PACKAGE LEAFLET: INFORMATION FOR THE USER

Ciprotan 10mg Film-coated Tablets
Ciprotan 20mg 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 citalopram (see also "Other medicines and Ciprotan"). If you stop taking citalopram 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

Talk to your doctor or pharmacist before taking Ciprotan.

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.

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 attempt, 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 interests. 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.

Tell your doctor if you have or have had any of the illnesses or medical conditions listed below. Your doctor will decide if you should take Ciprotan or not.

Ask 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 citalopram immediately.
- you have epilepsy that is not well controlled.
- If you have any seizures, either for the first time or if you have more seizures than usual, you must stop taking Ciprotan and tell your doctor.
- you are treated with electro-convulsive therapy (ECT).
- you have or have had episodes of mania (overactive behaviour or thoughts). If you start suffering from mania again, your doctor will discontinue treatment with Ciprotan.
- you have so-called psychosis with depressive episodes. Ciprotan might make your psychotic symptoms worse.
- you develop symptoms such as an inner sense of restlessness and an inability to sit or stand still usually associated with feelings of distress (akathisia). This is most likely to occur within the first few weeks of treatment. Increasing the dose of Ciprotan may make these feelings worse (see section “Possible side effects”).
- you have a history of bleeding disorders or if you are pregnant (see ‘Pregnancy’). Ciprotan may increase the risk of bleeding.
- you suffer from severe kidney disease. The effects of Ciprotan on people with kidney disease are not known.
- you suffer from liver damage or liver disease. You will need a lower dose of Ciprotan and will need to have regular checkups.

- 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 have diabetes. Your doctor may need to adjust the dose of insulin or other medicine used to lower your blood sugar.
- you start feeling sick and unwell with weak muscles or confused while being treated with Ciprotan.
- you are susceptible for certain cardiac disorders (prolongation of the so called QTc interval in the ECG) or you have a suspected congenital long QT-syndrome or you have low blood levels of potassium or magnesium (hypokalaemia/hypomagnesaemia).
- you suffer or have suffered from heart problems or have recently had a heart attack.
- you have a low resting heart-rate 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).
- you experience a fast or irregular heartbeat, fainting, collapse or dizziness on standing up which may indicate abnormal functioning of the heart rate.
- you have problems with your eyes, such as certain kinds of glaucoma

Also tell your doctor if you are taking
- a type of medicine for migraine known as a triptan (e.g. sumatriptan), the strong pain killer tramadol, or if you are taking the supplements oxitriptan or tryptophan.
- any herbal preparations that contain St John's wort (*Hypericum perforatum*). You are more likely to have undesirable effects. You should stop taking St John's wort and tell your doctor.
- medicines that influence blood coagulation or increase bleeding risk.

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

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

Taking Ciprotan at the same time as some other medications may affect the way in which they work, or enhance their side effects, and vice versa (i.e. interactions may occur).

- Medications belonging to the MAO inhibitor group (medicines to treat depression or Parkinson's disease). Very severe side effects may occur, including a condition known as serotonin syndrome (see section 2 under "DO NOT take Ciprotan").
- Tramadol (a strong pain killer), sumatriptan or other 'triptans' (medicines used to treat migraine), oxitriptan and tryptophan (a dietary supplement and serotonin precursor)

Taking Ciprotan with these medicines is not recommended.
- Anticoagulants (e.g. warfarin) and other medicines that can affect blood clotting such as non-steroidal anti-inflammatory drugs (anti-inflammatory painkillers like naproxen and ibuprofen), acetylsalicylic acid, dipyridamole and ticlopidine (medicines used to reduce the risk of thrombosis).
- Medicines known as 'atypical antipsychotics', phenothiazines, or tricyclic antidepressants. These can also increase the risk of haemorrhage.
- Herbal preparations containing St John's wort (*Hypericum perforatum*). These should not be taken at the same time as Ciprotan because the undesirable effects may get worse.
- Cimetidine, omeprazole, esomeprazole and lansoprazole (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. Your doctor may reduce the dose of citalopram if undesirable effects occur when using these medicines together with citalopram.
- Lithium (a medicine to treat mania and depression).
  Caution should be exercised in combination with Citalopram. As usual, levels of lithium in the

blood should be regularly monitored.
- Medicines lowering the seizure threshold, e.g. other antidepressants (tricyclics, SSRIs), neuroleptics (used to treat psychosis as for example schizophrenia and mania, e.g. phenothiazines, butyrophenones, thioxanthenes), mefloquine (medicine used to treat malaria), bupropion (medicine that may be used when quitting smoking, antidepressant) and tramadol (pain killer): concomitant use can cause seizures.
- 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 with medicines
- that cause a so-called QT-interval prolongation in the ECG
- that decrease blood levels of potassium or magnesium (which may also cause a QT-interval prolongation)
- for heart rhythm problems
- that may affect the heart's rhythm
  - 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-malarian treatment particularly halofantrine),
  - certain antihistamines (astemizole, mizolastine)

Use of these medicines with Ciprotan increases the risk of heart rhythm disorders.

