Directions for Use

Read all of this package leaflet carefully before you start taking this medicinal product.
- Keep the package leaflet. It may be possible that you would like to read it later again.
- If you have any further questions, please ask your doctor or pharmacist.
- This medicinal product has been prescribed personally for you and must not be passed on to others. It may harm them even if their symptoms are the same as yours.

This package leaflet contains:

Paroxat® 40 mg

Film-coated Tablets

Active substance: paroxetine hydrochloride

The pharmaceutically active ingredient is paroxetine hydrochloride.

Each film-coated tablet contains 44.4 mg paroxetine hydrochloride, corresponding to 40 mg paroxetine.

The other ingredients are:
carboxymethyl starch sodium (type A) (Ph.Eur.), microcrystalline cellulose, copovidone, hypromellose, magnesium stearate (Ph.Eur.), mannitol (Ph.Eur.), colloidal silicon dioxide, talc, titanium dioxide (E 171)

Pharmaceutical form and contents
Paroxat® 40 mg film-coated tablets are available in packs containing 20, 50 and 100 film-coated tablets.

1. What are Paroxat® 40 mg film-coated tablets, and what are they used for?

Paroxat® 40 mg film-coated tablets are a medicinal product to treat certain psychiatric disorders (antidepressant, selective serotonin re-uptake inhibitor [SSRI]).

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Paroxat® 40 mg film-coated tablets are used to treat
- depressive illnesses (episode of major depression)
- obsessive-compulsive disorder
- panic disorder with or without agoraphobia (fear of leaving the house, entering buildings, being in crowds and on public places)
- social anxiety disorder/social phobia (anxiety to make a fool of oneself in front of other persons and thus avoiding to get into contact with others)
- generalised anxiety disorders
- post-traumatic stress disorder (anxiety after severe traumatic events, such as car accident, physical strain, natural disaster)

2. What must you heed before taking Paroxat® 40 mg film-coated tablets?

Paroxat® 40 mg film-coated tablets must not be taken:
- if you are hypersensitive (allergic) to the pharmaceutically active substance paroxetine or to any of the other ingredients of Paroxat® 40 mg film-coated tablets.
- if you concurrently take medicinal products that inhibit the body-own enzyme monoamine oxidase (so-called MAO inhibitors). Treatment with Paroxat® 40 mg film-coated tablets can be initiated two weeks at the earliest after discontinuation of an irreversible MAO inhibitor or 24 hours at the earliest after discontinuation of a reversible MAO inhibitor (e.g. moclobemide). At least one week should pass between discontinuation of Paroxat® 40 mg film-coated tablets and initiation of therapy with an MAO inhibitor.
- if you are concurrently treated with thioridazine. Paroxat® 40 mg film-coated tablets can increase the concentration of thioridazine in the blood (see section "Interactions with other medicinal products"). Administration of thioridazine alone can lead to a prolonged QT interval (prolongation of a part of the spread of excitation in the heart detectable in ECG) in association with severe ventricular arrhythmias such as torsades de pointes (certain severe form of arrhythmias) and sudden death.

Special caution when taking Paroxat® 40 mg film-coated tablets is required
After the end of treatment with an irreversible MAO inhibitor, treatment with Paroxat® 40 mg film-coated tablets should be started cautiously not until after two weeks or i.e. after the end of treatment with a reversible MAO inhibitor not until after 24 hours, and the dose should be increased gradually up to the optimal effect (see sections 2. "What must you heed before taking Paroxat® 40 mg film-coated tablets?" under "Paroxat® 40 mg film-coated tablets must not be taken" and "Interactions with other medicinal products").

The clinical picture of depressive illnesses is associated with an increased risk of suicidal thoughts, self-damaging behaviour and suicide. The risk persists until clear remission occurs, which is possibly not the case during the first few weeks or more. The patients should therefore be closely monitored until improvement occurs. Clinical experience with antidepressant therapies generally shows that the risk of suicide may increase in the early stages of recovery.

