MEDIPREX® 10 mg
Scored film-coated tablet
Escitalopram

Read all of this leaflet carefully before you start using this medicine.
- Keep this leaflet. You may need to read it again.
- If you have any further qiestions,ask your doctor.
- This medicine has been prescribed for you. Do not pass it on to others .It may harm them even if their symptoms are the same as yours.
- If any of side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

1. What MEDIPREX 10 mgscored film-coated tablets is and what it is used for?
2. What you need to know before you take MEDIPREX 10 mgscored film-coated tablets?
3. How to take MEDIPREX 10 mg scored film-coated tablets?
4. Possible side effects?
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6. Contents of the pack and other information

1. WHAT MEDIPREX 10 mg SCORED FILM TABLETSIS AND WHAT IT IS USED FOR

Pharmacotherapeutic class:
MEDIPREXcontains the active substance escitalopram. Escitalopram belongs to a group of antidepressants called selective serotonin reuptake inhibitors (SSRIs). These medicines act on the serotonin-system in the brain by increasing the serotonin level.Disturbances in the serotonin-system are considered an important factor in the development of depression and related diseases.

Indications:
Treatment of major depressive episodes
• Treatment of panic disorder with or without agoraphobia
• Treatment of social anxiety disorder (social phobia).
• Treatment of generalized anxiety disorder
• Treatment of Obsessive Compulsive Disorders
It may take a couple of weeks before you start to feel better. Continue to take MEDIPREX even if it takes some time before you feel any improvement in your condition.
You must talk to a doctor if you do not feel better or if you feel worse.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE MEDIPREX 10 mg SCORED FILM TABLETS

Do not take MEDIPREX 10 mg :
•if you are allergic to escitalopram or any of the other ingredients of this medicine (listed in the section 6).
•if you are taking medicines called monoamine oxidase inhibitors (MAOIs), including moclobemide, selegiline and linezolid.
•if you are born with or have had an episode of abnormal heart rhythm (seen at ECG; an examination to evaluate how the heart is functioning).
•if you take medicines for heart rhythm problems or that may affect the heart's rhythm (see section 2 "Other medicines and MEDIPREX").

Warnings and precautions
Talk to your doctor or pharmacist before taking this medicine. Please tell your doctor if you have any other condition or illness, as your doctor may need to take this into consideration. In particular, tell yourdoctor:
•if you have epilepsy. Treatment with MEDIPREX should be stopped if seizures occur for the first time, or if there is an increase in the seizure frequency (see also section 4 "Possible side effects»).
•if you suffer from impaired liver or kidney function. Your doctor may need to adjust your dosage.
•if you have diabetes. Treatment with MEDIPREX may alter glycaemic control. Insulin and/or oral hypogly caemic dosage may need to be adjusted.
•if you have a decreased level of sodium in the blood.
•if you have a tendency to easily develop bleedings or bruises.
if you are receiving electroconvulsive treatment.
•if you have coronary heart disease.
•if you suffer or have suffered from heart problems or have recently had a heart attack.
•if you have a low resting heart-rate and/or you know that you may have salt depletion as a result of pro longed severe diarrhoea and vomiting (being sick) or usage of diuretics (water tablets).
•if you experience a fast or irregular heartbeat, fainting, collapse or dizziness on standing up, which may indicate abnormal functioning of the heart rate.
•if you have or have previously had eye problems, such as certain kinds of glaucoma (increased pressure in the eye).
Please note
Some patients with manic-depressive illness may enter into a manic phase. This is characterized by unusual and rapidly changing ideas, inappropriate happiness and excessive physical activity. If you experience this, contact your doctor.
Symptoms such as restlessness or difficulty in sitting or standing still can also occur during the first weeks of the treatment.
Tell your doctor immediately if you experience these symptoms.
Thoughts of suicide and worsening of your depression
If you are depressed 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.
You may be more likely to think like this:
•if you have previously had thoughts about killing or harming yourself.
•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 and ask them to read this leaflet. You might ask them to tell you if they think your depression is getting worse, or if they are worried about changes in your behaviour.
Use in children and adolescents
MEDIPREX 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 attempts, suicidal thoughts and hostility (predominately aggression, oppositional behaviour and anger) when they take this class of medicines. Despite this, your doctor may prescribe MEDIPREX for patients under 18 because he/she decides that this is in their best interest. If your doctor has prescribed MEDIPREX for a patient under 18 and you want to discuss this, please go back to your doctor. You should inform your doctor if any symptoms listed above develop or worsen when patients under 18 are taking MEDIPREX. Also, the long term safety effects concerning growth, maturation and cognitive and behavioural development of MEDIPREX in this age group have not yet been demonstrated.

