

# Citoles<sup>®</sup> 10 mg Film Tablet

(PHARMALINE)

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**For oral use.****Active Substance:** 10 mg escitalopram (as oxalate).**Excipients:** Ac-Di-Sol, microcrystalline cellulose, colloidal silicon dioxide (Aerosil 200), talc, magnesium stearate, P.V.P K30, Opadry II 85F18422 White (polyvinyl alcohol, titanium dioxide, polyethylene glycol 3350, talc).**Because it contains important information for you, read all of this LEAFLET carefully before you start taking this medicine.**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please consult your doctor or your pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others.
- Tell your doctor you are taking this medicine if you go to a doctor or to a hospital.
- Follow the instructions in this leaflet. Do not use higher or lower dose than the dose that is recommended for you.

**In this leaflet there are the titles of:**

1. What is CITOLES and what it is used for?
2. Before you take CITOLES.
3. How to take CITOLES?
4. What are possible side effects?
5. How to store CITOLES?

**1. What is CITOLES and what it is used for?**

- CITOLES 10 mg film tablet is an oval, white, scored, film-coated tablet that contains 10 mg of escitalopram.
- CITOLES is marketed in package containing 28 tablets.
- CITOLES contains escitalopram. This medicine is used to treat depression (major depressive episodes), panic disorder with or without agoraphobia, social anxiety disorder and generalized anxiety disorders and obsessive-compulsive disorder.
- 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.

It may take a couple of weeks before you start to feel better. Continue to take escitalopram even if it takes some time before you feel any improvement in your condition.

Consult your doctor if you do not feel better or you feel that you are getting worse.

**2. Before you take CITOLES****DO NOT TAKE CITOLES in the following situations**

- If you are allergic (hypersensitive) to escitalopram or any of the other ingredients of CITOLES (see "Excipients").
- If you take other medicines that belongs to a group called MAO inhibitors (monoamine oxidase inhibitors), including selegiline (used in the treatment of Parkinson's disease), moclobemide (used in the treatment of depression) or linezolid (an antibiotic).
- If you are taking pimozide.
- 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 (Class IA and III antiarrhythmics, antipsychotics [e.g. phenothiazine derivatives, pimozide, haloperidol], tricyclic antidepressants, some antimicrobial compounds [e.g. sparfloxacin, moxifloxacin, erythromycin IV, pentamidine, anti-malarial treatment particularly halofantrine], certain antihistamines [e.g. astemizole, mizolastine] [see, "Taking other medicines").

**TAKE SPECIAL CARE with CITOLES in the following situations**

Consult your doctor or pharmacist before taking CITOLES.

Please consult your doctor if you have any other condition or illness, as your doctor may need to take this into consideration.

**In particular, consult your doctor:**

- If you have epilepsy. Treatment with CITOLES should be stopped if seizures occur for the first time, or if there is an increase in the seizure frequency (see also section "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 CITOLES may alter glycemic control. Insulin and/or oral hypoglycemic 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 (electroshock) 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 prolonged severe diarrhea and vomiting (being sick) or usage of diuretics (water tablets).
- If you experience a fast or irregular heart beat, fainting, collapse or dizziness on standing up, which may indicate abnormal functioning of the heart rate.
- If you have suffered from an eye problem related to enlargement of pupil (mydriasis).

It is recommended to be cautious in patients with patients who have high risk of torsade de pointes (a cardiac rhythm disturbance), e.g. patients with congestive heart disease, recent myocardia infarction, low heart rate, or patients predisposed to hypokalemia (low blood potassium level) or hypomagnesemia (low blood magnesium level) due to concomitant disease or medication use.

**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, consult your doctor.

Symptoms such as restlessness or difficulty to sit or stand still can also occur during the first weeks of the treatment. Consult your doctor immediately if you experience these symptoms.

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 yourselves. These may be increased when first starting antidepressants, since these medicines all take time to work, usually about 2 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 behavior 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, consult your doctor or go to a hospital straight away.

