

## Parlotin 20 MG

### PATIENT INFORMATION LEAFLET

#### Paroxetine 20mg 30 Tablets

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

If you have more questions, ask your doctor or pharmacist.

This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

#### In this leaflet:

1. What PARLOTIN is and what it is used for.
2. Before you take PARLOTIN
3. How to take PARLOTIN
4. Possible side effects.
5. Storing PARLOTIN

The active ingredient is paroxetine (paroxetine hydrochloride anhydrous)

The tablets also contain:

Core: magnesium stearate, sodium starch glycolate, mannitol and cellulose microcrystalline.

Sub-coating: Eudragit in Ethanol 5% (Polimetacrilato (Eudragit E 100) and Ethanol)

Coating: Opadry AMB white (polyvinyl alcohol-part hydrolysed, titanium dioxide, talc, lecithin, soya, xanthan gum and purified water).

#### Marketing Authorization Holder

Bluepharma Indústria Farmacêutica S.A.

S. Martinho do Bispo · 3045-016 Coimbra · Portugal

#### Manufacturer

Bluepharma Indústria Farmacêutica S.A. · Portugal

#### 1. What PARLOTIN is and what it is used for

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

Paroxetine 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 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 PARLOTIN

Do not take PARLOTIN if

- you are taking medicines called monoamine oxidase inhibitors (MAOIs, including moclobemide), or have taken them at any time within the last two weeks. Your doctor will advise you how you should begin taking paroxetine once you have stopped taking the MAOI
- you are taking a tranquilliser called thioridazine
- you have previously had an allergic reaction to paroxetine or any of the other tablet ingredients (listed above)

If any of these apply to you, tell your doctor without taking PARLOTIN.

#### Check with your doctor

- Are you taking any other medicines (see Other medicines and PARLOTIN)?
- 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, breastfeeding and PARLOTIN)?

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 PARLOTIN.

#### Thoughts of harming yourself

People who are depressed and/or suffer from anxiety disorders can sometimes have thoughts of harming or killing themselves. These may be increased when you first start taking antidepressants, since these medicines all take time to work.

Certain groups of patients may be more likely to think like this:

- If you are a young adult, for example aged 18 to 29
- If you have previously had thoughts about killing or harming yourself
- If you get these thoughts at any time, contact your doctor or go to a hospital straight away.

#### Children and adolescents under 18

PARLOTIN 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. If your doctor has prescribed paroxetine for you (or your child) and you want to discuss this, please go back to your doctor.

In studies of paroxetine 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). These studies also showed that the same symptoms affected children and adolescents taking sugar pills (placebo) instead of paroxetine, although these were seen less often.

Some patients in these studies of under 18s had withdrawal effects when they stopped taking paroxetine. These effects were mostly similar to those seen in adults after stopping paroxetine (see Section 5, Stopping paroxetine). 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).

#### Pregnancy, breastfeeding and PARLOTIN

If you are already taking paroxetine and have just found out that you are pregnant, you should talk to your doctor immediately. Also if you are planning to get pregnant, talk to your doctor. This is because some studies have suggested an increase in the risk of heart defects in babies whose mothers received paroxetine in the first few months of pregnancy. These studies found that less than 2 in 100 babies (2%) whose mothers received paroxetine in early pregnancy had a heart defect, compared with the normal rate of 1 in 100 babies (1%) seen in the general population.

You and your doctor may decide that it is better for you 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.

If you are taking paroxetine in the last 3 months of pregnancy, let your midwife know as your baby might have some symptoms when it is born.

These symptoms usually begin during the first 24 hours after the baby is born. 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, tremors, jitters or fits. If your baby has any of these symptoms when it is born and you are concerned, contact your doctor or midwife 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 breastfeeding.

