

Bluefish Pharmaceuticals						Date: 22.02.2022	
Reason of change	Comments received from RA on 22.02.2022					Revision No.	02
Product name	Ondansetron Orodispersible Tablets			Artwork code	BF035ONDXXUK_PIXX_BL_SOF_SOF05_02		
Strength	4 mg/8 mg	Packs	NA	Blister Layout No. : NA		Pantone Shades	
Country	United Kingdom	Manufacturer	SOFARIMEX BR - SOFARIMEX	No. of Colors: 01		P. Black C	
Dimension	150 x 420 mm			Remarks			
Component	Package Leaflet	Artwork made to	100%	Font size - Heading 15, 12.5 pts., Rest all 8.5 pts			
Braille	NA						
Reviewed & Approved by: RA		eLabel errand No.		CC No.			
		2022-23\1-1					
Revision History	R1 - Revised text received from RA on 16.02.2022 (for Keyline Check). - 18.02.2022						

150 mm

United Kingdom

Package leaflet: Information for the user

Ondansetron 4 mg orodispersible tablets Ondansetron 8 mg orodispersible tablets ondansetron



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.

1. What is in this leaflet:
2. What **Ondansetron orodispersible tablets** is and what it is used for
3. What you need to know before you take **Ondansetron orodispersible tablets**
4. How to take **Ondansetron orodispersible tablets**
5. Possible side effects
6. How to store **Ondansetron orodispersible tablets**
7. Contents of the pack and other information

1. What Ondansetron orodispersible tablets are and what it is used for

Ondansetron orodispersible tablet is a fast dissolving tablet when placed on top of the tongue. Ondansetron orodispersible tablets contains ondansetron which belongs to a group of medicines that stop you feeling sick or being sick, so called anti-emetics.

Ondansetron orodispersible tablets may:

- stop the effects of nausea and vomiting caused by cytotoxic chemotherapy in children and adults
- prevent post-operative nausea and vomiting in children and adults
- stop the effects of nausea and vomiting caused by radiotherapy in adults

If you are not sure why they have been prescribed for you, ask your doctor.

2. What you need to know before you take before you take Ondansetron orodispersible tablets

Do not take Ondansetron orodispersible tablets

- if you are allergic to ondansetron, or any of the other ingredients of this medicine (listed in section 6).
- if you are taking apomorphine (used to treat Parkinson's disease).

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Ondansetron orodispersible tablets

- if you are pregnant or likely to become pregnant soon.
- if you are breast-feeding.
- if you have liver disease.
- if you have a blockage in your gut or if you suffer from severe constipation
- if it is children below the age of 2 years or with a body surface of less than 0.6 m².

Other medicines and Ondansetron orodispersible tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines like phenytoin, carbamazepine, rifampicin, tramadol.

Pregnancy and breast-feeding

Only use Ondansetron orodispersible tablets during the first trimester of pregnancy after discussion with your doctor of the potential benefits and risks to you and your unborn baby of the different treatment options. This is because Ondansetron orodispersible tablets can slightly increase the risk of a baby being born with cleft lip and/or cleft palate (openings or splits in the upper lip and/or the roof of the mouth). If you are already pregnant, think you might be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking Ondansetron orodispersible tablet. If you are a woman of childbearing potential you may be advised to use effective contraception.

Ondansetron probably passes into the mother's milk. Therefore it is recommended that mothers taking Ondansetron orodispersible tablets do not breast-feed.

Driving and using machines

Ondansetron orodispersible tablets has no influence on the ability to drive and use machines.

Ondansetron Bluefish orodispersible tablets contain aspartame, glucose, maltodextrin, sorbitol, sulphur dioxide and sodium

Ondansetron Bluefish orodispersible tablets contain aspartame (E 951). This medicine contains 0.88 mg aspartame in each 4 mg orodispersible tablet and 1.76 mg aspartame in each 8 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.

Ondansetron orodispersible tablets contain glucose and maltodextrin. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. May be harmful to the teeth.

Ondansetron Bluefish orodispersible tablets contain sorbitol (E 420). This medicine contains 8.4 mg sorbitol in each 4 mg orodispersible tablet and 16.98 mg sorbitol in each 8 mg orodispersible tablet.

Ondansetron orodispersible tablets contain sulphur dioxide (E 220). May rarely cause severe hypersensitivity reactions and bronchospasm.

Ondansetron Bluefish orodispersible tablets contain sodium. This medicine contains less than 1 mmol sodium (23 mg) per orodispersible tablet, that is to say essentially 'sodium-free'.

