Package leaflet: Information for the user

Ciprotan 10 mg film-coated tablets
Ciprotan 20 mg film-coated tablets

citalopram

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Ciprotan is and what it is used for

Ciprotan is an antidepressant. It belongs to a group of medicines called selective serotonin re-uptake inhibitors (SSRIs).

Ciprotan is used to
- treat episodes of major depression

2. What you need to know before you take Ciprotan

DO NOT take Ciprotan
- if you are allergic to citalopram or any of the other ingredients of this medicine (listed in section 6)
- if you are taking a type of medicine known as a monoamine oxidase (MAO) inhibitor. These medicines are normally used for treatment of depression or Parkinson's disease. The MAO-inhibitor selegiline may be taken at the same time as citalopram, provided the dose of selegiline is not more than 10 mg per day
- if you have recently taken MAO-inhibitors. Depending on the type of MAO-inhibitor, you may have to wait for up to 14 days after stopping the MAO-inhibitor before starting to take Ciprotan (see also "Other medicines and Ciprotan"). If you stop taking Ciprotan and you want to start taking an MAO-inhibitor, you will have to wait for at least 7 days
- if you are taking linezolid (used to treat bacterial infections), unless you are closely observed by your doctor and your blood pressure is monitored.
- if you are taking pimozide (a medicine used to treat schizophrenia and chronic psychosis)
- 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. Also refer to the section "Other medicines and Ciprotan" below

Warnings and precautions
Please tell your doctor if you have any other condition or illness, as your doctor may need to take this into consideration. Talk to your doctor or pharmacist before taking Ciprotan

- if you have or have had episodes of mania or panic disorder
- if you suffer from impaired liver or kidney function. Your doctor may need to adjust your dosage
- if you have diabetes. Treatment with Ciprotan may alter glycaemic control. Insulin and/or oral hypoglycaemic dosage may need to be adjusted
- if you have epilepsy. Treatment with Ciprotan should be stopped if seizures occur or if there is an increase in the seizure frequency (see also section 4 “Possible side effects")
- if you have some kind of bleeding disorder, or if you are pregnant (see ‘Pregnancy, breast-feeding and fertility’).
- if you have a decreased level of sodium in the blood
- if you are receiving electroconvulsive therapy (ECT)
- if you suffer or have suffered from heart problems or have recently had a heart attack
- if you have a low resting heartrate and/or you know that you may have salt depletion as a result of prolonged 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 a problem with dilatation of the pupil of the eye (mydriasis) or if you have or have previously had eye problems, such as certain kinds of glaucoma (increased pressure in the eye).
- if you have so-called psychosis with depressive episodes. Ciprotan might make your psychotic symptoms worse
- if you are prone to certain heart conditions (called “prolongation of the QT interval”, seen on ECG, a trace of the electrical activity of the heart) or you are suspected of having an inborn alteration of the heart rhythm (called “congenital long QT-syndrome”) or you have low blood levels of potassium or magnesium (hypokalaemia/hypomagnesaemia)

Please consult your doctor, even if these statements were applicable to you at any time in the past.

Talk to your doctor if
- you develop a so-called **serotonin syndrome** with symptoms including severe agitation, tremor, muscle twitching and fever. If this happens, your doctor will stop treatment with Ciprotan immediately
- you develop symptoms such as **sleeplessness and agitation**. These are quite common at the start of treatment and your doctor might prescribe a lower dose for you
- you start **feeling sick and unwell** with **weak muscles** or **confused** while being treated with Ciprotan

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 to sit or stand still (akathisia) can also occur during the first weeks of the treatment. Tell your doctor immediately if you experience these symptoms.

Medicines like Ciprotan (so called SSRIs/SNRIs) may cause symptoms of sexual dysfunction (see section 4). In some cases, these symptoms have continued after stopping treatment.

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.

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 young adults (less than 25 years old) with psychiatric conditions who were treated with an antidepressant

If you have thoughts of harming or killing yourself at any time, **contact your doctor or go to a hospital straight away.**

You may find it helpful to tell a relative or close friend that you are depressed or have an anxiety disorder and ask them to read this leaflet. You might ask them to tell you if they think your depression or anxiety is getting worse, or if they are worried about changes in your behaviour.

Children and adolescents
Ciprotan 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 (predominantly aggression, oppositional behaviour and anger) when they take this class of medicines. Despite this, your doctor may prescribe Ciprotan for patients under 18 because he/she decides that this is in their best interest. If your doctor has prescribed Ciprotan 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 Ciprotan. Also, the long-term safety effects concerning growth, maturation and cognitive and behavioural development of Ciprotan in this age group have not yet been demonstrated.

