Package leaflet: Information for the user

Mirtazapine Bluefish 15 mg orodispersible tablets
Mirtazapine Bluefish 30 mg orodispersible tablets
Mirtazapine Bluefish 45 mg orodispersible tablets
mirtazapine

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 or nurse.
- 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 or nurse.This includes any possible side effects not listed in this leaflet. See section 4

What is in this leaflet:

1. What Mirtazapine Bluefish is and what it is used for

Mirtazapine Bluefish is one of a group of medicines called antidepressants**.** Mirtazapine Bluefish is used to treat depressive illness in adults. Mirtazapine Bluefish will take 1 to 2 weeks before it starts working. After 2 to 4 weeks you may start feeling better. You must talk to your doctor if you do not feel better or if you feel worse after 2 to 4 weeks. More information is in section 3 heading "When can you expect to start feeling better".

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

Do not take Mirtazapine Bluefish
- if you are allergic to mirtazapine or any of the other ingredients of this medicine (listed in section 6).
- if you are taking or have recently taken (within the last two weeks) medicines called monoamine oxidase inhibitors (MAO-Is).

Warnings and precautions
Talk to your doctor or pharmacist or nurse before taking Mirtazapine Bluefish.

DO NOT TAKE - OR - TELL YOUR DOCTOR BEFORE TAKING Mirtazapin Bluefish:
- if you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking Mirtazapin Bluefish or other medicinal product(s).

Children and adolescents Mirtazapine Bluefish should normally not be used for children and adolescents under 18 years because efficacy was not demonstrated. 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 Mirtazapine Bluefish for patients under 18 because he/she decides that this is in their best interests. If your doctor has prescribed Mirtazapine 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 Mirtazapine Bluefish. Also, the long-term safety effects concerning growth, maturation and cognitive and behavioural development of Mirtazapine Bluefish in this age group have not yet been demonstrated. In addition, significant weight gain has been observed in this age category more often when treated with Mirtazapine Bluefish compared with adults.

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 you first start taking 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.

Also take special care with Mirtazapine Bluefish
- if you have, or have ever had one of the following conditions.
  → Tell your doctor about these conditions before taking Mirtazapine Bluefish, if not done previously.
  - **seizures** (epilepsy). If you develop seizures or your seizures become more frequent, stop taking Mirtazapine Bluefish and contact your doctor immediately;
  - **liver disease**, including jaundice. If jaundice occurs, stop taking Mirtazapine Bluefish and contact your doctor immediately;
  - **kidney disease**;
  - **heart disease**, or **low blood pressure**;
  - **schizophrenia**. If psychotic symptoms, such as paranoid thoughts become more frequent or severe, contact your doctor straight away;
  - **manic depression** (alternating periods of feeling elated/overactivity and depressed mood). If you start feeling elated or over-excited, stop taking Mirtazapine Bluefish and contact your doctor immediately;
  - **diabetes** (you may need to adjust your dose of insulin or other antidiabetic medicines);
  - **eye disease**, such as increased pressure in the eye (glaucoma);
  - **difficulty in passing water** (urinating), which might be caused by an enlarged prostate.
- if you develop signs of infection such as inexplicable high fever, sore throat and mouth ulcers.
  →Stop taking Mirtazapine Bluefish and consult your doctor immediately for a blood test.
  In rare cases these symptoms can be signs of disturbances in blood cell production in the bone marrow. While rare, these symptoms most commonly appear after 4-6 weeks of treatment.
- Serious skin reactions including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN) and drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported with the use of mirtazapin. Stop using and seek medical attention immediately if you notice any of the symptoms described in section 4 in relation to these serious skin reactions.
  If you have ever developed any severe skin reactions, treatment with Mirtazapin Bluefish should not be restarted.

- if you are an elderly person. You could be more sensitive to the side-effects of antidepressants.

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

Do not take Mirtazapine Bluefish in combination with:

- **monoamine oxidase inhibitors** (MAO inhibitors). Also, do not take Mirtazapine Bluefish during the two weeks after you have stopped taking MAO inhibitors. If you stop taking Mirtazapine Bluefish, do not take MAO inhibitors during the next two weeks either.
  Examples of MAO inhibitors are moclobemide, tranylcypromine (both are antidepressants) and selegiline (used for Parkinson's disease).