Other psychiatric conditions for which Paroxat® 40 mg film-coated tablets are prescribed can also be associated with an increased risk of suicide. In addition, these conditions may occur together with a depressive illness (episodes of major depression). The same precautions observed when treating patients with depressive illnesses (episodes of major depression) should therefore be observed when treating patients with other psychiatric disorders.

If not otherwise prescribed by the doctor, the usual dose is:

Depressive illnesses
The recommended dose is ½ film-coated tablet (corresponding to 20 mg paroxetine) per day. In general, improvement starts after one week, but may only become evident from the second week of therapy. As with all antidepressant medicinal products, your doctor will review the dosage and adjust it, if necessary, within 3 to 4 weeks of initiation of therapy. Afterwards, your doctor will adjust the dose according to the clinical course. If you do not sufficiently respond to the recommended dose of ½ film-coated tablet (corresponding to 20 mg paroxetine) per day, your doctor may gradually increase the dose, depending on your response, in 10 mg steps up to a maximum dose of 1 ¼ film-coated tablets (corresponding to 50 mg paroxetine) per day.

Patients with depression should be further treated for a sufficient period of at least 6 months to ensure that they are free from symptoms.

Obsessive-compulsive disorder
The recommended dose is 1 film-coated tablet (corresponding to 40 mg paroxetine) per day. The initial dose should be ½ film-coated tablet (corresponding to 20 mg paroxetine) per day and may be increased gradually in 10 mg increments to the recommended dose. If you do not sufficiently respond to the recommended dose after some weeks, your doctor may gradually increase the dose up to a maximum of 1 ½ film-coated tablets (corresponding to 60 mg paroxetine) per day.

Patients with an obsessive-compulsive disorder should be treated for a sufficiently long period to ensure that they are free from symptoms. This period may be several months or more.

Panic disorder
The recommended dose is 1 film-coated tablet (corresponding to 40 mg paroxetine) per day. The initial dose should be ¼ film-coated tablet (corresponding to 10 mg paroxetine) per day and should, depending on the response to therapy, be increased in 10 mg steps up to the recommended dose. A low initial dose is recommended in order to minimize the risk of an exacerbation of panic symptomatology, which may generally occur in the early phase of the panic disorder to be treated. If you do not sufficiently respond to the recommended dose after some weeks, your doctor may increase the dose gradually up to a maximum of 1 ½ film-coated tablets (corresponding to 60 mg paroxetine) per day.

Patients with a panic disorder should be treated for a sufficiently long period to ensure that they are free from symptoms. This period may be several months or more.

Social anxiety disorder/social phobia
The recommended dose is ½ film-coated tablet (corresponding to 20 mg paroxetine) per day. If you do not sufficiently respond to the recommended dose after some weeks, your doctor may gradually increase the dose up to a maximum of 1 ¼ film-coated tablets (corresponding to 50 mg paroxetine) per day.
The benefit of treatment should be reviewed at regular intervals during long-term treatment.

Generalised anxiety disorder
The recommended dose is ½ film-coated tablet (corresponding to 20 mg paroxetine) per day. If you do not sufficiently respond to the recommended dose after some weeks, your doctor may gradually increase the dose in 10 mg steps up to a maximum of 1 ¼ film-coated tablets (corresponding to 50 mg paroxetine) per day.
The benefit of treatment should be reviewed at regular intervals during long-term treatment.

Post-traumatic stress disorder
The recommended dose is ½ film-coated tablet (corresponding to 20 mg paroxetine) per day. If you do not sufficiently respond to the recommended dose after some weeks, your doctor may gradually increase the dose in 10 mg steps up to a maximum of 1 ¼ film-coated tablets (corresponding to 50 mg paroxetine) per day.
The benefit of treatment should be reviewed at regular intervals during long-term treatment.

Comment for usage
You should take Paroxat® 40 mg film-coated tablets once daily, together with breakfast in the morning. The film-coated tablets should be swallowed, if possible, unchewed.

Withdrawal symptoms after the end of treatment with Paroxat® 40 mg film-coated tablets
Abrupt discontinuation should be avoided (see section 2. "What must you heed before taking Paroxat® 40 mg film-coated tablets?" under "Special caution when taking Paroxat® 40 mg film-coated tablets is required") and section 4. "Which side effects are possible?" under "Side effects"). In clinical studies, the daily dose was reduced by 10 mg per day at weekly intervals during the taper phase.
If intolerable withdrawal symptoms occur after dose reduction or discontinuation of the medicinal product, inform your doctor. He/she may consider that you take again your dose previously taken in order to decrease it then in smaller steps.

