Package leaflet: Information for the user

Citalopram Bluefish 10 mg film-coated tablets
Citalopram Bluefish 20 mg film-coated tablets
Citalopram Bluefish 40 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 Citalopram Bluefish is and what it is used for .

Citalopram belongs to a group of antidepressants called selective serotonin re-uptake inhibitors (SSRIs). Everyone has a substance called serotonin in their brain. It is not fully understood how citalopram works, but it may help by acting on the serotonin system in the brain.

Citalopram Bluefish is used in the treatment of depression.(major depressive episodes).

2. What you need to know before you take Citalopram Bluefish

Do not take Citalopram Bluefish:
- if you are allergic to citalopram or any of the other ingredients of this medicine (listed in section 6) .
- if you are taking or have recently taken medicines called monoamine oxidase inhibitors (MAOIs; amongst others used to treat depression). Before starting with Citalopram Bluefish, you must talk to your doctor, because you may have to wait for up to 14 days after quitting the use of a MAOI. The MAOI selegiline (used to treat Parkinson's disease) may be used, but not in doses exceeding 10 mg per day. When changing from Citalopram Bluefish to MAOIs, you have to wait for at least seven days before you start taking MAOIs.
- 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 (medicine used to treat certain psychiatric conditions)
- 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 Citalopram Bluefish" below*.
- If any of this applies to you please inform your doctor <u>before</u> taking Citalopram Bluefish.

Warnings and precautions
Talk to your doctor or pharmacist before taking Citalopram Bluefish

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.
- Take special care if you develop symptoms such as inner sense of restlessness and psychomotor agitation such as an inability to sit or stand still usually associated with subjective distress (akathisia). This is most likely to occur within the first few weeks of treatment. Increasing the dose of Citalopram Bluefish may make these feelings worse (see section 4. "Possible side effects").

Please inform your doctor, if any of the conditions below is applicable to you, since they may affect the treatment you should receive. Tell your doctor:

- if you are taking any other medicines (see "Other medicines and Citalopram Bluefish"). Some medicines may increase the side effects of Citalopram Bluefish and may sometimes cause very serious reactions.
- if you have diabetes, because your doctor may need to adjust the dosage of insulin or other medicine used to lower your blood sugar.
- if you have epilepsy or a history of fits or start suffering from seizures during treatment with Citalopram Bluefish. Your doctor may decide to discontinue therapy with Citalopram Bluefish, if a seizure occurs
- if you are having electro-convulsive therapy (ECT)
- if you suffer from episodes of mania/hypomania (overactive behaviour or thoughts). Your doctor may decide to discontinue therapy with Citalopram Bluefish if you are entering a manic phase.
- if you have a history of bleeding disorders or bleed easily, if you are pregnant (see 'Pregnancy, breast-feeding and fertility') or if you use medicines which possibly increase tendency to bleed (see section "Other medicines and Citalopram Bluefish").
- if you are susceptible for certain cardiac disorders (prolongation of the so called QT interval in the ECG) or you have a suspected congenital long QT-syndrome or you have low blood levels of potassium or magnesium
- if you have other psychiatric conditions (psychosis)
- if you suffer from liver or kidney problems. Your doctor may need to reduce the dose of Citalopram Bluefish.
- 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 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

Tell your doctor immediately, if some of the following symptoms are developing during therapy with Citalopram Bluefish, because then you may have something called serotonin syndrome, a potentially life-threatening condition. The symptoms include: feeling restless, feeling shaky, sudden movements of the muscles and fever. If this happens, your doctor will stop treatment with Citalopram Bluefish immediately.

Citalopram Bluefish can in rare cases, predominantly in elderly patients, cause reduced levels of sodium in the blood and an inappropriate secretion of a hormone of the brain regulating the water balance of the body (syndrome of inappropriate anti-diuretic hormone secretion [SIADH]). Inform your doctor if you start feeling sick and unwell with weak muscles or confused while being treated with Citalopram Bluefish.

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

Withdrawal symptoms seen on discontinuation
Withdrawal symptoms when treatment is discontinued are common, particularly if discontinuation of Citalopram Bluefish is abrupt. The risk of withdrawal symptoms may be dependent on several factors including the duration and dose of therapy and the rate of dose reduction. Dizziness, sensory disturbances (including paraesthesia and electric shock sensations), sleep disturbances (including insomnia and intense dreams), agitation or anxiety, nausea and/or vomiting, tremor, confusion, sweating, headache, diarrhoea, palpitations, emotional instability, irritability, and visual disturbances have been reported. Generally these symptoms are mild to moderate; however, in some patients they may be severe in intensity. They usually occur within the first few days of discontinuing treatment, but there have been very rare reports of such symptoms in patients who have inadvertently missed a dose. Generally these symptoms are self-limiting and usually resolve within 2 weeks, though in some individuals they may be prolonged (2-3 months or more). It is therefore advised that Citalopram Bluefish should be gradually tapered when discontinuing treatment over a period of several weeks or months, according to your needs.