Take care when taking Mirtazapine Bluefish in combination with:

- **antidepressants such as SSRIs, venlafaxine and L-tryptophan, or triptans** (used to treat migraine)**, tramadol** (a pain-killer), **linezolid** (an antibiotic), **lithium** (used to treat some psychiatric conditions) methylene blue (used to treat high levels of methemoglobin in the blood) **and St. John's Wort – Hypericum perforatum preparations** (a herbal remedy for depression). In very rare cases Mirtazapine Bluefish alone or the combination of Mirtazapine Bluefish with these medicines, can lead to a so-called serotonin syndrome. Some of the symptoms of this syndrome are: inexplicable fever, sweating, increased heart rate, diarrhoea, (uncontrollable) muscle contractions, shivering, overactive reflexes, restlessness, mood changes, and unconsciousness. If you get a combination of these symptoms, talk to your doctor immediately.
- **the antidepressant nefazodone**. It can increase the amount of Mirtazapine Bluefish in your blood. Inform your doctor if you are using this medicine. It might be needed to lower the dose of Mirtazapine Bluefish, or when use of nefazodone is stopped, to increase the dose of Mirtazapine Bluefish again.
- **medicines for anxiety or insomnia** such as benzodiazepines;
  medicines for schizophrenia such as olanzapine;
  medicines for allergies such as cetirizine;
  medicines for severe pain such as morphine.
  In combination with these medicines Mirtazapine Bluefish can increase the drowsiness caused by these medicines.
- **medicines for infections;** medicines for bacterial infections (such as erythromycin); medicines for fungal infections (such as ketoconazole) and medicines for HIV/AIDS (such as HIVprotease inhibitors) and **drugs for stomach ulcers** (such as cimetidine).
  In combination with Mirtazapine Bluefish these medicines can increase the amount of Mirtazapine Bluefish in your blood. Inform your doctor if you are using these medicines. It might be needed to lower the dose of Mirtazapine Bluefish, or when these medicines are stopped, to increase the dose of Mirtazapine Bluefish again.
- **medicines for epilepsy** such as carbamazepine and phenytoin;
  medicines for tuberculosis such as rifampicin.
  In combination with Mirtazapine Bluefish these medicines can reduce the amount of Mirtazapine Bluefish in your blood. Inform your doctor if you are using these medicines. It might be needed to increase the dose of Mirtazapine Bluefish, or when these medicines are stopped to lower the dose of Mirtazapine Bluefish again.
- **medicines to prevent blood clotting** such as warfarin.
  Mirtazapine Bluefish can increase the effects of warfarin on the blood. Inform your doctor if you are using this medicine. In case of combination it is advised that a doctor monitors your blood carefully.

Mirtazapine Bluefish with food, drink and alcohol
You may get drowsy if you drink alcohol while you are taking Mirtazapine Bluefish.
You are advised not to drink any alcohol.
You can take Mirtazapine Bluefish 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.
Limited experience with Mirtazapine Bluefish administration to pregnant women does not indicate an increased risk. However, caution should be exercised when used during pregnancy.
Make sure your midwife and/or doctor knows you are on Mirtazapine Bluefish. When taken during pregnancy, similar drugs (SSRIs) 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 Mirtazapine Bluefish and you become pregnant or you plan to get pregnant, ask your doctor whether you may continue taking Mirtazapine Bluefish. If you use Mirtazapine Bluefish until, or shortly before birth, your baby should be supervised for possible adverse effects.
Ask your doctor whether you can breast-feed, while taking Mirtazapine Bluefish.

Driving and using machines
Mirtazapine Bluefish can affect your concentration or alertness. Make sure your abilities are not affected before driving or operating machinery. If your doctor has prescribed Mirtazapine Bluefish for a patient under 18 years make sure the concentration and alertness is not affected before participation in traffic (e.g. on bicycle).

Mirtazapin Bluefish contains aspartame (E951)
This medicine contains 3 mg, 6 mg, and 9 mg aspartame in each 15 mg, 30 mg, 45 mg orodispersible tablet.

Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

3. How to take Mirtazapine Bluefish

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

How much to take
The recommended starting dose is 15 or 30 mg every day. Your doctor may advise you to increase your dose after a few days to the amount that is best for you (between 15 and 45 mg per day). The dose is usually the same for all ages. However, if you are an elderly person or if you have renal or liver disease, your doctor may adapt the dose.

When to take Mirtazapine Bluefish
→ Take Mirtazapine Bluefish at the same time each day**.**
It is best to take Mirtazapine Bluefish as a single dose before you go to bed. However your doctor may suggest to split your dose of Mirtazapine Bluefish– once in the morning and once at night-time before you go to bed. The higher dose should be taken before you go to bed.

Take the orodispersible tablet as follows
Take your tablets orally.

1. Do not crush the orodispersible tablet
In order to prevent crushing the orodispersible tablet, do not push against the tablet pocket (Figure A).

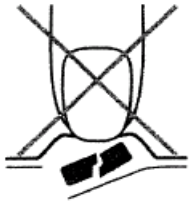

Fig. A.

2. Tear off one tablet pocket
Each blister contains six tablet pockets, which are separated by perforations. Tear off one tablet pocket along the dotted lines (Figure 1).