If you notice your suicidal thoughts and self-damaging intentions, immediately inform your doctor or caregiver!

The risk can be increased, particularly if you belong to the group of young adults between 18 and 29 years, if you have already made a suicide attempt prior to treatment or if you have ever thought of suicide or if you were at high risk of suicide, and your doctor should closely monitor you. Close monitoring is also recommended if you have not yet been treated with an antidepressant.

Use of Paroxat® 40 mg film-coated tablets can be connected with the development of a condition of inner restlessness and inability to sit or stand still, usually associated with subjective distress. This occurs particularly in the first weeks of treatment. Dose increases can be detrimental in these cases.

On rare occasions, development of certain concurrent serotonergic effects (serotonin syndrome or neuroleptic malignant syndrome-like events) may occur in association with treatment of Paroxat® 40 mg film-coated tablets, particularly when given in combination with other serotonergic and/or neuroleptic substances. As these syndromes may possibly result in potentially life-threatening conditions, treatment with Paroxat® 40 mg film-coated tablets should be discontinued if such events (characterised by a series of symptoms such as increase in body temperature, rigidity, muscular twitching, autonomic instability with possible rapid fluctuations of vital parameters [e.g. respiration and blood pressure], mental changes including confusion, irritability, extreme agitation progressing to delirium and coma) occur, and supportive symptomatic treatment should be initiated.

Paroxat® 40 mg film-coated tablets should not be used in combination with serotonin-precursors (such as L-tryptophan, oxitriptan) due to the risk of a serotonergic syndrome (see sections 2. "What must you heed before taking Paroxat® 40 mg film-coated tablets?" under "Paroxat® 40 mg film-coated tablets must not be taken" and "Interactions with other medicinal products").

Inform your doctor if you suffer or have suffered from one or more of the following diseases. Treatment with Paroxat® 40 mg film-coated tablets must be carried out with special caution in these cases.

Manic episodes (abnormally euphoric or irritable mood): As with all antidepressants, Paroxat® 40 mg film-coated tablets should be discontinued in each patient entering a manic episode.
Severe renal dysfunction or hepatic insufficiency: (see 3. "How are Paroxat® 40 mg film-coated tablets to be taken?" under section "If not otherwise prescribed by the doctor, the usual dose is:").
Epilepsy or seizures: Overall the incidence of seizures is less than 0.1% in all patients treated with Paroxat® 40 mg film-coated tablets. The preparation should be discontinued if seizures occur.
Diabetes mellitus: Treatment with Paroxat® 40 mg film-coated tablets may alter glycaemic control, and the dosage of insulin and/or oral antidiabetics must be adjusted.
Coincident electroconvulsive therapy: There is only little clinical experience about concomitant use of Paroxat® 40 mg film-coated tablets with electroconvulsive therapy.
Existing closed-angle glaucoma (specific form of the disease glaucoma) or glaucoma in the medical history: As with other medicinal products of this substance class (SSRI), Paroxat® 40 mg film-coated tablets can cause dilated pupils in rare cases.
Heart disease in the medical history: The usual precautions should be observed.
Risk of hyponatraemia (lowered sodium values in blood), particularly in elderly patients, e.g. due to coincident intake of other medicinal products or due to cirrhosis: Hyponatraemia is generally reversible after discontinuation of Paroxat® 40 mg film-coated tablets.
Known bleeding tendency, bleeding in the medical history, presence of favouring factors for bleeding, treatment with medicinal products increasing the bleeding risk (oral anticoagulants, medicinal products impairing platelet function or other medicinal products increasing the bleeding risk such as atypical antipsychotics such as clozapine, neuroleptics of the phenothiazine type, most of tricyclic antidepressants, acetylsalicylic acid, non-steroidal antirheumatics, COX2 inhibitors): Bleeding of skin and mucosa such as ecchymoses (large-scale skin bleeding), purpura (small-dot, red skin changes) and bleeding in the gastrointestinal tract were observed during treatment with Paroxat® 40 mg film-coated tablets or other medicinal products of this substance class (SSRI). Elderly patients are possibly at increased risk.