Other medicines and Ciprotan
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Tell 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 substance. If you have taken any of these medicines you will need to wait 14 days before you start taking Ciprotan. After stopping Ciprotan you must allow 7 days before taking any of these medicines.
- "Reversible, selective MAO-A inhibitors", containing moclobemide (used to treat depression)
- Linezolid (an antibiotic)
- Lithium (used in the prophylaxis and treatment of manic-depressive disorder)
- Food supplements with serotonergic effects such as tryptophan and oxitriptan [also known as 5-hydroxytryptophan (5-HTP)]
- Imipramine and desipramine (both used to treat depression)
- "Irreversible MAO-B inhibitors", containing selegiline (used to treat Parkinson's disease); these increase the risk of side effects. The dose of selegiline must not exceed 10 mg per day.
- Metoprolol (used for high blood pressure and/or heart disease); the blood levels of metoprolol are increased. Dose adjustment may be required.
- Sumatriptan and similar medicines (used to treat migraine), tramadol and similar medicines (opioids, used to treat severe pain); these increase the risk of side effects; if you get any unusual symptoms when using this combination you should see your doctor.
- Cimetidine, lansoprazole, omeprazole and esomeprazole (antacids, used to treat stomach ulcers), fluconazole (used to treat fungal infections), fluvoxamine (antidepressant) and ticlopidine (used to reduce the risk of stroke). These may cause increased blood levels of citalopram.
- Medicines known to affect the platelet function (e.g. some antipsychotic drugs, acetylsalicylic acid (used as pain killer or blood thinner), non-steroidal anti-inflammatory drugs like ibuprofen or naproxen (used as pain killer or to treat arthritis), dipyridamole and ticlopidine (used to reduce the risk of thrombosis), phenothiazines, tricyclic antidepressants; slightly increased risk of bleeding abnormalities.
- Preparations containing St John's Wort (*Hypericum perforatum*) (an herbal remedy used to treat depression) - concomitant intake with Ciprotan may increase the risk of side effects.
- 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, e.g. phenothiazines, thioxanthenes and butyrophenones) and antidepressants (tricyclics, SSRIs) due to a possible risk of a lowered threshold for seizures
- Medicines that decrease blood levels of potassium or magnesium as these conditions increase the risk of life-threatening heart rhythm disorder

- Certain medicines may be removed from the body more slowly when used together with citalopram. These medicines include flecainide and propafenone (medicines used to treat heart rhythm disorders), metoprolol (when used to treat cardiac failure), antidepressants such as desipramine, clomipramine and nortriptyline (medicines used to treat depression), certain antipsychotics such as risperidone, thioridazine and haloperidol. Your doctor may adjust the dosage of your medicines.

Do not take Ciprotan if you take medicines for heart rhythm problems or medicines that may affect the heart's rhythm, e.g. Class IA and III antiarrhythmics, antipsychotics (e.g. phenothiazines derivatives, pimozide, haloperidol), tricyclic antidepressants, certain antimicrobial agents (e.g. sparfloxacin, moxifloxacin, erythromycin IV, pentamidine, anti-malarial treatment particularly halofantrine), certain antihistamines (astemizole, mizolastine). If you have any further questions about this you should speak to your doctor.

Ciprotan with food, drink and alcohol
The tablets can be taken with or without food. Although no particular problems have been found between Ciprotan and alcohol, the use of alcohol should be avoided during treatment with Ciprotan.

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.

Pregnancy
Do not take Ciprotan if you are pregnant or planning to become pregnant, unless your doctor considers it absolutely necessary.

Published data on the use of citalopram in pregnant women (more than 2 500 outcomes of use) do not indicate the occurrence of congenital malformations. However, do not use this medicine during pregnancy unless you have discussed the risks and benefits with your doctor.

Make sure your midwife and/or doctor know you are on Ciprotan. When taken during pregnancy, particularly in the last 3 months of pregnancy, medicines like Ciprotan 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 you are taking Ciprotan in the last 3 months of pregnancy, let your doctor know as your baby might have some symptoms when it is born. These symptoms usually begin during the first 24 hours after the baby is born. They include not being able to sleep or feed properly, trouble with breathing, a blueish skin or being too hot or cold, being sick, crying a lot, stiff or floppy muscles, lethargy, tremors, jitters or fits. If your baby has any of these symptoms when it is born, contact your doctor immediately who will be able to advise you.

If you take Ciprotan near the end of your pregnancy, there may be an increased risk of heavy vaginal bleeding shortly after birth, especially if you have a history of bleeding disorders. Your doctor or midwife should be aware that you are taking Ciprotan so they can advise you.

Breast-feeding
Citalopram passes into breast milk in small amounts and a risk to the suckling baby cannot be excluded. If you are taking Ciprotan, talk to your doctor before you start breast-feeding.