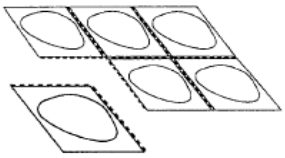

Fig. 1.

3. Peel off the lid
Carefully peel off the lidding foil, starting in the corner indicated by the arrow (Figures 2 and 3).

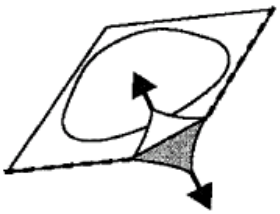

Fig. 2.

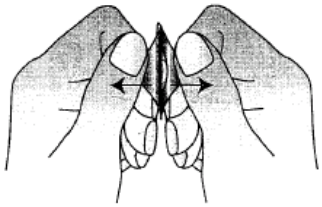

Fig. 3.

4. Take out the orodispersible tablet
Take out the orodispersible tablet with dry hands and place it on the tongue.
(Figure 4).

Fig. 4.
It will rapidly disintegrate and can be swallowed without water.

When can you expect to start feeling better
Usually Mirtazapine Bluefish will start working after 1 to 2 weeks and after 2 to 4 weeks you may start to feel better.

It is important that, during the first few weeks of the treatment, you talk with your doctor about the effects of Mirtazapine Bluefish:
→2 to 4 weeks after you have started taking Mirtazapine Bluefish, talk to your doctor about how this medicine has affected you.
If you still don't feel better, your doctor may prescribe a higher dose. In that case, talk to your doctor again after another 2 to 4 weeks. Usually you will need to take Mirtazapine Bluefish until your symptoms of depression have disappeared for 4 to 6 months.

If you take more Mirtazapine Bluefish than you should
→If you or someone else have taken too much Mirtazapine Bluefish, call a doctor straight away**.**
The most likely signs of an overdose of Mirtazapine Bluefish (without other medicines or alcohol) are **drowsiness**, **disorientation and increased heart rate**.

If you forget to take Mirtazapine Bluefish
If you are supposed to take your dose **once a day**
- Do not take a double dose to make up for a forgotten dose. Take your next dose at the normal time.

If you are supposed to take your dose **twice a day**
- if you have forgotten to take your morning dose, simply take it together with your evening dose.
- if you have forgotten to take your evening dose, do not take it with the next morning dose; just skip it and continue with your normal morning and evening doses.
- if you have forgotten to take both doses, do not attempt to make up for the missed doses. Skip both doses and continue the next day with your normal morning and evening doses.

If you stop taking Mirtazapine Bluefish
→ Only stop taking Mirtazapine Bluefish in consultation with your doctor.
If you stop too early, your depression might come back. Once you are feeling better, talk to your doctor. Your doctor will decide when treatment can be stopped.
Do not suddenly stop taking Mirtazapine Bluefish, even when your depression has lifted. If you suddenly stop taking Mirtazapine Bluefish you may feel sick, dizzy, agitated or anxious, and have headaches. These symptoms can be avoided by stopping gradually. Your doctor will tell you how to decrease the dose gradually.

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

4. Possible side effects

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

If you experience any of the following serious side effects, stop taking mirtazapine and tell your doctor immediately.

Uncommon: may affect up to 1 in 100 people
- feeling elated or emotionally 'high' (mania)

Rare: may affect up to 1 in 1,000 people
- yellow colouring of eyes or skin; this may suggest disturbance in liver function (jaundice)

Not known: frequency cannot be estimated from the available data
- signs of infection such as sudden unexplainable high fever, sore throat and mouth ulcers (agranulocytosis). In rare cases Mirtazapin Bluefish can cause disturbances in the production of blood cells (bone marrow depression). Some people become less resistant to infection because Mirtazapin Bluefish can cause a temporary shortage of white blood cells (granulocytopenia). In rare cases Mirtazapin Bluefish can also cause a shortage of red and white blood cells, as well as blood platelets (aplastic anemia), a shortage of blood platelets (thrombocytopenia) or an increase in the number of white blood cells (eosinophilia)

- epileptic attack (convulsions)
- a combination of symptoms such as inexplicable fever, sweating, increased heart rate, diarrhoea, (uncontrollable) muscle contractions, shivering, overactive reflexes, restlessness, mood changes, unconsciousness and increased salivation. In very rare cases these can be signs of serotonin syndrome
- thoughts of harming or killing yourself
- Severe skin reactions:
    - Reddish patches on the trunk which are target-like macules or circular, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms (Stevens-Johnson syndrome, toxic epidermal necrolysis).
    - Widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome).