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 planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy
There is only limited experience in the use of Ciprotan during pregnancy. Do not take Ciprotan if you are pregnant or planning to become pregnant, unless your doctor considers it absolutely necessary. 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.

Nonetheless, you should not stop treatment with Ciprotan abruptly. 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 bluish 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 so there is a risk of an effect on the baby. 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 medicines that affect 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.

The recommended dose is:

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 people (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 people 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 "Warnings and precautions").

Patients with special risks

Adults with kidney problems
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.

Adults with liver problems
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 administration
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 get any of the following symptoms you should **stop taking** Ciprotan **and see your doctor immediately:**

- Fast, irregular heartbeat, fainting which could be symptoms of a life-threatening condition known as Torsades de Pointes

Very common: may affect more than 1 in 10 people

- sleepiness, difficulty in sleeping, sleeplessness, agitation, nervousness
- headache, tremor, dizziness
- difficulty focussing the eyes
- noticeable heartbeat (palpitations)
- feeling sick (nausea), dry mouth, constipation, diarrhoea
- increased sweating
- general weakness (asthenia)

Common: may affect up to 1 in 10 people

- weight decrease or increase
- sleep disorders, difficulty concentrating, abnormal dreaming, loss of memory (amnesia), anxiety,

decreased libido, increased appetite, decreased appetite, loss of appetite, feeling of indifference (apathy), confusion
- migraine, feeling of pins and needles (paraesthesia)
- visual disorders
- ringing in the ears (tinnitus)
- increased pulse
- orthostatic hypotension (a fall in the blood pressure on standing up), low blood pressure, high blood pressure
- runny nose (rhinitis), inflamed paranasal sinuses (sinusitis)
- indigestion, vomiting, abdominal pain, flatulence, increased salivation, taste abnormalities
- rash, itching
- urinary disorders, increased urination
- ejaculation failure, problems with ejaculation, female anorgasmia, abnormal orgasm (female), abnormal or painful periods, impotence
- tiredness (fatigue), yawning, disturbance in attention
- muscle pain, joint pain
- withdrawal symptoms such as dizziness, nausea, vomiting, tremor, confusion, sweating, headache, diarrhoea, pins and needles and electric shock sensations, sleep disturbances (including insomnia and intense dreams), agitation or anxiety, palpitations, emotional instability, irritability, and visual disturbances (see section 3 “If you stop taking Ciprotan”).

Uncommon: may affect up to 1 in 100 people
- feeling of happiness (euphoria), increased libido
- aggression
- sense of unreality / feeling detached from yourself (depersonalisation), hallucination, feeling elated or over-exited, which causes unusual behaviour (mania)
- excessive dilatation of the pupil (mydriasis)
- disorders of movement, such as abnormal posture and writhing movements (extrapyramidal disorder), convulsions
- reduced heart rate
- coughing
- an increase of liver enzymes (detected by blood test)
- sensitivity to sunlight (photosensitivity), hives (urticaria), hair loss (alopecia), red or purple discolourations on the skin (purpura)
- lack of ability to urinate (urinary retention)
- too much fluid in the body’s tissues (oedema)
- allergic reactions, loss of consciousness, malaise

Rare: may affect up to 1 in 1,000 people
- low amount of blood sodium (hyponatraemia), a syndrome that affects the body’s production of urine (SIADH)
- serotonin syndrome
- haemorrhages, including bleeding in the womb, digestive system, skin, and mucous membranes
- inflammation of the liver (hepatitis)
- fever (pyrexia)

Very rare: may affect up to 1 in 10,000 people
- panic attack (these symptoms may be due to the underlying disease)
- heart rhythm disorders
- painful swelling of skin and mucous membranes due to fluid retention (e.g. of the throat and

tongue), breathing difficulties and/or itching and rash (angioedema)
- abnormal milky discharge from the breast glands (galactorrhoea)
- severe hypersensitivity reactions (anaphylactoid reactions) 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

Not known: frequency cannot be estimated from the available data
- 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)
- grinding of the teeth (bruxism)
- restlessness
- low concentration of potassium in the blood (hypokalemia)
- abnormal ECG heart tracing (QT-prolongation)
- nosebleed (epistaxis)
- abnormal liver function test
- bruise (ecchymosis)
- bleeding of the uterus (metrorrhagia)
- heavy vaginal bleeding shortly after birth (postpartum haemorrhage), see 'Pregnancy' in section 2 for more information
- painful erection of the penis (priapism)
- unpleasant feelings of restlessness or an inability to sit or stand still (akathisia; see section 2 "Warnings and precautions")
- thoughts of suicide and suicidal behaviours
  Cases of suicidal thoughts and suicidal behaviours have been reported during citalopram therapy or early after treatment discontinuation (see section 2 "Warnings and precautions").

Other possible side effects
An increased risk of bone fractures has been observed in patients taking this type of medicine.

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 PharmacovigilanceWebsite: www.hpra.ieBy 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 100×1 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:
Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland
STADA Arzneimittel AG, Stadastrasse 2-18, 61118 Bad Vilbel, Germany

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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