Package leaflet: Information for the user

Pramipexole Bluefish 0.18 mg tablets
pramipexole

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 Pramipexole Bluefish is and what it is used for

Pramipexole Bluefish contains the active substance pramipexole and belongs to a group of medicines known as dopamine agonists, which stimulate dopamine receptors in the brain. Stimulation of the dopamine receptors triggers nerve impulses in the brain that help to control body movements.

Pramipexole Bluefish is used to:
- treat the symptoms of primary Parkinson's disease in adults. It can be used alone or in combination with levodopa (another medicine for Parkinson's disease).

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

Do not take Pramipexole Bluefish:
- if you are allergic (hypersensitive) to pramipexole or to any of the other ingredients of this medicine (see listed in Section 6).

Warnings and precautions:
Talk to your doctor before taking Pramipexole Bluefish. Tell your doctor if you have (had) or develop any medical conditions or symptoms, especially any of the following:
- Kidney disease.
- Hallucinations (seeing, hearing or feeling things that are not there). Most hallucinations are visual.
- Dyskinesia (e.g. abnormal, uncontrolled movements of the limbs). If you have advanced Parkinson's disease and are also taking levodopa, you might develop dyskinesia during the uptitration of Pramipexole Bluefish.
- Dystonia (inability of keeping your body and neck straight and upright (axial dystonia)). In particular, you may experience forward flexion of the head and neck (also called antecollis), forward bending of the lower back (also called camptocormia) or sidewards bending of the back (also called pleurothotonus or Pisa Syndrome). If this happens, your doctor may want to change your medication.

- Sleepiness and episodes of suddenly falling asleep.
- Psychosis, (e.g. comparable with symptoms of schizophrenia).
- Vision impairment. You should have regular eye examinations during treatment with Pramipexole Bluefish.
- Severe heart or blood vessels disease. You will need to have your blood pressure checked regularly, especially at the beginning of treatment. This is to avoid postural hypotension (a fall in blood pressure on standing up).
- Augmentation. You may experience that symptoms start earlier than usual, be more intense and involve other limbs.
- Excessive use and craving for the product.

Tell your doctor if you or your family/carer notices that you are developing urges or cravings to behave in ways that are unusual for you and you cannot resist the impulse, drive or temptation to carry out certain activities that could harm yourself or others. These are called impulse control disorders and can include behaviours such as addictive gambling, excessive eating or spending, an abnormally high sex drive or preoccupation with an increase in sexual thoughts or feelings. Your doctor may need to adjust or stop your dose.

Tell your doctor if you or your family/carer notices that you are developing mania (agitation, feeling elated or over-excited) or delirium (decreased awareness, confusion, loss of reality). Your doctor may need to adjust or stop your dose.

Tell your doctor if you experience symptoms such as depression, apathy, anxiety, fatigue, sweating or pain after stopping or reducing your Pramipexole Bluefish treatment. If the problems persist more than a few weeks, your doctor may need to adjust your treatment.

Children and adolescents
Pramipexole Bluefish is not recommended for use in children or adolescents under 18 years.

Other medicines and Pramipexole Bluefish
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines, herbal remedies, health foods or supplements that you have obtained without a prescription.

You should avoid taking Pramipexole Bluefish together with antipsychotic medicines.

Take care if you are taking the following medicines:
- cimetidine (to treat excess stomach acid and stomach ulcers);
- amantadine (which can be used to treat Parkinson's disease);
- mexiletine (to treat irregular heartbeats, a condition known as ventricular arrhythmia);
- zidovudine (which can be used to treat the acquired immune deficiency syndrome (AIDS), a disease of the human immune system);
- cisplatin (to treat various types of cancers);
- quinine (which can be used for the prevention of painful night-time leg cramps and for the treatment of a type of malaria known as falciparum malaria (malignant malaria));
- procainamide (to treat irregular heart beat).

If you are taking levodopa, the dose of levodopa is recommended to be reduced when you start treatment with Pramipexole Bluefish.

Take care if you are using any medicines that calm you down (have a sedative effect) or if you are drinking alcohol. In these cases Pramipexole Bluefish may affect your ability to drive and operate machinery.

Pramipexole Bluefish with food, drink and alcohol

- You should be cautious while drinking alcohol during treatment with Pramipexole Bluefish.
- Pramipexole Bluefish can be taken with or without food.

Pregnancy and breast-feeding

Pregnancy

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. Tell your doctor if you are pregnant, think you might be pregnant or if you intend to become pregnant. Your doctor will then discuss with you if you should continue to take Pramipexole Bluefish.

The effect of Pramipexole Bluefish on the unborn child is not known. Therefore, do not take Pramipexole Bluefish if you are pregnant unless your doctor tells you to do so.

Breast-feeding

Pramipexole Bluefish should not be used during breast-feeding. Pramipexole Bluefish can:

- reduce the production of breast milk.
- It can pass into the breast milk and can reach your baby. If use of Pramipexole Bluefish is unavoidable, breast-feeding should be stopped.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

- Pramipexole Bluefish can cause hallucinations (seeing, hearing or feeling things that are not there). If affected, do not drive or use machines.