There is a probability to increase suicidal thoughts and suicide attempt with the use of antidepressant drugs especially in children and young adults under the age of 25 years. Therefore, all patients should be monitored by the family of the patient or caregiver for unexpected behavioral changes such as anxiety and akathisia, or suicide probability especially during the initial few months of a course of drug therapy, or at times of dose changes, either increases or decreases.

**Use in children and adolescents**

CITOLES 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 behavior and anger) when they take this class of medicines. Despite this, your doctor may prescribe CITOLES for patients under 18 because he/she decides that this is in their best interest. If your doctor has prescribed CITOLES for a patient under 18 and you want to discuss this, please consult your doctor. You should inform your doctor if any symptoms listed above develop or worsen when patients under 18 are taking CITOLES. Also, the long-term safety effects concerning growth, maturation and cognitive and behavioral development of CITOLES in this age group have not yet been demonstrated.

If these warnings are valid for you even if in the past, please consult your doctor.

**Taking CITOLES with food and drink**

CITOLES can be taken with or without food (see section "How to take CITOLES").

As with many medicines, combining CITOLES with alcohol is not advisable, although CITOLES is not expected to interact with alcohol.

**Pregnancy:**

Consult your doctor or pharmacist for advice before taking medicine.

Consult your doctor if you are pregnant or planning to become pregnant. Do not take CITOLES if you are pregnant, unless you and your doctor have discussed the risks and benefits involved.

If you take CITOLES during the last 3 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.

Consult your doctor you are taking CITOLES. When taken during pregnancy, particularly in the last 3 months of pregnancy, medicines like CITOLES may increase the risk of a serious condition in babies, called persistent pulmonary hypertension of the new born, 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 consult your doctor immediately.

If used during pregnancy CITOLES should never be stopped abruptly.

The use of SSRIs in pregnancy, particularly in late pregnancy may increase the risk of persistent pulmonary hypertension in the newborn.

If you noticed you became pregnant during your treatment, immediately consult to your doctor or pharmacist.

**Breast-feeding**

Consult your doctor or pharmacist for advice before taking medicine.

It is expected CITOLES to be excreted in mother milk. If you are breast-feeding your baby, do not use CITOLES; however you can use CITOLES by consulting your doctor on risks and benefits.

**Fertility:**

Citalopram, a medicine like escitalopram, 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 CITOLES affects you.

**Important information about some of the ingredients of CITOLES**

This medicine contains sodium. This should be taken into account in patients under controlled-sodium diet.

**Taking other medicines**

Consult your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

**Consult your doctor if you are taking any of the following medicines:**

- "Non-selective monoamine oxidase inhibitors (MAOIs)", containing phenelzine, iproniazid, isocarboxazid, nialamide, and tranylcypromine as active ingredients. If you have taken any of these medicines you will need to wait 14 days before you start taking CITOLES. After stopping CITOLES you must allow 7 days before taking any of these medicines.
- "Reversible, selective MAO-A inhibitors", containing moclobemide (used to treat depression).
- "Irreversible MAO-B inhibitors", containing selegiline (used to treat Parkinson's disease). These increase the risk of side effects.
- The antibiotic linezolid.
- Lithium (used in the treatment of manic-depressive disorder) and tryptophan (an amino acid used as nutrition supplement).
- Imipramine and desipramine (both used to treat depression).
- Sumatriptan and similar medicines (used to treat migraine) and tramadol (used against severe pain). These increase the risk of side effects.
- Cimetidine, lansoprazole and omeprazole (used to treat stomach ulcers), fluvoxamine (antidepressant) and ticlopidine (used to reduce the risk of stroke). These may cause increased blood levels of escitalopram.
- St. John's Wort (Hypericum perforatum) - a herbal remedy used for depression.
- Acetylsalicylic acid and non-steroidal anti-inflammatory drugs (medicines used for pain relief or to thin the blood, so called anti-coagulant). These may increase bleeding-tendency.
- Warfarin, dipyrindamole, 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 CITOLES in order to verify that your dose of anti-coagulant is still adequate.
- Mefloquine (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.
- Flecainide, propafenone, and metoprolol (used in cardio-vascular diseases) clomipramine, and nortriptyline (antidepressants) and risperidone, thioridazine, and haloperidol (antipsychotics). The dosage of CITOLES may need to be adjusted.
- Do not take CITOLES 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).

