o Blurred vision
o Yawning, dry mouth
o Diarrhoea or constipation
o Vomiting
o Weight gain
o Sweating

Uncommon side effects, likely to affect up to 1 in every 100 people:
o A brief increase in blood pressure, or a brief decrease that may make you feel dizzy or faint when you stand up suddenly
o A faster than normal heartbeat
o Lack of movement, stiffness, shaking or abnormal movements in the mouth and tongue
o Dilated pupils
o Skin rashes
o Feeling confused
o Having hallucinations (strange visions or sounds)
o An inability to urinate (urinary retention) or an uncontrollable, involuntary passing of urine (urinary incontinence).
o 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 side effects, likely to affect up to 1 in every 1000 people:
o Abnormal production of breast milk in men and women
o A slow heartbeat
o Effects on the liver showing up in blood tests of your liver function
o Panic attacks
o Overactive behaviour or thoughts (mania)
o Feeling detached from yourself (depersonalisation)
o Feeling anxious
o Irresistible urge to move the legs (Restless Legs Syndrome)
o Pain in the joints or muscles.

Very rare side effects, likely to affect up to 1 in every 10,000 people
o 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
o A widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (Stevens-Johnson syndrome)
o A widespread rash with blisters and skin peeling on much of the body surface (toxic epidermal necrolysis)
o 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
o Sensitivity to sunlight
o Painful erection of the penis that won't go away
o Unexpected bleeding, e.g bleeding gums, blood in urine or in vomit, or the appearance of unexpected bruises or broken blood vessels (broken veins).
o Some patients have developed buzzing, hissing, whistling, ringing or other persistent noise in the ears (tinnitus) when they take Paroxetine
o An increased risk of bone fractures has been observed in patients taking this type of medicines.

Possible withdrawal effects when stopping treatment Very common side effects, likely to affect more than 1 in 10 people
o Feeling dizzy, unsteady or off-balance
o Feeling like pins and needles, burning sensations and (less commonly) electric shock sensations, including in the head
o Some patients have developed buzzing, hissing, whistling, ringing or other persistent noise in the ears (tinnitus) when they take Paroxetine.
o Sleep disturbances (vivid dreams, nightmares, inability to sleep)
o Feeling anxious
o Headaches

Uncommon side effects, likely to affect up to 1 in every 100 people
o Feeling sick (nausea)
o Sweating (including night sweats)
o Feeling restless or agitated
o Tremor (shakiness)
o Feeling confused or disorientated
o Diarrhoea (loose stools)
o Feeling emotional or irritable
o Visual disturbances
o Fluttering or pounding heartbeat (palpitations)

Please see your doctor if you are worried about withdrawal effects when stopping Paroxetine.
If you get any side effects, talk to your doctor or, pharmacist.

How to store Paroxetine?
o Keep this medicine out of the reach and sight of children.
o Do not use this medicine after the expiry date which is stated on the carton and blister after EXP.
o This medicinal product does not require any special storage conditions.
o Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Manufactured by:
Kaizen Pharmaceuticals (Pvt.) Ltd.
E-127-129, North Western Industrial Zone,
Bin Qasim, Karachi-75020, Pakistan.

ART No. 549/1

Roxet® 20 mg Tablets

(Paroxetine)

COMPOSITION:

ROXET 20MG TABLETS
Each tablet contains:
Paroxetine Hydrochloride eq. to Paroxetine …… 20mg
Product complies USP Specs

What Paroxetine is and what it is used for
Paroxetine belongs to a group of medicines called Selective Serotonin Reuptake Inhibitors (SSRIs), which are antidepressants.
Paroxetine is used in the treatment of:
o Depression (major depressive episodes).
o Obsessive Compulsive Disorder (compulsive thoughts and compulsive actions) (OCD).
o Panic disorder with and without agoraphobia (e.g. fear of leaving the house, entering shops, or fear of public places).
o Social phobia (overwhelming fear or avoidance of everyday social situations).
o Generalized anxiety disorder (more permanent present fear, in which chronic nervous worrying is prominent).
o Post-traumatic stress disorder (anxiety caused by a traumatic event).

What you need to know before you take Paroxetine
Do not take Paroxetine
o If you are allergic to paroxetine or any of the other ingredients of this medicine,
o If you are taking medicines called monoamine oxidase inhibitors (MAOIs, including moclobemide and methylthioninium chloride (methylene blue)), or have taken them at any time within the last two weeks.
o Your doctor will advise you how you should begin taking Paroxetine once you have stopped taking the MAOI.
o Concomitant use of paroxetine with thioridazine or pimozide (medicines for psychosis) is contraindicated.