Fertility
Citalopram 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
Ciprotan has some effect on the ability to drive and use machines. Any medicine that affects the mind can reduce the ability to make judgements and to react to emergencies. Your ability to drive a car or

operate machinery could be affected. Do not drive or use machines until you know how Ciprotan affects you. Please ask your doctor or pharmacist if you are unsure.

3. How to take Ciprotan

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

Use in adults
The recommended dose is 20 mg per day. This may be increased by your doctor to a maximum of 40 mg per day.

Use in elderly patients (above 65 years of age)
The starting dose should be decreased to half of the recommended dose, e.g. 10-20 mg per day. Elderly patients should not usually receive more than 20 mg per day.

Use in children and adolescents
Ciprotan should not be used in the treatment of children and adolescents under the age of 18 years (see section 2 'Warnings and precautions').

Patients with special risks

Reduced renal function
If you have mild to moderate kidney disease, you may take the usual dose of Ciprotan. No information is available on treatment of people with severe renal impairment (creatinine clearance less than 30 ml/min) and therefore use of Ciprotan is not recommended.

Reduced hepatic function
Patients with liver damage or liver disease should receive a starting dose of 10 mg per day. Patients with liver complaints should not receive more than 20 mg per day. Patients with reduced liver function will be monitored closely by their doctor.

Method of administration
Please take the film-coated tablets once a day, either in the morning or in the evening, with a glass of water. The tablets can be taken with or without food.

Duration of treatment
The antidepressant effect of Ciprotan is expected to take at least two weeks to work. Treatment should continue until you have been free of symptoms for 4-6 months. Your doctor will find out the dose and duration of treatment according to the nature and severity of your illness and your personal reaction to the medicine.

If you take more Ciprotan than you should
If you accidentally take too many tablets, or if a child takes any Ciprotan, contact your doctor or nearest hospital casualty department immediately for advice.

The symptoms of an overdose with citalopram will depend on the dose but may include sleepiness, coma, stupor, fits (seizures), increased pulse, sweating, nausea, vomiting, blue lips and skin and hyperventilation (accelerated and stronger breathing) and rarely effects on the heart rhythm. Symptoms of the so-called serotonin syndrome may also occur.

If you forget to take Ciprotan
Do not worry. Simply leave out that dose completely and then take your next dose at the right time. Do not take a double dose to make up for a forgotten dose.

If you stop taking Ciprotan
Please talk to your doctor before you interrupt or stop treatment with Ciprotan, even if you feel better.

If Ciprotan is stopped suddenly, withdrawal symptoms may occur. These may include: dizziness, pins and needles and electric shock sensations, sleep disturbances (including insomnia and intense dreams), agitation or anxiety, nausea, vomiting, tremor, confusion, sweating, headache, diarrhoea, palpitations, emotional instability, irritability, and visual disturbances. Generally, these symptoms are mild to moderate and will disappear on their own within 2 weeks. However, in some patients these symptoms may be more severe, or go on for longer.

Ciprotan should be withdrawn slowly when terminating treatment. It is recommended to reduce the dose gradually over a period of at least 1-2 weeks.

If you get severe withdrawal effects when you stop taking Ciprotan, please see your doctor. He or she may ask you to start taking your tablets again and come off them more slowly.

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 following side effects have been reported at the frequencies shown.

If you experience any of the following symptoms **contact your doctor or go to the hospital straight away**:

Rare: may affect up to 1 in 1 000 people

- hyponatraemia: abnormally low blood levels of sodium which can cause tiredness, confusion, and muscle twitching

Not known: frequency cannot be estimated from the available data

- high fever, agitation, confusion, trembling and abrupt contractions of muscles; these may be signs of a rare condition called 'serotonin syndrome' which has been reported with the combined use of antidepressants
- severe hypersensitivity reaction (anaphylactic reaction) which may result in shock (strong decrease in blood pressure, paleness, agitation, weak and fast pulse, clammy skin and decreased consciousness) due to a sudden widening of the blood vessels
- swelling of skin, tongue, lips or face, feeling dizzy or having difficulties breathing or swallowing (serious allergic reaction)
- bleeding in the digestive system, including rectal bleeding (gastrointestinal haemorrhage)
- fast, irregular heartbeat, fainting which could be symptoms of a life-threatening condition known as 'Torsades de Pointes'

Other side effects:

The majority of the side effects listed below are mild. 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.

