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 more 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.

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

1. What PAROXAL is and what it is used for PAROXAL is a treatment for adults with depression (major depressive episode) and/or anxiety disorders. The anxiety disorders that PAROXAL is used to treat are: obsessive compulsive disorder (repetitive, obsessive thoughts with uncontrollable behaviour), panic disorder (panic attacks, including those caused by agoraphobia, which is a fear of open spaces), social anxiety disorder (fear or avoidance of social situations), post-traumatic stress disorder (anxiety caused by a traumatic event) and generalised anxiety disorder (generally feeling very anxious or nervous).

PAROXAL belongs to 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 howPAROXAL and other SSRIs work but they may help by increasing the level of serotonin in the brain. Treating depression or anxiety disorders properly is important to help you get better.

2. What you need to know before you take PAROXAL Do not take PAROXAL:

disorders properly is important to help you get better.

2. What you need to know before you take PAROXAL
Do not take PAROXAL:

If you are allergic to PAROXAL or any of the other ingredients of this medicine (listed in section 6). If you are taking medicines called monoamine oxidase inhibitors (MAOIs, including moclobemide, linezolid and methylthioninium chloride (methylene blue)), or have taken them at any time within the last two weeks. Your doctor will advise you how you should begin taking PAROXAL once you have stopped taking the MAOI.

If you are taking anti-psychotic medicines called thioridazine or pimozide.

If any of these apply to you, tell your doctor and do not take PAROXAL.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking PAROXAL.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking PAROXAL.

If you have polleps with your kidneys or liver or if you have heart trouble

If you have ever had episodes of mania (overactive behaviour or thoughts)

If you are having a treatment for severe depression called electro convulsive therapy (ECT)

If you have low levels of sodium in your blood

If you have glaucoma (high pressure in the eye)

If you are taking tamoxifen to treat breast cancer or fertility problems. PAROXAL may make tamoxifen less effective, so your doctor may recommend you take another antidepressant

If you have a history of bleeding disorders, or are you taking other medicines that may increase the risk of bleeding (these include medicines used to thin the blood, such as warfarin, antipsychotics such as perphenazine or clozapine, trivoic antidepressants, such as clomipramine, medicines used for pain and inflammation calculations used to thin the blood, such as warfarin, antipsychotics such as perphenazine or clozapine, trivoic antidepressants, such as clomipramine, medicines used for pain and inflammation calculations.

Patients under 18 years old (see 'Children and adolescents under 18') years.

Patients under 18 years old (see 'Chi

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. Please discuss these things with your doctor if you have any concerns. Important side effects seen with PAROXAL.

Some patients who take PAROXAL develop akathisia, where they feel restless and feel like they can't stor stand still. Other patients develop serotion is syndrome, where they have some or all of the following symptoms: feeling confused, feeling restless, sweating, shaking, shivering, hallucinations (strange visions or sounds), sudden jerks of the muscles or a fast heartheat. If you notice any of these symptoms, contact your doctor. For more information on these or other side effects of PAROXAL, see section 4, "Possible Side Effects."

Other medicines and PAROXAL.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Some medicines can affect the way PAROXAL works, or make it more likely that you'll have side effects. PAROXAL, and so affect the way some other medicines work. These include:

Medicines called monoamine oxidase inhibitors (MAOIs, including moclobemide to treat depression and methythioninum chloride (methylene blue)) see 'Do not take PAROXAL', in this section

Thioridazine or pimozide (which are anti-psychotics, used to treat psychiatric conditions) see 'Do not take PAROXAL', in this section

Thioridazine or pimozide (which are anti-psychotics, used to treat psychiatric conditions) see 'Do not take PAROXAL', in this section

medicines.

PAROXAL with food and alcohol

Do not drink alcohol while you are taking PAROXAL. Alcohol may make your symptoms or side
effects worse. Taking PAROXAL in the morning with food will reduce the likelihood of you feeling

sick (nausea). Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you might be pregnant or are planning to have a baby, ask
your doctor or pharmacist for advice before taking this medicine. PAROXAL is not recommended
during pregnancy as it may cause harm to the baby. Your doctor may decide that it is better for you
to change to another treatment or to gradually stop taking PAROXAL while you are pregnant. However,
depending on your circumstances, your doctor may suggest that it is better for you to keep taking
PAROXAL.

