprazole).
- Medicines to treat mania and depression (lithium).
- Other medicines to treat depression (such as amitriptyline, nortriptyline, nefazodone, fluoxetine, fluvoxamine).
- Medicines to treat schizophrenia and other mental disorders (such as perphenazine, levomepromazine and olanzapine).
- Medicines used to treat high blood pressure, chest pain or regulate the rate and rhythm of the heart (such as verapamil, diltiazem, flecainide, propafenone).
- Medicines used to treat bacterial infections (such as rifampicin, clarithromycin, telithromycin, erythromycin).

- Medicines used to treat fungal infections (such as ketoconazole, itraconazole, posaconazole, voriconazole, fluconazole).
- Medicines used to treat HIV/AIDS and Hepatitis C (protease inhibitors such as ritonavir, telaprevir).
- Medicines used to prevent nausea and vomiting after an operation or chemotherapy (aprepitant).
- Medicines known to increase the risk of changes in the electrical activity of the heart (e.g. some antipsychotics and antibiotics).

Some medicines may increase the side effects of sertraline and may sometimes cause very serious reactions.
Do not take any other medicines whilst taking sertraline without first talking to your doctor, especially:
- buprenorphine/ opioids. These medicines may interact with sertraline and you may experience symptoms such as involuntary, rhythmic contractions of muscles, including the muscles that control movement of the eye, agitation, hallucinations, coma, excessive sweating, tremor, exaggeration of reflexes, increased muscle tension, body temperature above 38°C. Contact your doctor when experiencing such symptoms.

Sertraline with food, drink and alcohol
Sertraline tablets can be taken with or without food. Alcohol should be avoided whilst taking Sertraline. Sertraline should not be taken in combination with grapefruit juice, as this may increase the level of sertraline in your body.

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.

If you take sertraline near the end of your pregnancy there may be an increased risk of heavy vaginal bleeding shortly after birth, especially if you have a history of bleeding disorders. Your doctor or midwife should be aware that you are taking sertraline so they can advise you.

The safety of sertraline has not fully been established in pregnant women. Sertraline will only be given to you when pregnant if your doctor considers that the benefit for you is greater than any possible risk to the developing baby.
Make sure your midwife and/or doctor know you are on Sertraline. When taken during pregnancy, particularly in the last 3 months of pregnancy, medicines like Sertraline 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.

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;
- increased reflex reactions;
- irritability;

- low blood sugar.

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.

There is evidence that sertraline passes into human breast milk. Sertraline should only be used in women during breast-feeding, if your doctor considers that the benefit exceeds any possible risk to the baby.

Some medicines like sertraline may 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
Psychotropic drugs such as sertraline may influence your ability to drive or use machines. You should therefore not drive or operate machinery, until you know how this medication affects your ability to perform these activities.

3. How to take Sertraline

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

The recommended dose is:
Adults:

Depression and Obsessive Compulsive Disorder
For depression and OCD, the usual effective dose is 50 mg/day. The daily dose may be increased in 50 mg increments and at intervals of at least one week over a period of weeks. The maximum recommended dose is 200 mg/day.

Panic disorder, Social anxiety disorder and Post Traumatic Stress Disorder:
For panic disorder, social anxiety disorder and post traumatic stress disorder, treatment should be started at 25 mg/day, and increased to 50 mg/day after one week. The daily dose then may be increased in 50 mg increments over a period of weeks. The maximum recommended dose is 200 mg/day.

Use in children and adolescents
Sertraline must only be used to treat children and adolescents suffering from OCD aged 6-17 years old.
Obsessive Compulsive Disorder:

Children aged 6 to 12: the recommended starting dose is 25 mg daily.
After one week, your doctor may increase this to 50 mg daily.
The maximum dose is 200 mg daily.
Adolescents aged 13 to 17: the recommended starting dose is 50 mg daily.
The maximum dose is 200 mg daily.

If you have liver or kidney problems, please tell your doctor and follow the doctor's instructions.

Method of administration
Sertraline tablets may be taken with or without food. Take your medication once daily either in the morning or evening.

Your doctor will advise you on how long to take this medication for. This will depend on the nature of your illness and how well you are responding to the treatment. It may take several weeks before your symptoms begin to improve. Treatment of depression should usually continue for 6 months after improvement.

If you take more Sertraline than you should
If you accidentally take too much Sertraline contact your doctor at once or go to the nearest hospital casualty department. Always take the labelled medicine package with you, whether there is any medication left or not.

Symptoms of overdose may include drowsiness, nausea and vomiting, rapid heart rate, shaking, agitation, dizziness and in rare cases unconsciousness.