Other medicines and MEDIPREX
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
Tell your doctor if you taking any of the following medicines:
•Monoamine oxidase inhibitors (MAOIs), combining phenelzine, iproniazid, isocarboxazid, nialamide, tranyl cypromine, moclobemide, selegiline and the antibiotic linezolid. If you have taken any of these medicines you will need to wait 14 days before you start taking MEDIPREX. After stopping MEDIPREX you must allow 7 days before taking any of these medicines.
•Lithium (used in the treatment of manic-depressive disorder) and tryptophan.
•Imipramine and desipramine (both used to treat depression).
•Sumatriptan and similar medicines (used to treat migraine) and tramadol (used against severe pain). Theseincrease the risk of sideeffects.
•Cimetidine, lansoprazole and omeprazole (used to treat stomach ulcers), fluvoxamine (antidepressant) and ticlopidine (used to reduce the risk of stroke). Thesemay cause increasedbloodlevels of MEDIPREX.
•St. John's Wort (*hypericumperforatum)* - a herbal remedy used for depression.
•Acetylsalicyclic acid (aspirin) and non-steroidal anti-inflammatory drugs (medicines used for pain relief or to thin the blood, so called anti-coagulant). Thesemayincreasebleedingtendency.
•Warfarin, dipyridamole, and phenprocoumon (medicines used to thin the blood, so called anti-coagulant). Your doctor will probably check the coagulation time of your blood when starting and discontinuing MEDIP REX in order to check that your dose of anti-coagulant is still adequate.
•Mefloquin (used to treat Malaria), bupropion (used to treat depression) and tramadol (used to treat severe pain) due to a possible risk of a lowered threshold for seizures.
•Neuroleptics (medicines to treat schizophrenia, psychosis) and antidepressants (tricyclic antidepressants and SSRIs) due to a possible risk of a lowered threshold for seizures, and antidepressants.
•Flecainide, propafenone, and metoprolol (used in cardiovascular diseases), clomipramine, and nortriptyline (antidepressants) and risperidone, thioridazine, and haloperidol (antipsychotics). The dosage of MEDIPREX may need to be adjusted.
•Medicines that decrease blood levels of potassium or magnesium, as these conditions increase the risk of life threatening heart rhythm disorders.
Do not take MEDIPREX if you take medicines for heart rhythm problems or medicines that may affect the heart's rhythm, such as Class IA and III antiarrhythmics, antipsychotics (e.g. phenothiazine derivatives, pimozide, haloperidol), tricyclic antidepressants, certain antimicrobial agents (e.g. sparfloxacin, moxifloxacin, erythromycin IV, pentamidine, anti-malarial treatment, particularly halofantrine), certain antihistamines (e.g.astemizole, mizolastine).
If you have any further questions about this you should speak to your doctor.
MEDIPREX with food, drink and alcohol
MEDIPREX can be taken with or without food (see section 3 "How to take MEDIPREX").
As with many medicines, combining MEDIPREX with alcohol is not advisable, although MEDIPREX 10 mg is not expected to interact with alcohol.
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. Do not take MEDIPREX if you are pregnant or breast-feeding, unless you and your doctor have discussed the risks and benefits involved.
If you take MEDIPREX during the last 7 months of your pregnancy you should be aware that the following effects may be seen in your newborn baby: trouble with breathing, bluish skin, fits, body temperature changes, feeding difficulties, vomiting, low blood sugar, stiff or floppy muscles, vivid reflexes, tremor, jitteriness, irritability, lethargy, constant crying, sleepiness and sleeping difficulties. If your newborn baby has any of these symptoms, please contact your doctor immediately.
Make sure your midwife and/or doctor know you are on MEDIPREX. When taken during pregnancy, particularly in the last 3 months of pregnancy, medicines like MEDIPREX 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.
If used during pregnancy MEDIPREX should never be stopped abruptly.
It is expected that MEDIPREX 10 mg will be excreted into breast milk.
Citalopram, a medicine like MEDIPREX, 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
You are advised not to drive a car or operate machinery until you know how MEDIPREX affects you.