PAROXAL. When taken during pregnancy, make sure your midwife and/or doctor know you are taking PAROXAL. When taken during pregnancy, particularly in the last 3 months of pregnancy, medicines like PAROXAL may increase the risk of a serious condition in babies, called persistent pulmonary hypertension of the newborn (PPHIN), 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.

Symptoms include:

-trouble with breathing
-a blue-ish skin or being too hot or cold
-blue lips
-vomiting or not feeding properly
-being very tired, not able to sleep or crying a lot
-stiff or flopy muscles
-tremors, litters or fits
-exaggerated reflexes
If your baby has any of these symptoms when it is born, or you are concerned about your baby's
health, contact your doctor or midwife who will be able to advise you.

PAROXAL may pass into breast milk in very small amounts. If you are taking PAROXAL, talk to your
doctor before you start breast-feeding,
PAROXAL 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
- Possible side effects of PAROXAL include dizziness, confusion, feeling sleepy or blurred vision. If you
do get these side effects, do not drive or use machinery.

do get these side effects, do not drive or use machinery.

3. How to take PAROXAL
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 doses for different conditions are set out in the table below.
Starting dose Recommended daily dose
Maximum daily dose

Inways take uns meucane exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended doses for different conditions are set out in the table below. Starting dose Recommended daily dose Maximum daily dose Depression 20 mg 20 mg 50 mg
Depression 20 mg 20 mg 50 mg
Desessive Compulsive Disorder 20 mg 40 mg 60 mg
Panic Disorder 10 mg 40 mg 60 mg
Social Anxiety Disorder 20 mg 20 mg 50 mg
Oseneralised Anxiety bisorder 20 mg 20 mg 50 mg
Generalised Anxiety bisorder 20 mg 20 mg 30 mg
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-Headaches.
Uncommon (may affect up to 1 in 100 people)
-Feeling sick (nausea)
-Sweating (including night sweats)
-Feeling resitiess or agitated
-Tremor (shakiness)
-Feeling contised or disorientated
-Diarrhoea (loose stools)
-Feeling enotional or irritable
-Visual disturbances

visual usand enlaws.

Fluttering or pounding heartbeat (palpitations).

Please see your doctor if you are worried about withdrawal effects when stopping PAROXAL. 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.

Side effects are more likely to happen in the first few weeks of taking PAROXAL. If any of the following happen tell your doctor immediately or go to your nearest hospital emergency department: Uncommon (may affect up to 1 in 100 people)

- Unusual bruising or bleeding, including vomiting blood or passing blood in your stools
- Being unable to pass water.

Rare (may affect up to 1 in 1,000 people)

- Seizures (fits)

- Restlessness and you feel like you can't sit or stand still, you may have a serious condition.

Rare (may affect up to 1 in 1,000 people)

Selizures (fits)

Restlessness and you feel like you can't sit or stand still, you may have a serious condition called akathisia. Increasing your dose of PAROXAL may make these feelings worse.

Tiredness, feeling weak or confused and have achy, stiff or uncoordinated muscles this may be because your blood is low in sodium.

Very rare (may affect up to 1 in 10,000 people)

Allergic reactions, which may be severe. If you develop a red and lumpy skin rash, swelling of the eyelids, face, lips, mouth or tongue, start to tich or have difficulty breathing (shortness of breath) or swallowing and feel weak or lightheaded resulting in collapser or loss of consciousness '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)

Syndrome of inappropriate antidiuretic hormone production (SIADH) which is a condition in which the body develops an excess of water and a decrease in sodium (salt) concentration, as a result of improper chemical signals. Patients with SIADH may become severely ill or may have a serious condition calledserotonin

improper chemical signals. Patients with SIADH may become severely in a may, at all

If you have some or all of the following symptoms you may have a serious condition callesterotonin syndrom: feel confused, restless, and suffer from sweating, shaking, shevering, hallucinations (strange visions or sounds), sudden jerks of the muscles or a fast heartbeat

Your eyes become painful and you develop blurred vision. This may be a sign of glaucoma

Your skin or whites of your eyes go yellow, which may be a sign of liver problems.