3. How to take Ondansetron orodispersible tablets

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

After starting to take your medicine

Ondansetron orodispersible tablets should start to work within one or two hours of taking a dose. If you are sick within one hour of taking a dose, then take the same dose again – otherwise do not take more Ondansetron orodispersible tablets than the label says. If you continue to feel sick then tell your doctor.

Treatment and prevention of nausea and vomiting in connection with chemotherapy or radiotherapy

Adults:

8 mg 1 to 2 hours before chemotherapy or radiotherapy followed by 8 mg 12 hours for up to 5 days. Your doctor may decide to give the first dose as an injection.

Elderly:

The same dose as for adults.

Use in Children (age 2 years and up) and adolescents under the age of 18 years:

The dose is individual and depends on the size/surface of the child. Ondansetron Bluefish should not be used for children with a total body surface of less than 0.6 m².

Children aged over 6 months and adolescents

- The usual dose for a child is up to 4 mg twice a day
- This can be given up to 5 days

Treatment and prevention of post-operative nausea and vomiting

Adults, prevention and treatment:

16 mg one hour prior to anaesthesia or alternatively, 8 mg administered one hour prior to anaesthesia followed by an additional 8 mg after 8 and 16 hours. Your doctor may choose to give you the medicine as injections.

Elderly, prevention and treatment:

There is limited experience with the use of ondansetron to elderly patients. Ondansetron is however tolerated well by patients above 65 years in chemotherapy (please refer to section above).

Patients with moderate or severe liver disease: the total daily dose should not be more than 8 mg.

Patients with poor sparteine/debrisoquine metabolism: No alteration of daily dosage or frequency of dosing is required.

The tablets must be taken as follows:

Do not remove Ondansetron Bluefish orodispersible tablets from its blister or pierce the foil until you are ready to take it.



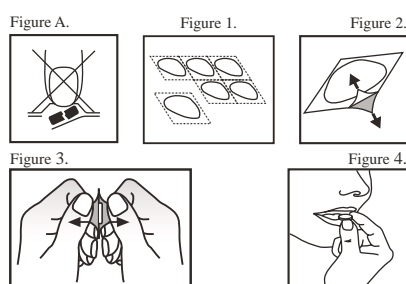
Insert Laetus Code

Laetus reading direction

In order to prevent the breakage of tablets, it is important not to push the tablet out of its recess (Figure A).

The tablets in each strip are separated from each other by perforations. Detach one tablet recess along the perforation (Figure 1). The covering foil should be removed carefully. Start with the corner that is marked with an arrow (Figures 2 and 3).

The tablet must be taken from the container with dry hands and placed on the tongue (Figure 4). The tablet will disintegrate, after which it can be swallowed with water.



If you take more Ondansetron orodispersible tablets than you should

If you or your child take more Ondansetron orodispersible tablets than you should, talk to a doctor or go to a hospital straight away. Take the medicine pack with you.

If you forget to take Ondansetron orodispersible tablets

Do not take a double dose to make up for a forgotten dose.

If you miss a dose and feel sick or vomit, take an Ondansetron orodispersible tablet as soon as possible and then carry on as before. If you miss a dose but do not feel sick take the next dose as on the label.

4. Possible side effects

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

A few people can be allergic to some medicines; if any of the following side effects come on soon after taking Ondansetron orodispersible tablets, stop taking them and tell your doctor immediately:

- **Sudden wheeziness and chest pain or chest tightness**
- **Swelling of eyelids, face, lips, mouth or tongue**
- **Skin rash - red spots or hives (skin lumps) anywhere on the body**
- **Collapse**

Other possible side effects:

Very common (may affect more than 1 in 10 people)

- Headache.

Common (may affect up to 1 in 10 people)

- Constipation.
- Sensation of warmth or flushing.

Uncommon (may affect up to 1 in 100 people)

- Arrhythmias, chest pain with or without ST segment depression, bradycardia.
- Asymptomatic increases in liver function tests.
- Seizures, movement disorders including extrapyramidal reactions such as dystonic reactions, oculogyric crisis and dyskinesia have been observed without definitive evidence of persistent clinical sequelae.
- Hiccups.
- Hypotension.

Rare (may affect up to 1 in 1,000 people)

- Immediate hypersensitivity reactions sometimes severe, including anaphylaxis.
- Dizziness during i.v. administration, which in most cases is prevented or resolved by lengthening the infusion period.
- Transient visual disturbances (eg. blurred vision) during i.v. administration.