Very common: may affect more than 1 in 10 people

- sleepiness
- difficulty in sleeping
- headache
- feeling sick (nausea)
- dry mouth (as dry mouth may increase the risk of tooth decay it is advisable to brush your teeth more often)
- increased sweating

Common: may affect up to 1 in 10 people

- appetite decreased, decreased weight
- anxiety, nervousness, decreased sexual drive, confusional state, abnormal dreams

- tremor
- tingling or numbness in the hands or feet, prickling of the skin (paraesthesia)
- dizziness, disturbance in attention
- ringing in the ears (tinnitus)
- yawning
- diarrhoea, vomiting, constipation
- itching
- muscle pain, joint pain
- men: ejaculation failure, problems with ejaculation, difficulty getting or keeping an erection
- women: may experience failure to achieve an orgasm
- tiredness (fatigue)
- fever

Uncommon: may affect up to 1 in 100 people
- appetite increased, increased weight
- feeling of happiness (euphoria)
- aggression
- sense of unreality / feeling detached from yourself (depersonalisation), hallucination
- feeling excessively elated, impulsive, irritable, or irrational (mania)
- fainting (syncope)
- enlarged pupils (mydriasis)
- slow heartbeat
- fast heartbeat
- sensitivity to sunlight (photosensitivity reaction), hives (urticaria), hair loss (alopecia), rash, red or purple patches/spots (smaller than 1 cm) of the skin caused by bleeding underneath (purpura)
- difficulties urinating (urinary retention)
- excessive menstrual bleeding
- swelling of the arms or legs (oedema)

Rare: may affect up to 1 in 1 000 people
- inflammation of the liver (hepatitis)
- involuntary muscle movements (dyskinesia)
- Grand mal seizure (a certain form of convulsions)
- taste disorder
- unusual bleeds (haemorrhages), including bleeding in the womb, skin, and mucous membranes

Not known: frequency cannot be estimated from the available data
- thoughts of harming yourself or thoughts of killing yourself (see also section 2 ‘Warnings and precautions’)
- reduction in blood platelets, which increases risk of bleeding or bruising (thrombocytopenia)
- excessive, undesirable (damaging, discomfort-producing and sometimes fatal) reactions produced by the normal immune system (hypersensitivity)
- panic attack
- grinding of the teeth (bruxism)
- restlessness
- low concentration of potassium in the blood (hypokalaemia)
- unusual muscle movements or stiffness
- involuntary movements of the muscles (akathisia)
- fits
- visual disturbance
- alteration of the heart rhythm (called “prolongation of QT interval”, seen on ECG, a trace of the

electrical activity of the heart
- nosebleed
- abnormal liver function test
- blue or purplish patches (bigger than 1 cm) of the skin caused by bleeding underneath (ecchymosis)
- painful swelling of skin and mucous membranes due to fluid retention (e.g. of the face, mouth, throat or tongue), breathing difficulties and/or itching and rash (angioedema)
- flow of milk in men and in women that are not nursing (galactorrhoea)
- irregular menstrual period (intermenstrual bleeding)
- heavy vaginal bleeding shortly after birth (postpartum haemorrhage), see 'Pregnancy' in section 2 for more information
- painful erection of the penis (priapism)
- increased blood levels of the hormone prolactin
- a fall in blood pressure on standing up (orthostatic hypotension)
- increase in the amount of urine excreted (inappropriate ADH secretion)
- increased risk of bone fractures (observed in patients taking these type of medicines)

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system:
HPRA Pharmacovigilance
Website: www.hpra.ie
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ciprotan

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 carton and the blister or bottle. 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 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.

6. Contents of the pack and other information

What Ciprotan contains
The active substance is citalopram.

Ciprotan 10 mg
1 film-coated tablet contains 12.495 mg citalopram hydrobromide, equivalent to 10 mg Citalopram.

Ciprotan 20 mg
1 film-coated tablet contains 24.99 mg citalopram hydrobromide, equivalent to 20 mg Citalopram.

The other ingredients are:
Core: mannitol, microcrystalline cellulose, colloidal silica, anhydrous, magnesium stearate
Coating: hypromellose, macrogol 6000, titanium dioxide (E171)

What Ciprotan looks like and contents of the pack
Ciprotan 10 mg
Round, white tablets with a diameter of 6 mm

Ciprotan 20 mg

Round, white tablets with a score line and diameter of 8 mm
The tablets can be divided into equal doses.

They are available in blister packs of 10, 14, 20, 28, 30, 50, 56, 98, 100 and 100x1 tablets per box as well as in a tablet container containing 250 and 500 tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Marketing authorisation holder:
Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

Manufacturer:
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This medicinal product is authorised in the Member States of the EEA under the following names:
- Denmark: Citalopram STADA
- Iceland: Citalopram STADA
- Ireland: Ciprotan 10 mg/20 mg film-coated tablets
- Italy: Citalopram EG 20 mg Compresse rivestite con film
- Luxembourg: Citalopram EG 10 mg/20 mg
- The Netherlands: Citalopram STADA 10 mg/20 mg filmomhulde tabletten

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