Not known (frequency cannot be estimated from the available data)

Have thoughts of harming or killing yourself. Suicidal behaviour has been reported during

PAROXAL therapy or early after treatment discontinuation.

Other possible side effects during treatment
Very common (may affect more than 1 in 10 people)

Feeling sick (nausea). Taking your medicine in the morning with food will reduce the chance of

this happening
Change in sex drive or sexual function. For example, lack of orgasm and, in men, abnormaèrection and ejaculation.
Common (may affect up to 1 in 10 people)
Decreased appetite
Not sieeping well (insomnia) or feeling sleepy
Abnormal dreams (including nightmares)
Feeling dizzy or shaky (tremors)
Headache
Feeling agitated
Feeling agitated
Feeling agitated
Feeling agitated
Feeling agitated
Feeling see or constipation
Weight gain
Sweating
Increases in cholesterol levels
Being sick (vomiting)
Unable to concentrate properly.
Uncommon (may affect up to 1 in 100 people)
A faster than normal heartbeat
A brief increase in blood pressure, or a brief decrease in blood pressure that may make you feel dizzy or faint when you stand up suddenly
Lack of movement, stiffness, shaking or abnormal movements in the mouth and tongue
Dilated pupils
Uncommonlabe, involuntary passing of urine (urinary incontinence)
If you are a diabetic patient you may notice a loss of control of your blood sugar levels whilst taking
PAROXAL. Please speak to your doctor about adjusting the dosage of your insulin or diabetes medications.
Rare (may affect up to 1 in 1,000 people)
Abnormal production of breast milk in men and women
A slow heartbeat
An increase of liver enzymes which can be seen in a blood test
Panic attacks
Overactive behaviour or thoughts (mania)
Feeling detached from yourself (depersonalisation)
Feeling anxious
Pain in the joints or muscles
Unexplained or unusual bleeding or bruising. These may be signs of having a low blood platelet count.
Not known (frequency cannot be estimated from the available data)
Aggression
Buzzing, hissing, whistling, ringing or persistent noise in the ears (Tinnitus).
An increased risk of bone fractures has been observed in patients taking this typ

taking sugar pills (placebo) instead of PAROXAL, although these were seen less often. In addition, patients under 18 also commonly (afecting 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).

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. By reporting side effects pour can help provide more information on the safety of this medicine.

5. How to store PAROXAL Do not store above 25°C. Store in the original package. Keep out of the sight and reach of children. Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Contents of the pack and other information
 What PAROXAL contains
 The active substance is paroxetine.
 Each PAROXAL_20 mg film-coated tablet contains 20 mg paroxetine as the hydrochloride anhydrate.

The other ingredients are: Each PAROXAL 30 mg film-coated tablet contains 30 mg paroxetine as the hydrochloride anhydrate. The other ingredients: microcrystalline cellulose, calcium hydrogen phosphate dehydrate, copovidone, crospovidone, colloidal silicon dioxide, opadry II white, talc, magnesium stearate, purified water.

> Date: 12.11.2015 Date: 12.11.2015

What PAROXAL look like and contents of the pack

Box of 30 film-coated of 20 mg paroxetine in blister pack (3 bllisters x 10 tablets)
Box of 30 film-coated of 30 mg paroxetine in blister pack (3 bllisters x 10 tablets)

Manufacturer and Marketing Authorisation Holder ZADA Pharmaceuticals Ltd. Donji Bistarac without number 75300 Lukavac Bosnia and Herzegovina

Date and number of marketing authorization: Δ PAROXAL, 30 film-coated tablets of 20 mg in box: Number: 04-07.3-2-5041/15 Δ PAROXAL, 30 film-coated tablets of 30 mg in box: Number: 04-07.3-2-5042/15

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