If intolerable symptoms occur following a decrease in the dose upon discontinuation of treatment, then resuming the previously prescribed dose may be considered. Subsequently, your doctor may continue decreasing the dose, but at a more gradual rate.

Children and adolescents

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

Other medicines and Citalopram Bluefish

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

If you are taking or have recently taken any of the medicines in the list below, and you have not already discussed these with your doctor, go back to your doctor and ask what to do. The dose may need to be changed or you may need to be given another medicine

- monoamine oxidase inhibitors, linezolid and pimozide (see “Do not take *Citalopram Bluefish*”)
- medicines called triptans such as sumatriptan (used to treat migraine)
- tramadol (medicine used to treat severe pain)), buprenorphine (used to treat drug addiction and pain)

- anticoagulants, dipyridamol and ticlopidine (medicines to thin the blood)
- acetylsalicylic acid, non-steroidal anti-inflammatory drugs (NSAID's) such as ibuprofen (medicines used to treat inflammation and pain)
- neuroleptics (phenothiazines [e.g. thioridazine], thioxanthenes, butyrophenones [e.g. haloperidol]), atypical antipsychotics, e.g. risperidone (medicines used to treat certain psychiatric conditions)
- tricyclic antidepressants (medicines used to treat depression)
- herbal remedies containing St. John's Wort (Hypericum perforatum)
- cimetidine, omeprazole, esomeprazole, lanzoprazole (medicines used to lower the production of stomach acid)
- fluconazole (used to treat fungal infections)
- tryptophan, oxitriptan (serotonin-precursors)
- lithium (medicine used to treat mania)
- imipramine, desipramine, clomipramine, nortryptyline (medicines used to treat depression)
- fluvoxamine (medicine used to treat depression and obsessive compulsive disorder)
- mefloquin (medicine used to treat malaria)
- bupropion (medicine used to treat depression and to support to give up smoking)
- flecainide, propafenone (medicines used to treat irregular heartbeat)
- metoprolol (medicine used to treat cardiac failure)
- medicinal products which may change the ECG (prolongation of the QT interval) or may cause low blood levels of potassium or magnesium. Please ask you doctor or pharmacist if the medicinal product(s) you are taking/using concomitantly with *Citalopram Bluefish* belong(s) to this group.

Some medicines may increase the side effects of citalopram and may sometimes cause very serious reactions. Do not take any other medicines whilst taking citalopram without first talking to your doctor. Citalopram may interact with these medicines and you may experience symptoms such as involuntary, rhythmic contractions of muscles, including the muscles that control movement of the eye, agitation, hallucinations, coma, excessive sweating, tremor, exaggeration of reflexes, increased muscle tension, body temperature above 38°C. Contact your doctor when experiencing such symptoms

DO NOT TAKE Citalopram Bluefish if you take medicines for heart rhythm problems or medicines that may affect the heart's rhythm, e.g. such as Class IA and III antiarrhythmics, antipsychotics (e.g. fentiazine derviatives, pimozide, haloperidol), tricyclic antidepressants , certain antimicrobial agents (e.g. sparfloxacin, moxifloxacin, erythromycin IV, pentamidine, anti-malarian treatment particularly halofantrine), certain antihistamines (astemizole, mizolastine). If you have any further questions about this you should speak to your doctor.

Citalopram Bluefish with food, drink and alcohol
It is recommended not to drink alcohol during treatment with Citalopram Bluefish.
Citalopram Bluefish can be taken with or without food.

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
Data suggest that the use of Citalopram during pregnancy does not lead to problems with the fetus. Therefore, Citalopram may be used if you are pregnant or planning to become pregnant taking into account the following issues..
You should not discontinue treatment with Citalopram Bluefish abruptly. If you are taking Citalopram Bluefish 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 blue-ish 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.

Make sure your midwife and/or doctor know you are on Citalopram Bluefish. When taken during pregnancy, particularly in the last 3 months of pregnancy, medicines like Citalopram Bluefish 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 take Citalopram Bluefish 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 Citalopram Bluefish so they can advise you.

Breast-feeding
Citalopram passes into breast milk in small amounts. There is a risk of an effect on the baby. If you are taking Citalopram Bluefish, 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
Citalopram Bluefish has minor or moderate influence on the ability to drive and use machines. However, medicinal products influencing the central nervous system can reduce the ability to make judgements and to react to emergencies. Do not drive or use machines until you know how Citalopram Bluefish affects you. Please ask your doctor or pharmacist if you are unsure about anything.