Very rare (may affect up to 1 in 10,000 people)

Transient blindness predominantly during intravenous administration

The majority of the blindness cases reported resolved within 20 minutes. Most patients had received chemotherapeutic agents, which included cisplatin. Some cases of transient blindness were reported as cortical in origin.

Strawberry flavour contains sulphur dioxide (E220) which may rarely cause severe hypersensitivity reactions and bronchospasm.

Not known (frequency cannot be estimated from the available data)

Myocardial ischemia

Signs include:

- sudden chest pain or
- chest tightness

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.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ondansetron orodispersible tablets

Keep this medicine out of the sight and reach of children.

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

Store below 30°C.

Do not use this medicine after the expiry date which is stated on the carton or foil after EXP. The expiry date refers to the last day of that month.

Do not use this medicine if you notice signs of deterioration, such as discolouration or broken tablets, are observed.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Ondansetron orodispersible tablets contains

The active substance is ondansetron. Each orodispersible tablet contains 4 mg or 8 mg ondansetron.

The other ingredients are: aspartame (E951), crospovidone type B, magnesium stearate (E572), microcrystalline cellulose (E460), pharmaburst TM C1, containing mannitol (E421), sorbitol (E420), crospovidone (type A) and colloidal silicon dioxide); strawberry flavouring, (containing glucose, maltodextrin, gum arabic E414 2.3% and sulphur dioxide E220); sodium stearyl fumarate.

What Ondansetron orodispersible tablets looks like and contents of the pack

Orodispersible tablets.

Ondansetron 4 mg and 8 mg orodispersible tablets

White, flat, round, bevel-edged tablet.

Ondansetron orodispersible tablets are provided in packs of 6x1, 10x1, 14x1, 20x1, 30x1, 50x1, 60x1, 100x1 tablets in aluminium/OPA/PVC unit-dose blister pack.

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

Sofarimex Industria Química e Farmacêutica S.A.
Av. das Indústrias- Alto do Colaride,
Cacem, 2735-213, Portugal

The package leaflet for the blind and partially sighted in other formats is made available on request.

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

Name of the Member State	Name of the medicinal product
Denmark	Ondansetron Bluefish 4 mg/ 8 mg smeltetabletter
Finland	Ondansetron Bluefish 4 mg/ 8 mg tabletti, suussa hajoava Ondansetron Bluefish 4 mg/ 8 mg munsönderfallande tabletter
Germany	Ondansetron Bluefish 4 mg/ 8 mg schmelztabletten
Norway	Ondansetron Bluefish 4 mg/ 8 mg smeltetabletter
Poland	Ondansetron Bluefish
Spain	Ondansetron Bluefish 4 mg/ 8 mg comprimidos bucodispersibles EFG
Sweden	Ondansetron Bluefish 4 mg/ 8 mg munsönderfallande tabletter
United Kingdom	Ondansetron 4 mg/ 8 mg orodispersible tablets

This leaflet was last revised in February 2022

Bluefish Pharmaceuticals						Date: 22.02.2022	
Reason of change	Revised for Batch Releaser - BLUEFISH					Revision No.	03
Product name	Ondansetron Orodispersible Tablets			Artwork code	BF035ONDXXUK_PIXX_BL_SOF_BFP05_03		
Strength	4 mg/8 mg	Packs	NA	Blister Layout No. :	Pantone Shades		
Country	United Kingdom	Manufacturer	SOFARIMEX BR - BLUEFISH	No. of Colors:	P. Black C		
Dimension	150 x 420 mm			Remarks	Font size - Heading 15, 12.5 pts., Rest all 8.5 pts		
Component	Package Leaflet	Artwork made to	100%	Remarks			
Braille	NA			Font size - Heading 15, 12.5 pts., Rest all 8.5 pts			
Reviewed & Approved by: RA		eLabel errand No.		CC No.			
		2022-23\1-1					
Revision History	R1 - Revised text received from RA on 16.02.2022 (for Keyline Check). - 18.02.2022		R2 - Comments received from RA on 22.02.2022 - 22.02.2022				

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- 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.

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6. How to store Ondansetron orodispersible tablets
7. Contents of the pack and other information

1. What Ondansetron orodispersible tablets are and what it is used for

Ondansetron orodispersible tablet is a fast dissolving tablet when placed on top of the tongue. Ondansetron orodispersible tablets contains ondansetron which belongs to a group of medicines that stop you feeling sick or being sick, so called anti-emetics.

Ondansetron orodispersible tablets may:

- stop the effects of nausea and vomiting caused by cytotoxic chemotherapy in children and adults
- prevent post-operative nausea and vomiting in children and adults
- stop the effects of nausea and vomiting caused by radiotherapy in adults

If you are not sure why they have been prescribed for you, ask your doctor.