- Pramipexole Bluefish has been associated with sleepiness and episodes of suddenly falling asleep, particularly in patients with Parkinson's disease. If you experience these side effects, you must not drive or operate machinery. You should tell your doctor if this occurs.

3. How to take Pramipexole Bluefish

Always take Pramipexole Bluefish exactly as your doctor has told you. Check with your doctor if you are not sure. The doctor will advise you on the right dosing.

You can take Pramipexole Bluefish with or without food. Swallow the tablets with water.

Parkinson's disease
The daily dose is to be taken divided into 3 equal doses.

During the first week, the usual dose is 1 tablet Pramipexole Bluefish 0.088 mg three times a day (equivalent to 0.264 mg daily):

	1st week
Number of tablets	1 tablet Pramipexole Bluefish 0.088 mg three times a day
Total daily dose (mg)	0.264

This will be increased every 5 - 7 days as directed by your doctor until your symptoms are controlled. (maintenance dose).

	2nd week	3rd week
Number of tablets	1 tablet Pramipexole Bluefish 0.18 mg three times a day OR 2 tablets Pramipexole Bluefish 0.088 mg three times a day	1 tablet Pramipexole Bluefish 0.35 mg three times a day **OR** 2 tablets Pramipexole Bluefish 0.18 mg three times a day
Total daily dose (mg)	0.54	1.1

The usual maintenance dose is 1.1 mg per day. However, your dose may have to be increased even further. If necessary, your doctor may increase your tablet dose up to a maximum of 3.3 mg of pramipexole a day. A lower maintenance dose of three Pramipexole Bluefish 0.088 mg tablets a day is also possible.

	Lowest maintenance dose	Highest maintenance dose
Number of tablets	1 tablet Pramipexole Bluefish 0.088 mg three times a day	1 tablet Pramipexole Bluefish 1.1 mg three times a day
Total daily dose (mg)	0.264	3.3

Patients with kidney disease
If you have moderate or severe kidney disease, your doctor will prescribe a lower dose. In this case, you will have to take the tablets only once or twice a day. If you have moderate kidney disease, the usual starting dose is 1 tablet Pramipexole Bluefish 0.088 mg twice a day. In severe kidney disease, the usual starting dose is just 1 tablet Pramipexole Bluefish0.088 mg a day.

If you take more Pramipexole Bluefish than you should
If you accidentally take too many tablets,

- Contact your doctor or nearest hospital casualty department immediately for advice.
- You may experience vomiting, restlessness, or any of the side effects as described in chapter 4 "Possible side effects".

If you forget to take Pramipexole Bluefish
Do not worry. Simply leave out that dose completely and then take your next dose at the right time. Do not try to make up for the missed dose.

If you stop taking Pramipexole Bluefish
Do not stop taking Pramipexole Bluefish without first talking to your doctor. If you have to stop taking this medicine, your doctor will reduce the dose gradually. This reduces the risk of worsening symptoms.

If you suffer from Parkinson's disease you should not stop treatment with Pramipexole Bluefish abruptly. A sudden stop could cause you to develop a medical condition called neuroleptic malignant syndrome which may represent a major health risk. These symptoms include:

- akinesia (loss of muscle movement),
- rigid muscles,
- fever,
- unstable blood pressure,
- tachycardia (increased heart rate),
- confusion,
- depressed level of consciousness (e.g. coma).

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

4. Possible side effects

Like all medicines, Pramipexole Bluefish can cause side effects, although not everybody gets them. Evaluation of these side effects is based on the following frequencies:

Very common	may affect more than 1 in 10 people
Common	may affect up to 1 in10 people
Uncommon	may affect up to 1 in 100 people
Rare	may affect up to 1 in 1000 people
Very rare	may affect up to 1 in 10,000 people
Not known	Frequency cannot be estimated from the available data.

If you suffer from Parkinson's disease, you may experience the following side effects:

Very common:
- Dyskinesia (e.g. abnormal, uncontrolled movements of the limbs)
- Sleepiness
- Dizziness
- Nausea (sickness)

Common:
- Urge to behave in an unusual way
- Hallucinations (seeing, hearing or feeling things that are not there)
- Confusion
- Tiredness (fatigue)
- Sleeplessness (insomnia)
- Excess of fluid, usually in the legs (peripheral oedema)
- Headache
- Hypotension (low blood pressure)
- Abnormal dreams
- Constipation
- Visual impairment
- Vomiting (being sick)
- Weight loss including decreased appetite

Uncommon:
- Paranoia (e.g. excessive fear for one's own well-being)
- Delusion
- Excessive daytime sleepiness and suddenly falling asleep
- Amnesia (memory disturbance)
- Hyperkinesia (increased movements and inability to keep still)
- Weight increase
- Allergic reactions (e.g. rash, itching, hypersensitivity)
- Fainting
- Cardiac failure (heart problems which can cause shortness of breath or ankle swelling)*
- Inappropriate antidiuretic hormone secretion*
- Restlessness
- Dyspnoea (difficulties to breathe)
- Hiccups