Warnings and precautions
o Talk to your doctor or pharmacist before taking Paroxetine
o Use in children and adolescents under 18 years of age: Paroxetine should normally not be used for children and adolescents under 18 years.
Also you should know that patients under 18 have an increased risk of side effects such as suicide attempt, suicidal thoughts and hostility (predominantly aggression, oppositional behavior 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 develop or worsen when patients under 18 are taking Paroxetine.
Also, the long-term safety effects concerning growth, maturation, cognitive and behavioral development of Paroxetine in this age group have not yet been demonstrated.
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) and unusual bruising or bleeding (such as nose bleeds).
o 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.

Other medicines and Paroxetine
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines
Some medicines can affect the way Paroxetine works, or make it more likely that you'll have side effects.
These include:
o Medicines called monoamine oxidase inhibitors (MAOIs, including moclobemide and methylthioninium chloride (methylene blue).
o Thioridazine or pimozide, which are anti-psychotics.
o Acetylsalicylic acid, ibuprofen or other medicines called NSAIDs (non-steroidal anti-inflammatory drugs) like celecoxib, etodolac and meloxicam, used for pain and inflammation.
o Tramadol and pethidine, painkillers
o Medicines called triptans, such as sumatriptan, used to treat migraine
o Other antidepressants including other SSRIs, and tricyclic antidepressants like clomipramine, nortriptyline and desipramine
o A dietary supplement called tryptophan
o Medicines such as lithium, risperidone, perphenazine and clozapine (called anti-psychotics) used to treat some psychiatric conditions.
o Fentanyl, used in anaesthesia or to treat chronic pain
o A combination of fosamprenavir and ritonavir, which is used to treat Human Immuno-deficiency Virus (HIV) infection.
o St John's Wort, a herbal remedy for depression
o Phenobarbital, phenytoin, sodium valproate or carbamazapine, used to treat fits or epilepsy
o Atomoxetine which is used to treat attention deficit hyperactivity disorder (ADHD)
o Procyclidine, used to relieve tremor, especially in Parkinson's disease.
o Warfarin or other medicines (called anticoagulants) used to thin the blood
o Propafenone, flecainide and medicines used to treat an irregular heart beat
o Metoprolol, a beta-blocker used to treat high blood pressure and heart problems.
o Pravastatin, used to treat high cholesterol
o Rifampicin, used to treat tuberculosis (TB) and leprosy
o Linezolid, an antibiotic
o Tamoxifen, which is used to treat breast cancer or fertility problems
If you are taking any of the medicines in this list, inform your doctor immediately. The dose may need to be changed or you may need to be given another medicine.

Paroxetine with food and drink and alcohol
o Food: The tablets should be taken in the morning with food. This will reduce the likelihood of you feeling sick (nausea).
o Alcohol: Do not drink alcohol while you are taking Paroxetine. Alcohol may take your symptoms or side effects worse

Pregnancy and, breast-feeding and fertility
o Pregnancy: Talk to your doctor as soon as possible if you are pregnant, if you might be pregnant, or if you're planning to become pregnant. In babies whose mother took paroxetine during the first few months of pregnancy, there have been some reports showing an increased risk of birth defects, in particular those affecting the heart.
However depending on your circumstances, your doctor may suggest that it is better for you to keep taking 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. Symptoms include: trouble breathing, blue-ish skin or being too hot or cold, vomiting or not feeding properly, being very tired, not able to sleep or crying a lot, tremors, jitters or fits.
o Breast-feeding: Paroxetine may pass into breast milk in very small amounts. If you are taking Paroxetine, go back and talk to your doctor before you start breast-feeding.
o Fertility: 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
Paroxetine may cause side-effects (such as dizziness, confusion, and feeling sleepy or blurred vision) that affect how well you concentrate and how quickly you can react. If you get these side effects, do not drive or operate machines, or do anything else where you need to be alert and concentrate.

Paroxetine contains lactose
Paroxetine contains small amount of lactose. If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicinal product.

How to take Paroxetine
o Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.
o Drink a glass of water with your medicine, preferably in the morning with food.
o The tablet or tablet halves should be swallowed rather than chewed.