2. What you need to know before you take before you take Ondansetron orodispersible tablets

Do not take Ondansetron orodispersible tablets

- if you are allergic to ondansetron, or any of the other ingredients of this medicine (listed in section 6).
- if you are taking apomorphine (used to treat Parkinson's disease).

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Ondansetron orodispersible tablets

- if you are pregnant or likely to become pregnant soon.
- if you are breast-feeding.
- if you have liver disease.
- if you have a blockage in your gut or if you suffer from severe constipation
- if it is children below the age of 2 years or with a body surface of less than 0.6 m².

Other medicines and Ondansetron orodispersible tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines like phenytoin, carbamazepine, rifampicin, tramadol.

Pregnancy and breast-feeding

Only use Ondansetron orodispersible tablets during the first trimester of pregnancy after discussion with your doctor of the potential benefits and risks to you and your unborn baby of the different treatment options. This is because Ondansetron orodispersible tablets can slightly increase the risk of a baby being born with cleft lip and/or cleft palate (openings or splits in the upper lip and/or the roof of the mouth). If you are already pregnant, think you might be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking Ondansetron orodispersible tablet. If you are a woman of childbearing potential you may be advised to use effective contraception.

Ondansetron probably passes into the mother's milk. Therefore it is recommended that mothers taking Ondansetron orodispersible tablets do not breast-feed.

Driving and using machines

Ondansetron orodispersible tablets has no influence on the ability to drive and use machines.

Ondansetron Bluefish orodispersible tablets contain aspartame, glucose, maltodextrin, sorbitol, sulphur dioxide and sodium

Ondansetron Bluefish orodispersible tablets contain aspartame (E 951). This medicine contains 0.88 mg aspartame in each 4 mg orodispersible tablet and 1.76 mg aspartame in each 8 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.

Ondansetron orodispersible tablets contain glucose and maltodextrin. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. May be harmful to the teeth.

Ondansetron Bluefish orodispersible tablets contain sorbitol (E 420). This medicine contains 8.4 mg sorbitol in each 4 mg orodispersible tablet and 16.98 mg sorbitol in each 8 mg orodispersible tablet.

Ondansetron orodispersible tablets contain sulphur dioxide (E 220). May rarely cause severe hypersensitivity reactions and bronchospasm.

Ondansetron Bluefish orodispersible tablets contain sodium. This medicine contains less than 1 mmol sodium (23 mg) per orodispersible tablet, that is to say essentially 'sodium-free'.

3. How to take Ondansetron orodispersible tablets

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

After starting to take your medicine

Ondansetron orodispersible tablets should start to work within one or two hours of taking a dose. If you are sick within one hour of taking a dose, then take the same dose again – otherwise do not take more Ondansetron orodispersible tablets than the label says. If you continue to feel sick then tell your doctor.

Treatment and prevention of nausea and vomiting in connection with chemotherapy or radiotherapy

Adults:

8 mg 1 to 2 hours before chemotherapy or radiotherapy followed by 8 mg 12 hours for up to 5 days. Your doctor may decide to give the first dose as an injection.

Elderly:

The same dose as for adults.

Use in Children (age 2 years and up) and adolescents under the age of 18 years:

The dose is individual and depends on the size/surface of the child. Ondansetron Bluefish should not be used for children with a total body surface of less than 0.6 m².

Children aged over 6 months and adolescents

- The usual dose for a child is up to 4 mg twice a day
- This can be given up to 5 days

Treatment and prevention of post-operative nausea and vomiting

Adults, prevention and treatment:

16 mg one hour prior to anaesthesia or alternatively, 8 mg administered one hour prior to anaesthesia followed by an additional 8 mg after 8 and 16 hours. Your doctor may choose to give you the medicine as injections.

Elderly, prevention and treatment:

There is limited experience with the use of ondansetron to elderly patients. Ondansetron is however tolerated well by patients above 65 years in chemotherapy (please refer to section above).

Patients with moderate or severe liver disease: the total daily dose should not be more than 8 mg.

Patients with poor sparteine/debrisoquine metabolism: No alteration of daily dosage or frequency of dosing is required.

The tablets must be taken as follows:

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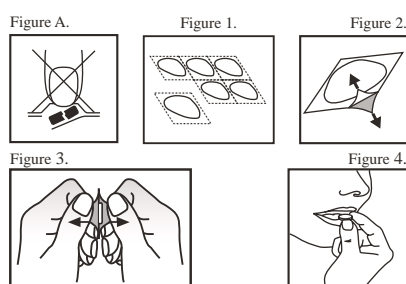
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Laetus reading direction

In order to prevent the breakage of tablets, it is important not to push the tablet out of its recess (Figure A).