After the end of therapy, withdrawal symptoms commonly occur, particularly if Paroxat® 40 mg film-coated tablets are discontinued abruptly (see section 4. "Which side effects are possible?" under "Side effects"). In clinical studies, adverse events seen on treatment discontinuation occurred in 30% of patients treated with Paroxat® 40 mg film-coated tablets compared to 20% of patients receiving an agent-free medication (placebo). The occurrence of withdrawal symptoms is not the same as the drug being addictive or producing dependence.
The risk of withdrawal symptoms may be dependent on several factors including the duration of therapy and dosage and the rate of dose reduction.
Dizziness, sensory disturbances (including tingling in arms and legs and electric shock sensation), sleep disturbances (including intense dreams), inner restlessness or anxiety, nausea, tremor, confusion, sweating, headache, diarrhoea, palpitations, emotional instability, irritability, and visual disturbances have been reported. Most of these symptoms are generally mild to moderate, however, in some patients they may also be severe in intensity. They usually occur within the first few days of discontinuing treatment, but there have been very rare reports of such symptoms in patients who have inadvertently missed a dose. Generally, these symptoms are self-limiting and spontaneously resolve within 2 weeks, though in some individuals they may be prolonged (two to three months or more after the end of treatment). It is therefore advised to discontinue treatment with Paroxat® 40 mg film-coated tablets gradually by stepwise reduction in the dose over a period of several weeks or months, according to the patient's needs (see section 4. "Which side effects are possible?" under "Withdrawal symptoms after cessation of treatment with Paroxat® 40 mg film-coated tablets").

Use in children and adolescents under 18 years of age
Paroxat® 40 mg film-coated tablets 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 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 Paroxat® 40 mg film-coated tablets for patients under 18 because he/she decides that this is in their best interests. If your doctor has prescribed Paroxat® 40 mg film-coated tablets 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 Paroxat® 40 mg film-coated tablets. Also, the long-term

Children (7 - 17 years of age)
Paroxat® 40 mg film-coated tablets should not be used for the treatment of children and adolescents, as in controlled clinical studies an increased risk of suicidal and hostile behaviour was detected. In addition, in these studies efficacy has not been adequately demonstrated (see section 2. "What must you heed before taking Paroxat® 40 mg film-coated tablets?" under "Special caution when taking Paroxat® 40 mg film-coated tablets is required") and section 4. "Which side effects are possible?" under "Side effects").

Children aged below 7 years
The use of Paroxat® 40 mg film-coated tablets has not been studied so far in children of less than 7 years of age. Paroxat® 40 mg film-coated tablets should not be used, as long as safety and efficacy in this age group have not been established.

Dosage in elderly patients (over 65 years)
Increased plasma concentrations of paroxetine occur in elderly subjects, but the range of these plasma concentrations overlaps with that measured in younger adults. The initial dose should be chosen according to the dosage recommendations stated above. Increasing the dose may be useful in some cases, but the maximum dose should not exceed 1 film-coated tablet (corresponding to 40 mg paroxetine) per day.

Dosage in impaired hepatic or renal function
If you suffer from a severe renal dysfunction (creatinine clearance < 30 ml/min) or a hepatic dysfunction, an increased paroxetine concentration in blood occurs. In these cases, lower dosages should be used. For this reason, consult your doctor.

If you have taken a higher quantity of Paroxat® 40 mg film-coated tablets than you should
Inform your doctor who can decide on measures possibly to be taken.
In addition to the symptoms listed in the section "Side effects", vomiting, dilated pupils, blood pressure changes, headache, fever, involuntary muscle contractions, motoric restlessness, increase in the heart rate and anxiety can occur as signs of an overdose. In such a case, please absolutely consult your doctor.

If you have forgotten to take Paroxat® 40 mg film-coated tablets
If you have forgotten the preceding intake, do not take double the dose.
Intake of Paroxat® 40 mg film-coated tablets is to be continued as prescribed by the doctor.