If you forget to take Sertraline
Do not take a double dose to make up for a forgotten dose. If you forget to take a dose, do not take the missed dose. Just take the next dose at the right time.

If you stop taking Sertraline
Do not stop taking Sertraline unless your doctor tells you to. Your doctor will want to gradually reduce your dose of Sertraline over several weeks, before you finally stop taking this medicine. If you suddenly stop taking this medicine you may experience side effects such as dizziness, numbness, sleep disturbances, agitation or anxiety, headaches, feeling sick, being sick and shaking. If you experience any of these side effects, or any other side effects whilst stopping taking Sertraline, please speak to your doctor.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.
Nausea is the most common side effect. The side effects depend on the dose and often disappear or lessen with continued treatment.

Tell your doctor immediately:
If you experience any of the following symptoms after taking this medicine, these symptoms can be serious.

- If you develop a severe skin rash that causes blistering (erythema multiforme), (this can affect the mouth and tongue). This may be a sign of a condition known as Stevens Johnson Syndrome, or Toxic Epidermal Necrolysis (TEN). Your doctor will stop your treatment in these cases.
- Allergic reaction or allergy, which may include symptoms such as an itchy skin rash, breathing problems, wheezing, swollen eyelids, face or lips.
- If you experience agitation, confusion, diarrhoea, high temperature and blood pressure, excessive sweating and rapid heartbeat. These are symptoms of Serotonin Syndrome. In rare cases this syndrome may occur when you are taking certain medicines at the same time as sertraline. Your doctor may wish to stop your treatment.
- If you develop yellow skin and eyes which may mean liver damage.
- If you experience depressive symptoms with ideas of harming or killing yourself (suicidal thoughts).
- If you start to get feelings of restlessness and are not able to sit or stand still after you start to take Sertraline. You should tell your doctor if you start to feel restless.
- If you have a fit (seizure).
- If you have a manic episode (see Section 2 “Warnings and precautions”).

The following side effects were seen in clinical trials in adults and after marketing.

Very common (may affect more than 1 in 10 people):
Insomnia, dizziness, sleepiness, headache, diarrhoea, feeling sick, dry mouth, ejaculation failure, fatigue.

Common (may affect up to 1 in 10 people):
- chest cold, sore throat, runny nose;
- decreased appetite, increased appetite;
- anxiety, depression, agitation, decreased sexual interest, nervousness, feeling strange, nightmare, teeth grinding;
- shaking, muscular movement problems (such as moving a lot, tense muscles, difficulty walking and stiffness, spasms and involuntary movements of muscles), numbness and tingling, muscle tense, lack of attention, abnormal taste;
- visual disturbance;
- ringing in ears;
- palpitations;
- hot flush;
- yawning;
- upset stomach, constipation, abdominal pain, vomiting, gas;
- increased sweating, rash;
- back pain, joint pain, muscle pain;
- menstrual irregularities, erectile dysfunction;
- malaise, chest pain, weakness, fever;
- weight increased;
- injury.

Uncommon (may affect up to 1 in 100 people):
- gastroenteritis, ear infection;
- tumour;
- hypersensitivity, seasonal allergy;
- low thyroid hormones;
- suicidal thoughts, suicidal behaviour, psychotic disorder, thinking abnormal, lack of caring, hallucination, aggression, euphoric mood, paranoia;
- amnesia, decreased feeling, involuntary muscle contractions, passing out, moving a lot, migraine, convulsion, dizziness while standing up, abnormal coordination, speech disorder;
- enlarged pupils;
- ear pain;
- fast heartbeat, heart problem;
- bleeding problems (such as stomach bleeding), high blood pressure, flushing, blood in urine;
- shortness of breath, nose bleed, breathing difficulty, possible wheezing;
- tarry stools, tooth disorder, inflammation of the oesophagus, tongue problem, haemorrhoids, increased saliva, difficulty swallowing, burping, tongue disorder;
- eye swelling, hives, hair loss, itching, purple spots on skin, skin problem with blisters, dry skin, face oedema, cold sweat;
- osteoarthritis, muscle twitching, muscle cramps, muscular weakness;
- increase in frequency of urination, problem urinating unable to urinate, urinary incontinence, increase in urination, night time urination;
- sexual dysfunction, excessive vaginal bleeding, vaginal haemorrhage, female sexual dysfunction;
- swelling in legs, chills, difficulty walking, thirst;

- increase in liver enzyme levels, weight decreased;
- **Cases of suicidal ideation and suicidal behaviours have been reported during sertraline therapy or early after treatment discontinuation (see section 2).**