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The tablet must be taken from the container with dry hands and placed on the tongue (Figure 4). The tablet will disintegrate, after which it can be swallowed with water.



If you take more Ondansetron orodispersible tablets than you should

If you or your child take more Ondansetron orodispersible tablets than you should, talk to a doctor or go to a hospital straight away. Take the medicine pack with you.

If you forget to take Ondansetron orodispersible tablets

Do not take a double dose to make up for a forgotten dose.

If you miss a dose and feel sick or vomit, take an Ondansetron orodispersible tablet as soon as possible and then carry on as before. If you miss a dose but do not feel sick take the next dose as on the label.

4. Possible side effects

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

A few people can be allergic to some medicines; if any of the following side effects come on soon after taking Ondansetron orodispersible tablets, stop taking them and tell your doctor immediately:

- **Sudden wheeziness and chest pain or chest tightness**
- **Swelling of eyelids, face, lips, mouth or tongue**
- **Skin rash - red spots or hives (skin lumps) anywhere on the body**
- **Collapse**

Other possible side effects:

Very common (may affect more than 1 in 10 people)

- Headache.

Common (may affect up to 1 in 10 people)

- Constipation.
- Sensation of warmth or flushing.

Uncommon (may affect up to 1 in 100 people)

- Arrhythmias, chest pain with or without ST segment depression, bradycardia.
- Asymptomatic increases in liver function tests.
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- Hiccups.
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Rare (may affect up to 1 in 1,000 people)

- Immediate hypersensitivity reactions sometimes severe, including anaphylaxis.
- Dizziness during i.v. administration, which in most cases is prevented or resolved by lengthening the infusion period.
- Transient visual disturbances (eg. blurred vision) during i.v. administration.

Very rare (may affect up to 1 in 10,000 people)

Transient blindness predominantly during intravenous administration

The majority of the blindness cases reported resolved within 20 minutes. Most patients had received chemotherapeutic agents, which included cisplatin. Some cases of transient blindness were reported as cortical in origin.

Strawberry flavour contains sulphur dioxide (E220) which may rarely cause severe hypersensitivity reactions and bronchospasm.

Not known (frequency cannot be estimated from the available data)

Myocardial ischemia

Signs include:

- sudden chest pain or
- chest tightness

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.

Reporting of side effects

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5. How to store Ondansetron orodispersible tablets

Keep this medicine out of the sight and reach of children.

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

Store below 30°C.

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6. Contents of the pack and other information

What Ondansetron orodispersible tablets contains

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The other ingredients are: aspartame (E951), crospovidone type B, magnesium stearate (E572), microcrystalline cellulose (E460), pharmaburst TM C1, containing mannitol (E421), sorbitol (E420), crospovidone (type A) and colloidal silicon dioxide; strawberry flavouring, (containing glucose, maltodextrin, gum arabic E414 2.3% and sulphur dioxide E220); sodium stearyl fumarate.

What Ondansetron orodispersible tablets looks like and contents of the pack

Orodispersible tablets.

Ondansetron 4 mg and 8 mg orodispersible tablets

White, flat, round, bevel-edged tablet.

Ondansetron orodispersible tablets are provided in packs of 6x1, 10x1, 14x1, 20x1, 30x1, 50x1, 60x1, 100x1 tablets in aluminium/OPA/PVC unit-dose blister pack.

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 Pharmaceuticals AB
Gävlegatan 22,
113 30 Stockholm, Sweden

The package leaflet for the blind and partially sighted in other formats is made available on request.

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

Name of the Member State	Name of the medicinal product
Denmark	Ondansetron Bluefish 4 mg/ 8 mg smeltetabletter
Finland	Ondansetron Bluefish 4 mg/ 8 mg tabletti, suussa hajoava Ondansetron Bluefish 4 mg/ 8 mg munsönderfallande tabletter
Germany	Ondansetron Bluefish 4 mg/ 8 mg schmelztabletten
Norway	Ondansetron Bluefish 4 mg/ 8 mg smeltetabletter
Poland	Ondansetron Bluefish
Spain	Ondansetron Bluefish 4 mg/ 8 mg comprimidos bucodispersibles EFG
Sweden	Ondansetron Bluefish 4 mg/ 8 mg munsönderfallande tabletter
United Kingdom	Ondansetron 4 mg/ 8 mg orodispersible tablets

This leaflet was last revised in February 2022