- Medicines that decrease blood potassium and magnesium level increase the risk of life threatening cardiac rhythm disturbance.

If you are taking prescribing only or over-the-counter product, or you took recently, please consult your doctor or pharmacist about this condition.

### 3. How to take CITOLES?

#### Directions on proper usage and dose/administration frequency:

Always take CITOLES exactly as your doctor has told you. You should consult your doctor if you are not sure.

#### Adults

##### Depression

The normally recommended dose of CITOLES is 10 mg taken as one daily dose. The dose may be increased by your doctor to a maximum of 20 mg per day.

##### Panic disorder

The starting dose of CITOLES is 5 mg as one daily dose for the first week before increasing the dose to 10 mg per day. The dose may be further increased by your doctor to a maximum of 20 mg per day.

##### Social anxiety disorder

The normally recommended dose of CITOLES is 10 mg taken as one daily dose. Your doctor can either decrease your dose to 5 mg per day or increase the dose to a maximum of 20 mg per day, depending on how you respond to the medicine.

##### Generalized anxiety disorder

The normally recommended dose of CITOLES is 10 mg taken as one daily dose. The dose may be increased by your doctor to a maximum of 20 mg per day.

##### Obsessive-compulsive disorder

The normally recommended dose of CITOLES is 10 mg taken as one daily dose. The dose may be increased by your doctor to a maximum of 20 mg per day.

#### Administration route and method:

You can take CITOLES with or without food. Swallow the tablet with some water. Do not chew them, as the taste is bitter.

If necessary, you can divide the tablets by firstly placing the tablet on a flat surface with the score facing upwards. The tablets may then be broken by pressing down on each end of the tablet, using both forefingers as shown in the drawing.

#### Some age groups:

##### Use in children (below 18 years of age)

CITOLES should not be given to children and adolescents (under 18 years of age). For further information please see section 2 "Before you take CITOLES".

##### Elderly patients (above 65 years of age)

The recommended starting dose of CITOLES is 5 mg taken as one daily dose. The dose may be increased by your doctor to a maximum of 10 mg per day.

#### • Special populations:

##### Renal or hepatic insufficiency:

With mild to moderate impairment of kidney function, no dose adjustment is required.

In patients with mild to moderate hepatic insufficiency, the recommended starting dose of CITOLES is 5 mg as one daily dose for the first week. The dose may be further increased by your doctor to a maximum of 10 mg per day.

Caution is indicated for patients with severely impaired kidney or hepatic function.

#### Duration of treatment:

It may take a couple of weeks before you start to feel better. Continue to take CITOLES even if it takes some time before you feel any improvement in your condition.

Do not change the dose of your medicine without talking to your doctor first.

Continue to take CITOLES for as long as your doctor recommends. If you stop your treatment too soon, your symptoms may return. It is recommended that treatment should be continued for at least 6 months after you feel well again.

If you have an impression about the effect of CITOLES is too strong or too weak, consult your doctor or pharmacist.

#### If you take more CITOLES than you should:

Consult a doctor or a pharmacist if you took more CITOLES than you should.

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 CITOLES box/container with you when you go to the doctor or hospital.

#### If you forget to take CITOLES

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.

#### If you stop taking CITOLES

Do not stop taking CITOLES until your doctor tells you to do so. When you have completed your course of treatment, it is generally advised that the dose of CITOLES is gradually reduced over a number of weeks.

When you stop taking CITOLES, especially if it is abruptly, you may feel discontinuation symptoms. These are common when treatment with CITOLES is stopped. The risk is higher, when CITOLES has been used for a long time or in high doses 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 CITOLES, please consult your doctor. He or she may ask you to start taking your tablets again and come off them 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, diarrhea (loose stools), visual disturbances, fluttering or pounding heartbeat (palpitations).