The recommended dose is
Adults
o Depression
The recommended dose is 20 mg daily. Depending on your response, the dose may be increased gradually to 50 mg daily in 10 mg steps. The treatment should be continued for at least 6 months.
o Obsessive thoughts and obsessive actions (OCD)
The initial dose is 20 mg daily. Depending on your response, the dose may be increased gradually to 40 mg daily in 10 mg steps. The recommended dose is 40 mg daily. The maximum dose is 60 mg daily. The treatment should be continued for several months.
o Panic disorder
The initial dose is 10 mg daily. Depending on your response, the dose may be gradually increased to 40 mg daily in 10 mg steps. The recommended dose is 40 mg daily. The maximum dose is 60 mg daily. The treatment should be continued for several months.
o Social phobia, generalized anxiety disorder and post-traumatic stress disorder
The recommended dose is 20 mg daily. Depending on your response, the dose may be increased gradually to 50 mg in 10 mg steps. The maximum dose is 50 mg daily. Paroxetine should not be used by children and adolescents under the age of 18.

Elderly (more than 65 years)
Depending on your response the dose may be increased to 40 mg daily. The maximum dose is 40 mg daily.

Severe decreased kidney function
Your doctor prescribes a suitable dose for you.

Decreased liver function
Your doctor prescribes a suitable dose for you.

If you take more Paroxetine than you should
If you take more Paroxetine than you should, talk to your doctor or pharmacist or contact with the nearest hospital. Symptoms of overdose are, e.g. vomiting, dilated pupils, fever, blood pressure changes, headache, involuntary muscle contractions, agitation, anxiety and rapid heart rate.

If you forget to take Paroxetine
If you forget to take Paroxetine, omit the forgotten dose and take the next dose at the correct time. Do not take a double dose to make up for a forgotten dose.

If you stop taking Paroxetine
Do not stop taking Paroxetine without consulting to your doctor, even if you feel better.
If you stop suddenly after taking this medicine for a long time you can experience withdrawal effects; you may feel dizzy, have sensory disturbances (numbness or 'pins and needles', called paraesthesia, electric shock sensations and ringing in the ears), sleep disturbances (including intense dreams), feeling sick (nausea), diarrhoea, headaches, rapid and irregular heart beat (palpitations), tremor, sweating, visual disturbances, or feeling agitated, anxious, irritable or confused about where you are (disoriented). These symptoms are generally mild to moderate and go away on their own within two weeks. However, in some patient these symptoms may be more severe, or go on for longer. They usually happen in the first few days after stopping the medicine.
When stopping Paroxetine, 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 10 mg a week. 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 start taking your tablets again and come off them more slowly.
If you have any further questions on the use of this product, ask your doctor or pharmacist.

Possible Side Effects
Uncommon side effects likely to affect up to 1 in every 100 people. Contact your doctor immediately:
o If you have unusual bruising or bleeding, including vomiting blood or passing blood in your stools.
o If you find that you are not able to pass water.

Rare side effects likely to affect up to 1 in every 1000 people:
Uncommon side effects likely to affect up to 1 in every 100 people. Contact your doctor immediately:
o If you have unusual bruising or bleeding, including vomiting blood or passing blood in your stools.
o If you find that you are not able to pass water.
Rare side effects likely to affect up to 1 in every 1000 people:
o If you experience seizures (fits).
o 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.
o 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.

Very rare side effects, likely to affect up to 1 in every 10,000 people:
o Allergic reactions, which may be severe to Paroxetine 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.
o If you have some or all of the following symptoms you may have something called serotonin syndrome. The symptoms include: feeling confused, feeling restless, sweating, shaking, shivering, hallucinations (strange visions or sounds), sudden jerks of the muscles or a fast heartbeat. If you feel like this contact your doctor.
o Acute glaucoma. If your eyes become painful and you develop blurred vision, contact your doctor.

Frequency unknown
o Aggression.
o Some people have had thoughts of harming or killing themselves while taking Paroxetine or soon after stopping treatment (see Section 2, Before you take Paroxetine).
o Tooth grinding.

Other possible side effects during treatment
Very common side effects, likely to affect more than 1 in 10 people:
o Feeling sick (nausea). Taking your medicine in the morning with food will reduce the chance of this happening.
o Change in sex drive or sexual function. For example, lack of orgasm and, in men, abnormal erection and ejaculation.

Common side effects, likely to affect up to 1 in 10 people:
o Increases in the level of cholesterol in the blood
o Lack of appetite
o Not sleeping well (insomnia) or feeling sleepy
o Abnormal dreams (including nightmares)
o Feeling dizzy or shaky (tremors)
o Headache
o Difficulty in concentrating
o Feeling agitated
o Feeling unusually weak