Effects if treatment with Paroxat® 40 mg film-coated tablets is discontinued
Paroxat® 40 mg film-coated tablets should never be discontinued on your own responsibility. The success of therapy can be endangered thereby. Inform your doctor if intolerance, particularly skin rash, occurs or your clinical picture changes.

4. Which side effects are possible?

Like all medicinal products, Paroxat® 40 mg film-coated tablets can have side effects. Some of the adverse reactions described below may decrease in intensity and frequency with continued treatment and do not generally lead to cessation of therapy. Adverse reactions are listed below according to organ systems and frequency.

The following frequency data is the basis for the assessment of side effects:

very common:	more than 1 in 10 treated patients
common:	less than 1 in 10, but more than 1 in 100 treated patients
uncommon:	less than 1 in 100, but more than 1 in 1,000 treated patients
rare:	less than 1 in 1,000, but more than 1 in 10,000 treated patients
very rare:	less than 1 in 10,000 treated patients, including isolated cases

Side effects

Blood and lymphatic system disorders
Uncommon: abnormal bleeding, predominantly of the skin and mucous membranes (mainly so-called ecchymosis)
Very rare: thrombocytopenia (reduction in the number of blood platelets)

Immune system disorders
Very rare: allergic reactions including nettle rash (urticaria) and swelling, predominantly affecting the face (Quincke's oedema)

Endocrine disorders
Very rare: increased release of the hormone ADH which regulates the water balance

Metabolism and nutrition disorders
Common: loss of appetite
Rare: lowered sodium values in blood (hyponatraemia)

Lowered sodium values in blood have been reported predominantly in elderly patients and are attributable in some cases to a disorder of the hormone ADH which regulates the water balance.

Psychiatric disorders
Common: somnolence, sleeplessness
Uncommon: confusional states, hallucinations
Rare: manic reactions (abnormally euphoric or irritable mood), agitation (state of excitation with increased hyperactivity), anxiety, depersonalisation experience, panic attacks, akathisia (inability to remain sitting in a relaxed manner) (see section 2. "What must you heed before taking Paroxat® 40 mg film-coated tablets?" under "Special caution when taking Paroxat® 40 mg film-coated tablets is required").
These symptoms may also occur due to the underlying disease.

Nervous system disorders
Common: dizziness, tremor
Uncommon: abnormal involuntary movements (extrapyramidal disorders)
Rare: seizures
Very rare: serotonin syndrome (symptoms: motoric restlessness, confusion, sweating, hallucinations, increased reflexes, elevated muscular tension, chills, increase in the heart rate and tremor)

Movement disorders (extrapyramidal disorders) including longer-term contraction of facial muscles (orofacial dystonia) have been reported. The symptoms uncommonly occurred in patients with underlying movement disorders or concurrently treated with neuroleptics.

Eye disorders
Common: blurred vision

Paroxat® 40 mg film-coated tablets 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 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 Paroxat® 40 mg film-coated tablets for patients under 18 because he/she decides that this is in their best interests. If your doctor has prescribed Paroxat® 40 mg film-coated tablets 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 Paroxat® 40 mg film-coated tablets. Also, the long-term safety effects concerning growth, maturation and cognitive and behavioural development of Paroxat® 40 mg film-coated tablets in this age group have not yet been demonstrated.

Elderly patients (over 65 years)
see section 3. "How are Paroxat® 40 mg film-coated tablets to be taken?" under „If not otherwise prescribed by the doctor, the usual dose is:"

Pregnancy
Ask your doctor's or pharmacist's advice before taking any medicinal product.
No sufficient experience is available in pregnant women. Paroxat® 40 mg film-coated tablets should therefore be used during pregnancy only in compelling necessity and after careful assessment of the benefit-risk ratio.

If you plan to become pregnant or if you become pregnant during treatment, consult your doctor. Abrupt withdrawal of Paroxat® 40 mg film-coated tablets during pregnancy should be avoided (see section "Withdrawal symptoms after the end of treatment with Paroxat® 40 mg film-coated tablets").