If you have any further questions on the use of this product, consult your doctor or pharmacist.

#### 4. What are possible side effects?

Like all medicines, side effects may be occurred in patients sensitive to ingredients in CITOLES.

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.

#### Side effects are listed as indicated in the following categories:

Very common: affects more than 1 user in 10.

Common: affects more than 1 user in 100 and less than 1 user in 100.

Uncommon: affects more than 1 user in 1000 and less than 1 user in 100.

Rare: affects more than 1 person in every 10,000 treated, but less than 1 person in every 1000 treated.

Unknown: cannot be estimated from available data.

#### • Consult your doctor if you get any of the following side effects during treatment:

Uncommon:

- Unusual bleeding, including gastrointestinal bleeding .

Rare:

- If you experience swelling of skin, tongue, lips, or face, or have difficulties breathing or swallowing (allergic reaction), consult your doctor or go to a hospital straight away.
- If you have a high fever, agitation, confusion, trembling and abrupt contractions of muscles these may be signs of a rare condition called serotonin syndrome. If you feel like this consult your doctor.

If you experience the following side effects you should consult your doctor or go to the hospital straight away:

- Difficulties urinating .
- Seizures (fits), see also section "Take special care with CITOLES".
- Yellowing of the skin and the white in the eyes are signs of liver function impairment / hepatitis.
- Fast, irregular heartbeat, fainting which could be symptoms of a life-threatening condition known as Torsades de Pointes.

In addition to above the following side effects have been reported:

Very common:

- Nausea .
- Headache .

Common:

- Blocked or runny nose (sinusitis).
- Decreased or increased appetite.
- Anxiety, restlessness, abnormal dreams, difficulties falling asleep, feeling sleepy, dizziness, yawning, tremors, prickling of the skin
- Diarrhea, constipation, vomiting, dry mouth.
- Increased sweating.
- 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 and fever.
- Increased weight.

Uncommon:

- Nettle rash (urticaria), rash, itching (pruritus) .
- Grinding one's teeth, agitation, nervousness, panic attack, confusion state.
- Disturbed sleep, taste disturbance, fainting (syncope) .
- Enlarged pupils (mydriasis), visual disturbance, ringing in the ears (tinnitus) .
- Loss of hair.
- Excessive menstrual bleeding.
- Irregular menstrual period.
- Decreased weight.
- Fast heart beat.
- Swelling of the arms or legs.
- Nosebleeds.
- Abnormal bleeding including gastrointestinal bleeding.

Rare:

- Aggression, depersonalization, hallucination.
- Slow heart beat.

Some patients have reported (frequency can not be estimated from the available data):

- Thoughts of harming yourself or thoughts of killing yourself, see also section "Take special care with CITOLES" .
- Decreased levels of sodium in the blood (the symptoms are feeling sick and unwell with weak muscles or confused) .
- Dizziness when you stand up due to low blood pressure (orthostatic hypotension) .
- Abnormal liver function test (increased amounts of liver enzymes in the blood) .
- Movement disorders (involuntary movements of the muscles) .
- Painful erections (priapism).
- Bleeding disorders including skin and mucous bleeding (ecchymosis) and low level of blood platelets (thrombocytopenia) .
- Sudden swelling of skin or mucosa (angioedema) .
- Increase in the amount of urine excreted (inappropriate ADH secretion) .
- Flow of milk in men and in 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, measuring 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 escitalopram (the active ingredient of CITOLES). These are:

- Motor restlessness (akathisia)
- Anorexia

If you notice any side effects not listed in this leaflet, please consult your doctor or pharmacist.

#### 5. How to store CITOLES

Keep CITOLES out of the reach and sight of children, and in its package.

Store at room temperature under 25°C.

Do not use CITOLES after expiry date on the package. The expiry date refers to the last day of the month.

Reg. N° 219716/09

#### Marketing Authorization Holder:

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This leaflet was approved on 13/05/2015.

Produced by **Pharmaline** - Lebanon  
Licensed by **Tripharma** - Turkey

Rev. 05/2015 905128-C