Rare (may affect up to 1 in 1,000 people):
- diverticulitis, swollen lymph glands, decrease in clotting cells, decrease in white blood cells;
- severe allergic reaction;
- endocrine problems;
- high cholesterol, problems controlling blood sugar levels (diabetes), low blood sugar, increase in blood sugar levels, low blood salt;
- physical symptoms due to stress or emotions, terrifying abnormal dreams, drug dependence, sleep walking, premature ejaculation;
- coma, abnormal movements, difficulty moving, increased sensation, sudden severe headache (which may be a sign of a serious condition known as Reversible Cerebral Vasoconstriction Syndrome (RCVS)), sensory disturbance;
- spots in front of eyes, glaucoma, double vision, light hurts eye, blood in the eye, unequal sized pupils, vision abnormal, tear problem;
- heart attack, light-headedness, fainting, or chest discomfort which could be signs of changes in the electrical activity (seen on electrocardiogram) or abnormal rhythm of the heart, slow heartbeat;
- poor circulation of arms and legs;
- breathing fast, progressive scarring of lung tissue (Interstitial Lung Disease), closing up of throat, difficulty talking, breathing slow, hiccups;
- mouth ulceration, pancreatitis, blood in stool, tongue ulceration, sore mouth;
- problems with liver function, serious liver function problems, yellow skin and eyes (jaundice);
- skin reaction to sun, skin oedema, hair texture abnormal, skin odour abnormal, hair rash;
- breakdown of muscle tissue, bone disorder;
- urinary hesitation, decreased urination;
- breast discharge, dry vaginal area, genital discharge, red painful penis and foreskin, breast enlargement, prolonged erection;
- hernia, drug tolerance decreased;
- increase in blood cholesterol levels, abnormal laboratory tests, semen abnormal, problems with clotting;
- relaxation of blood vessels procedure;
- spots in front of eyes, glaucoma, double vision, light hurts eye, blood in the eye, unequal sized pupils, vision abnormal, tear problem.

Not known: frequency cannot be estimated from the available data:
- Inflammation of the colon (causing diarrhoea)
- lockjaw;
- bedwetting;
- heavy vaginal bleeding shortly after birth (postpartum haemorrhage), see Pregnancy, breast-feeding and fertility in section 2 for more information;
- partial loss of vision.
- muscle weakness and severe muscle pain, which can be a sign of multiple acyl-coenzyme A dehydrogenase deficiency (MADD)-like disorder.

Additional side effects in children and adolescents
In clinical trials with children and adolescents, the side effects were generally similar to adults (see above). The most common side effects in children and adolescents were headache, insomnia, diarrhoea and feeling sick.

Symptoms that can occur when treatment is discontinued
If you suddenly stop taking this medicine you may experience side effects such as dizziness, numbness, sleep disturbances, agitation or anxiety, headaches, feeling sick, being sick and shaking (see section 3. "If you stop taking Sertraline").

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 the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Sertraline

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

This medicinal product does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

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

6. Contents of the pack and other information

What Sertraline contains
The active substance is sertraline. Each film-coated tablet contains either 25 mg or 100 mg of sertraline (as sertraline hydrochloride).
The other ingredients are:
- **Tablet core**: Cellulose, Microcrystalline; Methylcellulose; Silica, colloidal anhydrous; Magnesium Stearate.
- **Tablet coat**: Hypromellose 2910; Hydroxypropylcellulose; Macrogol 8000; Titanium Dioxide (E171). Sertraline 100 mg film-coated Tablets also contain Yellow Iron Oxide (E172).

What Sertraline looks like and contents of the pack
Sertraline 25 mg film-coated tablets are white to off-white, oval, biconvex coated tablets, engraved "SE" bisect "25" on one side, and plain on the other side. The score line is not intended for breaking the tablet.

Sertraline 100 mg film-coated tablets are yellow oval shaped, scored, imprinted APO on one side, and "SER" bisect "100" on the other side. The tablet can be divided into equal doses.

Sertraline Tablets are available in clear Aluminium/PVC/PVDC blister packs of 7, 10, 14, 20, 28, 30, 50, 56, 60, 84, 90, 98, or 100 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Mercury Pharmaceuticals Limited
Dashwood House,

69 Old Broad Street,
London, EC2M 1QS,
United Kingdom

Manufacturer
ExtractumPharma Co. Ltd.
IV. Körzet 6.
Kunfehértó, 6413
Hungary

This leaflet was last revised in October 2026