3. HOW TO TAKE MEDIPREX 10 mg SCORED FILM TABLETS

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

Adults:

Depression:
The recommended dosage of MEDIPREX is 10 mg daily in one dose. The dosage may be increased by your doctor to a maximum of 20 mg per day.

Panic Disorder:
The initial dosage of MEDIPREX in the first week of treatment is 5 mg daily in one dose and then increased to 10 mg daily. The dosage may be increased by your doctor up to a maximum of 20 mg per day.

Social anxiety disorder:
The recommended dosage of MEDIPREX is 10 mg daily in one dose. Your doctor may decrease the dosage to 5 mg daily or increase it to a maximum of 20 mg per day, depending on your response to treatment.

Generalized anxiety disorder:
The recommended dosage of MEDIPREX is 10 mg daily in one dose. The dosage may be increased by your doctor to a maximum of 20 mg per day.

Obsessive Compulsive Disorders:
The recommended dosage of MEDIPREX is 10 mg daily in one dose. The dosage may be increased by your doctor up to a maximum of 20 mg per day

Elderly patients (above 65 years of age)
The recommended starting dose of MEDIPREX is 5 mg taken as one daily dose. The dose may be increased by your doctor to 10 mg per day.

Children and adolescents (below 18 years of age)
MEDIPREX should not normally be given to children and adolescents. For further information please see section 2 "What you need to know before you take escitalopram"
Swallow the tablet whole with some water. You can take the tablet with or without food.

How long should you continue to take MEDIPREX 10 mg
Your doctor will determine how long you should continue to take MEDIPREX. As with other medicines for the treatment of depression, it may take some weeks until you start to feel better. Continue to take the tablets even if it takes a while until you feel better.
In any event you should speak to your doctor in advance before you make any changes to the dose.
Duration of treatment varies. Continue to take the film-coated tablets as your doctor has prescribed, even if you are already feeling better. If you stop taking the tablets too early, your symptoms may return. Therefore, treatment should be continued for at least six months after your symptoms have subsided.

If you take more MEDIPREX than you should
If you take more than the prescribed dose of MEDIPREX, contact your doctor or nearest hospital emergency department immediately. Do this even if there are no signs of discomfort. Some of the signs of an overdose could be dizziness, tremor, agitation, convulsion, coma, nausea, vomiting, change in heart rhythm, decreased blood pressure and change in body fluid/salt balance. Take the MEDIPREX box/container with you when you go to the doctor or hospital.

If you forget to take MEDIPREX
Do not take a double dose to make up for forgotten doses. If you do forget to take 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 and carry on as usual.

Stopping MEDIPREX:
You should speak to your doctor in advance before you stop taking MEDIPREX. Please inform your doctor if you wish to stop treatment early.
Do not stop taking MEDIPREX until your doctor tells you to do so.When you have completed your course of treatment, it is generally advised that the dose of MEDIPREX is gradually reduced over a number of weeks. When you stop taking MEDIPREX, especially if it is abruptly, you may feel discontinuation symptoms. These are common when treatment with MEDIPREX is stopped. The risk is higher, when MEDIPREX has been used for a long time or in high dose or when the dose is reduced too quickly . Most people find that the symptoms are mild and go away on their own within two weeks. However, in some patients they may be severe in intensity or they may be prolonged (2 – 3 months or more). If you get severe discontinuation symptoms when you stop taking MEDIPREX, please contact your doctor . He or she may ask you to start taking your tablets again and reduce the dose more slowly.
Discontinuation symptoms include: 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, feeling sick (nausea), sweating (including night sweats), feeling restless or agitated, tremor (shakiness), feeling confused or disorientated, feeling emotional or irritable, diarrhoea (loose stools), visual disturbances, fluttering or pounding heartbeat (palpitations).
If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS ?

Like all medicines, this medicine can cause side effects, although not everybody gets them.
The side effects usually disappear after a few weeks of treatment. Please be aware that many of the effects may also be symptoms of your illness and therefore will improve when you start to get better.
Stop taking MEDIPREX and see a doctor or go to a hospital straight away if you get:
Uncommon (may affect up to 1 in 100 people):
• unusualbleeds, includinggastrointestinalbleeds
Rare (may affect up to 1 in 1000 people):
• swelling of skin, tongue, lips, or face, or have difficulties breathing or swallowing (allergic reaction).
• a high fever, agitation, confusion, trembling and abrupt contractions of muscles. These may be signs of a rare condition called serotonin syndrome.