Citalopram Bluefish contains lactose.
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Citalopram Bluefish contains sodium.
This medicine contains less than 1 mmol sodium (23 mg) per 10mg, 20mg and 40mg tablet, that is to say essentially ‘sodium-free’.

3. How to take Citalopram Bluefish

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

How much to take

The recommended dose is
Adults
Depression
The usual dose is 20 mg per day. This may be increased by your doctor to a maximum of 40 mg per day.

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.

Patients with special risks
Patients with liver complaints should not receive more than 20 mg per day.

Citalopram Bluefish should be taken as a single oral dose, either in the morning or in the evening. The film-coated tablet(s) can be taken with or without food, but with fluid.

The effect of Citalopram Bluefish is not felt straight away. It will take at least two weeks before you notice any improvement. After you are free of symptoms, Citalopram should be taken for another 4-6 months.

Discontinuation of therapy
Citalopram Bluefish should be withdrawn slowly in order to reduce the risk of withdrawal reactions. Your doctor will gradually reduce your dose over a period of at least 1-2 weeks (see "Take special care with Citalopram Bluefish").

If you take more Citalopram Bluefish than you should
If you think that you or anyone else may have taken too many film-coated tablets contact your doctor or nearest hospital casualty department immediately.
The following symptoms may occur: feeling sleepy, coma, inability of the body to move (stupor), seizure, increased heartbeat, increased sweating, nausea, vomiting, blue discolouration of the lips, tongue, skin and mucous membranes (caused by a lack of oxygen in the blood) and accelerated breathing.

Also a serotonin syndrome may occur (symptoms see "Take special care with Citalopram Bluefish").

If you forget to take Citalopram Bluefish
If you forget to take Citalopram Bluefish, take your dose when you remember and then take your next dose at the usual time. Do not take a double dose to make up for a forogotten dose.

If you stop taking Citalopram Bluefish
Do not stop using Citalopram Bluefish until your doctor tells you. Citalopram Bluefish should be withdrawn slowly, it is advised that the dose is gradually reduced over a period of at least 1-2 week. It is important that you follow the instructions of your doctor. Discontinuation of treatment with Citalopram Bluefish particularly if abrupt, may result in the appearance of withdrawal symptoms (see "Take special care with Citalopram Bluefish"). Talk to your doctor, if such withdrawal symptoms occur after you stopped taking Citalopram Bluefish.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Side effects observed with Citalopram Bluefish are in general mild and transient. They are most prominent during the first weeks of treatment and usually attenuate as the depressive state improves.

If you experience one of the following side effects, you should stop taking Citalopram and seek immediate medical advice:
- thoughts of suicide and suicidal behaviour
- disorders of movement (extrapyramidal symptoms)
- restlessness and inability to stand or sit still (akathisia)
- severe allergic reactions (with relevant symptoms)
- swelling of skin and mucous membranes due to fluid retention and angioedema (with relevant symptoms)

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

The side-effects reported for citalopram are described below and are presented according to the frequency at which they occur.

The frequencies are defined as

very common	*may affect more than 1 in 10 people*
common	*may affect up to 1 in 10 people*
uncommon	*may affect up to 1 in 100 people*
rare	*may affect up to 1 in 1,000 people*
not known	*frequency cannot be estimated from the available data*

Very common
- feeling sleepy, sleeplessness
- headache
- Feeling sick (nausea), dry mouth, increased sweating

Common
- tremor, dizziness
- decreased appetite, decreased weight, weight loss (anorexia)
- agitation, anxiety, nervousness, confusion
- decreased sex drive (libido)
- sensation of tingling, pricking or numbness in skin (paraesthesia)
- problems with concentration
- ringing in ears (tinnitus)
- diarrhoea, vomiting, constipation, indigestion (dyspepsia), stomach pain, wind (flatulence), increased saliva
- muscle pain (myalgia), joint pain (arthralgia)
- itching (pruritus)
- tiredness, yawning
- inability in women to achieve orgasm, menstrual pain, impotence, ejaculation failure
- abnormal dreaming, memory loss (amnesia), absence of emotion or enthusiasm

Uncommon
- slow heart beat
- fast heart beat
- increased appetite, increased weight
- aggression, feeling detached from yourself (depersonalisation), hallucinations, mania (feeling highly excited, being over-active and easily irritated or distracted), euphoria (a state of optimism, cheerfulness and well-being), increased sex drive (libido)
- fainting (syncope)
- dilated pupils (mydriasis)
- hives (urticaria)
- rash
- hair loss (alopecia)
- redness or red spots on the skin (purpura)
- photosensitivity (skin rash caused by exposure to sunlight)
- problems passing urine (urinary retention)
- Heavy menstrual period (menorrhagia)
- oedema (generalised swelling)