Other possible side effects with Mirtazapine Bluefish are:

Very common: may affect more than 1 in 10 people
- increase in appetite and weight gain
- drowsiness or sleepiness
- headache
- dry mouth

Common: may affect up to 1 in 10 people
- lethargy
- dizziness
- shakiness or tremor
- nausea
- diarrhea
- constipation
- vomiting
- rash or skin eruptions (exanthema)
- pain in your joints (arthralgia) or muscles (myalgia)
- back pain
- feeling dizzy or faint when you stand up suddenly (orthostatic hypotension)
- swelling (typically in ankles or feet) caused by fluid retention (oedema)
- tiredness
- vivid dreams
- confusion
- feeling anxious
- sleeping problems
- Memory problems, which in most cases resolved when treatment was stopped.

Uncommon: may affect up to 1 in 100 people
- abnormal sensation in the skin e.g. burning, stinging, tickling or tingling (paraesthesia)
- restless legs
- fainting (syncope)
- sensations of numbness in the mouth (oral hypoaesthesia)
- low blood pressure
- nightmares
- feeling agitated
- hallucinations
- urge to move

Rare: may affect up to 1 in 1,000 people
- muscle twitching or contractions (myoclonus)
- aggression
- abdominal pain and nausea; this may suggest inflammation of the pancreas (pancreatitis)

Not known: frequency cannot be estimated from the available data
- sleep walking (Somnambulism)
- abnormal sensations in the mouth (oral paraesthesia)
- swelling in the mouth (mouth oedema)
- swelling throughout the body (generalized oedema)
- localized swelling
- severe skin reactions (dermatitis bullous, erythema multiforme)
- speech disorder
- hyponatraemia
- inappropriate anti-diuretic hormone secretion
- increased creatine kinase blood levels
- difficulty in passing urine (urinary retention)
- muscle pain, stiffness and/or weakness, darkening or discoloration of the urine (rhabdomyolysis).
- increased prolactin hormone levels in blood (hyperprolactinemia, including symptoms of enlarged breasts and/or milky nipple discharge)
- prolonged painful erection of the penis

Additional side effects in children and adolescents
In children under 18 years the following adverse events were observed commonly in clinical trials: significant weight gain, hives and increased blood triglycerides.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist immediately.

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.
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 Mirtazapine 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 carton and blister 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 yor pharmacists how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Mirtazapine Bluefish contains

- The active substance is mirtazapine. Each orodispersible tablet contains 15 mg, 30 mg or 45 mg mirtazapine.

- The other ingredients are crospovidone (type B), mannitol (E421), Cellulose, microcrystalline, aspartame (E951), silica colloidal anhydrous, magnesium stearate, strawberry guarana flavor [maltodextrin, propylene glycol, artificial flavours, acetic acid] and peppermint flavor [artificial flavours, corn starch].

What Mirtazapine Bluefish looks like and contents of the pack

Orodispersible tablet.

Mirtazapine Bluefish 15 mg orodispersible tablets:
White, round orodispersible tablets debossed with "36"on one side and 'A' on the other side with an embossed circular edge.

Mirtazapine Bluefish 30 mg orodispersible tablets:
White, round orodispersible tablets debossed with "37" on one side and 'A' on the other side with an embossed circular edge.

Mirtazapine Bluefish 45 mg orodispersible tablets:
White, round orodispersible tablets debossed with "38" on one side and 'A' on the other side with an embossed circular edge.

15 mg & 30 mg:
Mirtazapine Bluefish orodispersible tablets are available in Polyamide/ Aluminium/ PVC/ Paper/ Polyster/ Aluminium perforated unit dose blister packs of 6, 18, 30, 48, 60, 90 and 96 tablets.

45 mg:
Mirtazapine Bluefish orodispersible tablets are available in Polyamide/ Aluminium/ PVC/ Paper/ Polyster/ Aluminium perforated unit dose blister packs of 6, 18, 30, 48, 90 and 96 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Bluefish Pharmaceuticals AB
P.O. Box 49013
100 28 Stockholm
Sweden

Manufacturer
Bluefish Pharmaceticals 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*
Austria	Mirtazapin Bluefish 15 mg/ 30 mg/ 45 mg Schmelztabletten
Denmark	Mirtazapin Bluefish 15 mg smeltetabletter
France	MIRTAZAPINE BLUEFISH 15 mg comprimés orodispersibles
Ireland	Mirtazapine Bluefish 15 mg/ 30 mg/ 45 mg orodispersible tablets
Island	Mirtazapin Bluefish 15 mg / 30 mg / 45 mg munndreifitöflur tablets
Norway	Mirtazapin Bluefish 15 mg/ 30 mg/ 45 mg smeltetabletter
Portugal	Mirtazapina Bluefish
Spain	Mirtazapina Bluefish 15 mg/ 30 mg/ 45 mg comprimidos bucodispersables
Sweden	Mirtazapin Bluefish 15 mg/ 30 mg/ 45 mg munsönderfallande tabletter
United Kingdom (Northern Ireland)	Mirtazapine 15 mg/ 30 mg/ 45 mg orodispersible tablets

This leaflet was last revised in