Talk to a doctor straightaway if you notice any of the following side effects (frequency not known):
• Difficultiesurinating
• Seizures (fits), see also section 2 "Warnings and precautions"
• Yellowing of the skin and the white in the eyes (signs of liver function impairment/hepatitis)
• Fast, irregular heart beat, fainting, which could be symptoms of a life-threatening condition known as Torsade de Pointes
• Thoughts of harming yourself or thoughts of killing yourself (see also section 2 "What you need to know before you take MEDIPREX 10 mg").

In addition to the above, the following side effects have been reported:
Very common (may affect more than 1 in 10 people):
• Feeling sick (nausea)
• Headache
Common (may affect up to 1 in 10 people):
• Blocked or runny nose (sinusitis)
• Decreased or increasedappetite
• Anxiety, restlessness, abnormal dreams, difficulties falling asleep, feeling sleepy, dizziness, yawning, tremors, prickling of the skin
• Diarrhoea, constipation, vomiting, dry mouth
• Increasedsweating
• Pain in muscle and joints (arthralgia and myalgia)
• Sexual disturbances (delayed ejaculation, problems with erection, decreased sexual drive and women may experience difficulties achieving orgasm)
• Fatigue, fever
• Increasedweight
Uncommon (may affect up to 1 in 100 people):
• Nettle rash (urticaria), rash, itching (pruritus)
• Grinding one's teeth, agitation, nervousness, panic attack, confusion
• Disturbed sleep, taste disturbance, fainting (syncope)
• Enlarged pupils (mydriasis), visual disturbance, ringing in the ears (tinnitus)
• Loss of hair
• Vaginal bleeding
• Decreaseedweight
• Fastheart beat
• Swelling of the arms or legs
• Nosebleeds
Rare (may affect up to 1 in 1000 people):
• Aggression, depersonalisation, hallucination
• Slow heart beat
Some patients have reported (frequency cannot be estimated from the available data):
• Decreased levels of sodium in the blood (the symptoms are feeling sick and unwell with weak muscles or confusion)
• Dizziness when you stand up due to low blood pressure (orthostatic hypotension)
• Abnormal liver function tests (increased amounts of liver enzymes in the blood)
• Movement disorders (involuntary movements of the muscles)
• Painfulerections (priapism)
• Bleeding disorders including skin and mucous bleeding (bruising) and low level of blood platelets (thrombycytopenia)
• Sudden swelling of skin or mucosa (angioedemas)
• Increase in the amount of urine excreted (inappropriate ADH secretion)
• Flow of milk in men and women that are not nursing
• Mania
• An increased risk of bone fractures has been observed in patients taking this type of medicines
• Alteration of the heart rhythm (called "prolongation of QT interval", seen on ECG, electrical activity of the heart)
In addition, a number of side effects are known to occur with drugs that work in a similar way to MEDIPREX 10 mg (the active ingredient of MEDIPREX 10 mg film-coated tablets). These are:
• Motorrestlessness (akathisia)
• Loss of appetite

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

5. HOW TO STORE MEDIPREX 10 mg?

Keep this medicine out of the sight and reach of children.
Do not use this medicine after the expiry date which is stated on the outer carton and the blister (EXP).
The expiry date refers to the last day of that month.
This medicinal product does not require any special storage conditions.
Do not throw away any medicine via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

Full list of active substances and excipients
What MEDIPREX 10mg scoredfilm-coated tablets contains?

MEDIPREX 10 mg	
Active substance :	
Escitalopram (in the form of oxalate)	10 mg (12,77 mg)
Excipients :	
Microcrystalline Cellulose, anhydrous colloidal silica, Talc, Croscarmellose sodium, Magnesium stearate, white opadry (polyvinyl alcohol, titanium dioxide, polyethylene glycol / macrogol, talc)	

What MEDIPREX 10 mg contains and contents of the pack:
Mediprex is a White oblong film-coated scored tablet.
MEDIPREX is available in a box of 15 tablets and box of 30 tablets.
M.A. N°: List I

Marketing authorisation holder and manufacturer :
Les laboratoires MédiS
P.B. 206 - 8000 Nabeul – Tunisia
Tel : +216 72 235 006 / Fax : +216 72 235 016
E-mail : contact@labomedis.com

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This is a Medicament
- 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 instructions 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 for you.
- Do not repeat the same prescription without consulting your doctor

Keep all medicaments out of reach of children

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