Rare
- bleeding (e.g. vaginal, gastrointestinal, skin and soft tissue bleeding)

- a major fit ('grand mal convulsion'), involuntary movements (dyskinesia)
- taste abnormalities
- liver inflammation (hepatitis)
- fever (pyrexia)
- lower amount of blood sodium levels (hyponatraemia)

Not known
- reduced number of blood platelets (thrombocytopenia)
- abnormality of the rhythm or rate of the heart beat (arrhythmia)
- swelling (angio-oedema) of the skin or of the tissue lining internal cavities of the body (mucous membrane)
- a sudden, severe allergic reaction (anaphylactic reaction) characterized by a sharp drop in blood pressure, itchy skin rash, swelling of the lips, tongue or throat, and breathing difficulties
- allergy (hypersensitivity)
- condition known as SIADH (syndrome of inappropriate secretion of antidiuretic hormone) predominantly in the elderly
- low levels of potassium in the blood
- panic attacks, teeth grinding (bruxism), restlessness
- thoughts of suicide or suicidal behaviour
- fits (convulsions)
- serotonin syndrome (symptoms such as high fever, trembling, muscle twitches and anxiety)
- extrapyramidal disorder (e.g. involuntary movements, shaking, muscle rigidity and muscle contractions)
- feeling of restlessness and not being able to keep still (akathisia)
- movement disorder
- vision disturbance
- heart condition called QT-prolongation (irregular heartbeat recognisable on ECG)
- dizziness when standing up fast caused by low blood pressure (orthostatic hypotension)
- nosebleed
- blood in the stools (gastrointestinal or rectal haemorrhage)
- abnormal liver function test
- bruising (ecchymosis)
- abnormal milk secretion from the breasts in men (galactorrhoea)
- painful prolonged erection (priapism)
- increased blood levels of the hormone prolactin
- irregular menstrual bleeding (metrorrhagia)
- an increased risk of bone fractures has been observed in patients taking this type of medicines.
- Heavy vaginal bleeding shortly after birth (postpartum haemorrhage), see Pregnancy, breast-feeding and fertility in section 2 for more information

Cases of people developing thoughts of harming or killing themselves, or showing such behaviour have been reported during the use of citalopram or shortly after stopping treatment.

An increased risk of bone fractures has been observed in patients taking this type of medicines.

Withdrawal symptoms seen on discontinuation
See "Take special care with Citalopram Bluefish".

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

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 Citalopram Bluefish

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 blister and carton after 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 medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Citalopram Bluefish contains

- The active substance is Citalopram.
- Citalopram Bluefish 10mg, 20 mg and 40 mg film-coated tablets contain Citalopram hydrobromide equivalent to 10 mg, 20 mg and 40 mg Citalopram per tablet respectively.
- The other ingredients are

  Tablet core:
  Copovidone
  croscarmellose sodium (E468)
  glycerol (E471)
  lactose monohydrate
  magnesium stearate (E470b)
  maize starch
  microcrystalline cellulose (E460)

  Film coating:
  Hypromellose (E464)
  microcrystalline cellulose (E460)
  polyoxyethylene stearate (E431)
  titanium dioxide (E171)

What Citalopram Bluefish looks like and contents of the pack

Citalopram Bluefish 10 mg and 20 mg film-coated tablets packed in PVC/PVDC/Al blister are available in pack sizes of 14, 20, 28, 30, 50, or 100 tablets per carton.

Citalopram Bluefish 40 mg film-coated tablets packed in PVC/PVDC/Al blister are available in pack sizes of 20, 28, 30, 50, or 100 tablets per carton.

Not all pack sizes/strengths may be marketed.

Marketing Authorisation Holder

Bluefish Pharmaceuticals AB
P.O.Box 49013
10028 Stockholm
Sweden

Manufacturer
Bluefish Pharmaceuticals AB
Gävlegatan 22
113 30 Stockholm
Sweden

This medicinal product is authorized in the Member States of the EEA under the following names:

Name of the Member State	**Name of the Medicinal Product**
Ireland(IE)	Citalopram Bluefish 10 mg film-coated Tablets Citalopram Bluefish 20 mg film-coated Tablets Citalopram Bluefish 40 mg film-coated tablets
Iceland (IS)	Citalopram Bluefish 10 mg filmuhúðaðar töflur Citalopram Bluefish 20 mg filmuhúðaðar töflur Citalopram Bluefish 40 mg filmuhúðaðar töflur
France (FR)	Citalopram Bluefish 20 mg comprimé pelliculé sécable
Sweden (SE)	Citalopram Bluefish 10 mg filmdragerade tabletter Citalopram Bluefish 20 mg filmdragerade tabletter Citalopram Bluefish 40 mg filmdragerade tabletter

This leaflet was last revised in