Neonates should be observed if maternal use of Paroxat® 40 mg film-coated tablets continues into the late stages of pregnancy (particularly in the third trimester).

The following symptoms may occur in the neonate after maternal use of Paroxat® 40 mg film-coated tablets in late stages of pregnancy: dyspnoea, bluish discoloration of the skin (cyanosis), respiratory arrest, seizures, changing body temperature, difficulties when drinking, vomiting, hypoglycaemia, elevated or lowered blood pressure, increased reflexes, tremor, anxious/nervous trembling, irritability, lethargy, sleepiness, sleep disturbances and constant crying. The symptoms can be due either to effects on serotonergic metabolism or due to withdrawal symptoms. In the majority of cases, the complications begin immediately or very soon (less than 24 hours) after birth.

Lactation period
Ask your doctor's or pharmacist's advice before taking any medicinal product.

As the active substance paroxetine passes into mother's milk, Paroxat® 40 mg film-coated tablets must not be used in the lactation period unless the expected benefit for the mother outweighs the potential risk for the child.

Ability to drive and use machines
An influence on the ability to drive is generally not to be expected. In the individual case, however, unforeseeable effects on the central nervous system, particularly at the beginning of treatment, cannot be excluded. Caution is therefore required.
Concurrent consumption of alcohol is generally not advised during treatment with Paroxat® 40 mg film-coated tablets.

Interactions with other medicinal products
Please inform your doctor or pharmacist if you are taking or have recently taken other medicinal products even if these are medicinal products not subject to medical prescription.

Substances interfering in the serotonergic system
Paroxat® 40 mg film-coated tablets interfere in the serotonergic system, so co-administration of other substances also interfering in the serotonergic system (e.g. MAO inhibitors, L-tryptophan/oxitriptan, triptans [agents against migraine], tramadol, linezolid, other SSRIs, lithium and St. John's wort preparations [Hypericum perforatum]) may lead to the occurrence of corresponding effects (serotonin syndrome: see sections 2. "What must you heed before taking Paroxat® 40 mg film-coated tablets?" under "Paroxat® 40 mg film-coated tablets must not be taken" and "Special caution when taking Paroxat® 40 mg film-coated tablets is required").

Caution is advised and closer clinical monitoring is required if you receive these medicinal products in combination with Paroxat® 40 mg film-coated tablets.

Procyclidine
Daily intake of Paroxat® 40 mg film-coated tablets significantly increases the blood level of procyclidine (medicinal product against Parkinson's disease). If anticholinergic effects (among others dry mouth, visual disturbances, constipation) occur, the dose of procyclidine should be reduced.

Agents against seizures (antiepileptics)
Carbamazepine, phenytoin, valproic acid. Concomitant administration does not seem to have any effect on the pharmacokinetic/pharmacodynamic profile in epileptic patients.

Drug-metabolising enzymes
The metabolization of paroxetine, its distribution and its excretion (pharmacokinetics) can be influenced by activation or inhibition of drug-metabolising enzymes.

When Paroxat® 40 mg film-coated tablets are concurrently used with substances known to inhibit drug-metabolising enzymes, paroxetine should be dosed in the lower range.
No adjustment of the initial dosage is necessary when Paroxat® 40 mg film-coated tablets are used together with a known enzyme-inducing medicinal product (e.g. carbamazepine, rifampicin, phenobarbital, phenytoin). Each subsequent dose adjustment should be determined by the clinical effect (efficacy and tolerability).

Medicinal products the degradation of which is influenced by Paroxat® 40 mg film-coated tablets
As with other antidepressants, including other SSRIs, Paroxat® 40 mg film-coated tablets inhibit a certain liver enzyme involved in the degradation of medicinal products (cytochrome P450 enzyme CYP2D6). Inhibition of this enzyme may lead to increased plasma concentrations of co-administered medicinal products also metabolised by this enzyme.
These include certain tricyclic antidepressants (e.g. clomipramine, nortriptyline, and desipramine), neuroleptics of the phenothiazine type (e.g. perphenazine and thioridazine, see section 2. "What must you heed before taking Paroxat® 40 mg film-coated tablets?" under "Paroxat® 40 mg film-coated tablets must not be taken"), risperidone, certain Type 1c antiarrhythmics (e.g. propafenone and flecainide) and metoprolol. It is not recommended to use Paroxat® 40 mg film-coated tablets in combination with metoprolol when given in cardiac insufficiency, because of the narrow therapeutic range of metoprolol in this indication.