- Pneumonia (infection of the lungs)
- Inability to resist the impulse, drive or temptation to perform an action that could be harmful to you or others, which may include:
  - Strong impulse to gamble excessively despite serious personal or family consequences.
  - Altered or increased sexual interest and behaviour of significant concern to you or to others, for example, an increased sexual drive.
  - Uncontrollable excessive shopping or spending
  - Binge eating (eating large amounts of food in a short time period) or compulsive eating (eating more food than normal and more than is needed to satisfy your hunger) *
  - Delirium-(decreased awareness, confusion, loss of reality)

Rare:
- Mania (agitation, feeling elated or over-excited)

Not known
After stopping or reducing your Pramipexole Bluefish treament: Depression, apathy, anxiety, fatigue, sweating or pain may occur (called dopamine agonist withdrawal syndrome or DAWS).

Tell your doctor if you experience any of these behaviours; he will discuss ways of managing or reducing the symptoms.

For the side effects marked with * a precise frequency estimation is not possible, since these side effects were not observed in clinical studies among 2,762 patients treated with pramipexole. The frequency category is probably not greater than "uncommon".

If you suffer from other indications, you may experience the following side effects:

Very common:
- Nausea (sickness)

Common:
- Changes in sleep pattern, such as sleeplessness (insomnia) and sleepiness
- Tiredness (fatigue)
- Headache
- Abnormal dreams
- Constipation
- Dizziness
- Vomiting (being sick)

Uncommon:
- Urge to behave in an unusual way*
- Cardiac failure (heart problems which can cause shortness of breath or ankle swelling)*
- Inappropriate antidiuretic hormone secretion*
- Dyskinesia (e.g. abnormal, uncontrolled movements of the limbs)
- Hyperkinesia (increased movements and inability to keep still)*
- Paranoia (e.g. excessive fear for one's own well-being)*
- Delusion*
- Amnesia (memory disturbance)*
- Hallucinations (seeing, hearing or feeling things that are not there)
- Confusion
- Excessive daytime sleepiness and suddenly falling asleep
- Weight increase
- Hypotension (low blood pressure)
- Excess of fluid, usually in the legs (peripheral oedema)
- Allergic reactions (e.g. rash, itching, hypersensitivity)

- Fainting
- Restlessness
- Visual impairment
- Weight loss including decreased appetite
- Dyspnoea (difficulties to breathe)
- Hiccups
- Pneumonia (infection of the lungs)*
- Inability to resist the impulse, drive or temptation to perform an action that could be harmful to you or others, which may include:
  - Strong impulse to gamble excessively despite serious personal or family consequences.*
  - Altered or increased sexual interest and behaviour of significant concern to you or to others, for example, an increased sexual drive.*
  - Uncontrollable excessive shopping or spending*
  - Binge eating (eating large amounts of food in a short time period) or compulsive eating (eating more food than normal and more than is needed to satisfy your hunger)*
- Mania (agitation, feeling elated or over-excited)*
- Delirium (decreased awareness, confusion, loss of reality)*

Not known
After stopping or reducing your Pramipexole Bluefish treatment: Depression, apathy, anxiety, fatigue, sweating or pain may occur (called dopamine agonist withdrawal syndrome or DAWS).

Tell your doctor if you experience any of these behaviours; he will discuss ways of managing or reducing the symptoms.

For the side effects marked with * a precise frequency estimation is not possible, since these side effects were not observed in clinical studies among 1,395 patients treated with pramipexole. The frequency category is probably not greater than "uncommon".

Reporting 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, Earlsfort Terrace, IRL-Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine

5. How to store Pramipexole 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 after EXP. The expiry date refers to the last day of that month.

Store in the original package to protect the tablets from light.

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 Pramipexole Bluefish contains
The active substance is pramipexole.

Each Pramipexole Bluefish 0.18 mg tablet contains 0.18 mg of pramipexole base (as 0.25 mg of pramipexole dihydrochloride monohydrate).

The other ingredients are: mannitol, maize starch, silica, colloidal anhydrous, povidone(K-29/32) and magnesium stearate.

What Pramipexole Bluefish looks like and contents of the pack
Pramipexole Bluefish 0.18 mg tablets are white, oblong, 9 mm x 4.5 mm, uncoated tablets with score line and tablets can be divided into equal halves.

Pramipexole Bluefish is available in aluminium blister, 30 or 100 tablets.

Marketing Authorisation Holder and Manufacturer:

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

Manufacturer
Bluefish Pharmaceuticals AB
Gävlegatan 22
113 30 Stockholm
Sweden

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

Austria	Pramipexol Bluefish 0,18 mg Tabletten
Denmark	Pramipexol Bluefish
Ireland	Pramipexole Bluefish 0.18 mg tablets
Spain	Pramipexole Bluefish 0,18 mg comprimidos

This leaflet was last revised in