#### Other medicines and PARLOTIN

Some medicines can cause problems if you take them with paroxetine

- Aspirin, ibuprofen or other medicines called NSAIDs (non-steroidal anti-inflammatory drugs) like celecoxib, etodolac, meloxicam and ferecoxib, used for pain and inflammation · Tramadol, a painkiller
  - 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
  - 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)
  - Prochloridine, 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.
  - 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. They will know if it is safe for you to do so.

#### PARLOTIN and alcohol

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

#### Driving and using machinery

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

#### 3. How to take your tablets

Take your tablets in the morning with food. Swallow them with a drink of water. The white tablets can be cut in half.

Do not chew.

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

Sometimes you may need to take more than one tablet or half a tablet.

This label will show you how many tablets to take.

Your doctor will advise you what dose to take when you first start taking PARLOTIN. 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, 10mg at a time, up to a maximum daily dose. The usual doses for different conditions are set out in the table below.

• Depression

Starting dose 20mg

Recommended daily dose 20mg

Maximum daily dose 50mg

• Obsessive Compulsive Disorder (obsessions and compulsions)

Starting dose 20mg

Recommended daily dose 40mg

Maximum daily dose 60mg

• Panic Disorder (panic attacks)

Starting dose 10mg

Recommended daily dose 40mg

Maximum daily dose 60mg

• Social Anxiety Disorder (fear or avoidance of social situations)

Starting dose 20mg

Recommended daily dose 20mg

Maximum daily dose 50mg

• Post Traumatic Stress Disorder

Starting dose 20mg

Recommended daily dose 20mg

Maximum daily dose 50mg

• Generalised Anxiety Disorder

Starting dose 20mg

Recommended daily dose 20mg

Maximum daily dose 50mg

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 tablets.

This may be for many months or even longer.

#### Older people

The maximum dose for people over 65 is 40mg 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 than usual. If you have severe liver or kidney disease the maximum dose is 20mg 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 many tablets?

Never take more tablets than your doctor recommends. If you take too many PARLOTIN tablets (or someone else does), tell your doctor or a hospital straight away. Show them the pack of tablets.

#### What to do if you're feeling no better

PARLOTIN 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.

#### Do not stop taking PARLOTIN until your doctor tells you to.

When stopping PARLOTIN, 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 you take by 10mg a week. Most people find that any symptoms on stopping paroxetine are mild and go away on their own within two weeks. For some people, these symptoms may be more severe, or go on for longer.

If you get withdrawal effects when you are coming off your tablets your doctor may decide that you should come off them more slowly. If you get severe withdrawal effects when you stop taking paroxetine, please see your doctor. He or she may ask you to start taking your tablets again and come off them more slowly.

If you do get withdrawal effects, you will still be able to stop PARLOTIN

#### 4. Possible side-effects

As with other medicines PARLOTIN 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 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 PARLOTIN: 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. These 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.

#### 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:

• Lack of appetite

• Not sleeping well (insomnia) or feeling sleepy

• Feeling dizzy or shaky (tremors)

• Feeling agitated

• Blurred vision

• Yawning, dry mouth

• Diarrhoea or constipation

• Weight gain.

Likely to affect up to 1 in every 100 people:

• Brief increase or decrease in blood pressure, a faster than normal heartbeat

• Lack of movement, stiffness, shaking or abnormal movements in the mouth and tongue

• Skin rashes

• Feeling confused

• Having hallucinations (strange visions or sounds).

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 anxious

• Pain in the joints or muscles.

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

• 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.

If you have any concerns while you are taking paroxetine talk to your doctor or pharmacist who will be able to advise you.

#### Possible withdrawal effects when stopping treatment

Studies show that 3 in 10 patients notice one or more symptoms on stopping PARLOTIN. 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

• 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.

#### 5. Storing PARLOTIN

STORE AT ROOM TEMPERATURE IN ORIGINAL PACKAGE AWAY FROM LIGHT AND HUMIDITY

Keep your tablets out of the reach and sight of children.

Do not take your tablets after the expiry date shown on the pack.

If you are using half tablets, be careful to keep them safely in the pack.

Finish all your tablets as the doctor tells you to.