Anticoagulant substances for oral intake
Interactions between Paroxat® 40 mg film-coated tablets and anticoagulant substances (oral anticoagulants) may occur. Concomitant administration of Paroxat® 40 mg film-coated tablets and oral anticoagulants can lead to an increased anticoagulation and bleeding tendency. Therefore, Paroxat® 40 mg film-coated tablets should be used with caution in patients treated with oral anticoagulants (see section 2. "What must you heed before taking Paroxat® 40 mg film-coated tablets?" under "Special caution when taking Paroxat® 40 mg film-coated tablets is required").

Non-steroidal antirheumatics, acetylsalicylic acid and other platelet aggregation inhibitors
Interactions between Paroxat® 40 mg film-coated tablets and non-steroidal antirheumatics/acetylsalicylic acid can occur. Concomitant use of Paroxat® 40 mg film-coated tablets and non-steroidal antirheumatics/acetylsalicylic acid can lead to an increased bleeding tendency (see section 2. "What must you heed before taking Paroxat® 40 mg film-coated tablets?" under "Special caution when taking Paroxat® 40 mg film-coated tablets is required").
Caution is advised in patients taking SSRIs concomitantly with oral anticoagulants, medicinal products affecting platelet function or increasing the bleeding tendency (e.g. atypical antipsychotics such as clozapine, phenothiazine derivatives, most tricyclic antidepressants, acetylsalicylic acid, non-steroidal antirheumatics, COX2 inhibitors) or in patients with a history of predisposing factors for bleeding or bleeding disorders.

Intake of Paroxat® 40 mg film-coated tablets together with food and beverages
Alcohol
As with other psychotropic drugs, alcohol is generally to be avoided during treatment with Paroxat® 40 mg film-coated tablets.

3. How are Paroxat® 40 mg film-coated tablets to be taken?

Take Paroxat® 40 mg film-coated tablets always exactly according to the doctor's orders, otherwise Paroxat® 40 mg film-coated tablets cannot act in the right way.
Please ask your doctor or pharmacist if you are not quite sure.

Method of use
For oral intake

Rare: seizures
Very rare: serotonin syndrome (symptoms: motoric restlessness, confusion, sweating, hallucinations, increased reflexes, elevated muscular tension, chills, increase in the heart rate and tremor)

Movement disorders (extrapyramidal disorders) including longer-term contraction of facial muscles (orofacial dystonia) have been reported. The symptoms uncommonly occurred in patients with underlying movement disorders or concurrently treated with neuroleptics.

Eye disorders
Common: blurred vision.
Very rare: sudden increase in intraocular pressure (acute glaucoma)

Cardiac disorders
Uncommon: increase in the pulse beat (sinus tachycardia)
Rare: decelerated pulse beat (bradycardia)

Vascular disorders
Uncommon: transient increase or decrease in the blood pressure

Transient increase or decrease in the blood pressure has been reported during treatment with Paroxat® 40 mg film-coated tablets, usually in patients with pre-existing high blood pressure or anxiety.

Respiratory, thoracic and mediastinal disorders
Common: involuntary, increased yawning

Gastrointestinal disorders
Very common: nausea
Common: constipation, diarrhoea, dry mouth
Very rare: bleeding of the gastrointestinal tract

Hepatobiliary disorders
Rare: elevation in liver enzyme values
Very rare: liver diseases (such as hepatitis, sometimes associated with jaundice and/or liver failure)

Elevations in liver enzyme values have been reported. Post-marketing reports of liver diseases (such as hepatitis, sometimes associated with jaundice and/or liver failure) have very rarely been received. Discontinuation of Paroxat® 40 mg film-coated tablets should be considered if elevated liver function values persist.

Skin and subcutaneous tissue disorders
Common: sweating
Uncommon: skin rash, itching
Very rare: photosensitivity reactions

Renal and urinary disorders
Uncommon: urinary retention

Reproductive system and breast disorders
Very common: sexual disorders
Rare: elevated blood level of the body-own hormone prolactin and outflow of secretion from the mammary gland (hyperprolactinaemia/galactorrhoea)
Very rare: painful continuous penile erection

Musculoskeletal and connective tissue disorders
Rare: joint pain, muscle pain

General symptoms
Common: states of weakness, weight gain
Very rare: swelling due to deposits of tissue fluid at arms and legs (peripheral oedema)

Withdrawal symptoms after cessation of treatment with Paroxat® 40 mg film-coated tablets
Common: dizziness, sensory disorders, sleep disturbances, anxiety, headache
Uncommon: motoric restlessness, nausea, tremor, confusion, sweating, emotional instability, visual disturbances, palpitations, diarrhoea, irritability

Discontinuation of Paroxat® 40 mg film-coated tablets (particularly when abrupt) can commonly lead to withdrawal symptoms such as dizziness, sensory disorders (including tingling in arms and legs and electric shock sensation), sleep disturbances (including intense dreams), motoric restlessness or anxiety, nausea, tremor, confusion, sweating, headache, diarrhoea, palpitations, emotional instability, irritability, and visual disturbances.

Most of these symptoms are mild or moderate and spontaneously subside, however, in some patients they may be severe or prolonged. In order to avoid withdrawal symptoms, Paroxat® 40 mg film-coated tablets should be terminated by stepwise reduction in the dose (see section 3. "How are Paroxat® 40 mg film-coated tablets to be taken?" under "If not otherwise prescribed by the doctor, the usual dose is:" and section 2. "What must you heed before taking Paroxat® 40 mg film-coated tablets?" under "Special caution when taking Paroxat® 40 mg film-coated tablets is required").

Side effects from clinical studies with children and adolescents
In short-term (up to 12 weeks) clinical studies with children and adolescents, the following adverse events were observed in at least 2% of patients treated with paroxetine and occurred at a rate at least twice that of placebo: increased suicidal behaviour (including suicide attempts and suicidal thoughts), self-damaging behaviour and increased aggressivity/hostility. Suicidal thoughts and suicide attempts were mainly observed in clinical studies in adolescents with depressive illnesses (episodes of major depression). Increased aggressivity/hostility occurred particularly in children with obsessive-compulsive disorder, and especially in children younger than 12 years. Additional symptoms that were more often seen in the paroxetine compared to placebo group were decreased appetite, tremor, sweating, hyperkinesia (increased hyperactivity with partially involuntary movements), motoric restlessness, emotional lability (including crying and mood fluctuations).

In studies in which treatment was terminated gradually, the following symptoms were reported in at least 2 in 100 patients during the taper phase or upon discontinuation of Paroxat® 40 mg film-coated tablets and occurred at a rate at least twice that of placebo: emotional lability (including crying, mood fluctuations, self-damaging behaviour, suicidal thoughts and suicide attempts), nervosity, dizziness, nausea and abdominal pain (see section 2. "What must you heed before taking Paroxat® 40 mg film-coated tablets?" under "Special caution when taking Paroxat® 40 mg film-coated tablets is required").

Countermeasures in case of side effects
If you experience undesirable effects of the medicinal product after intake of Paroxat® 40 mg film-coated tablets, please inform your attending doctor who will then decide on countermeasures possibly to be initiated.
It is necessary only in rare cases to interrupt or prematurely terminate treatment.

Please inform your doctor or pharmacist if you notice side effects not mentioned in this package leaflet.

5. How are Paroxat® 40 mg film-coated tablets to be stored?

Keep the medicinal product out of the reach and sight of children.

You must not use the medicinal product after the expiry date stated on the pack.

Do not store above 30 °C.

Last update of information
September 2005

This is a medicament

- A Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instruction of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.

Keep this medicine out of the reach of children.

Council of Arab Health Ministers Union of Arab Pharmacists

Please keep the medicinal product out of the reach and sight of children!
Your doctor, your pharmacy and HEXAL wish you a speedy recovery!