

PACKAGE LEAFLET: INFORMATION FOR THE USER

Diovan® 160mg film-coated tablets
(valsartan)

Your medicine is available using the above name but will be referred to as Diovan throughout this leaflet.

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 Diovan is and what it is used for
2. What you need to know before you take Diovan
3. How to take Diovan
4. Possible side effects
5. How to store Diovan
6. Contents of the pack and other information

1. What Diovan is and what it is used for

Diovan contains the active substance valsartan and belongs to a class of medicines known as angiotensin II receptor antagonists, which help to control high blood pressure. Angiotensin II is a substance in the body that causes vessels to tighten, thus causing your blood pressure to increase. Diovan works by blocking the effect of angiotensin II. As a result, blood vessels relax and blood pressure is lowered.

Diovan can be used for three different conditions:

- **to treat high blood pressure in adults and in children and adolescents 6 to 18 years of age.** High blood pressure increases the workload on the heart and arteries. If not treated it can damage the blood vessels of the brain, heart, and kidneys, and may result in a stroke, heart failure, or kidney failure. High blood pressure increases the risk of heart attacks. Lowering your blood pressure to normal reduces the risk of developing these disorders.
- **to treat adult patients after a recent heart attack** (myocardial infarction). "Recent" here means between 12 hours and 10 days.
- **to treat symptomatic heart failure in adult patients.** Diovan is used when a group of medicines called Angiotensin Converting Enzyme (ACE) inhibitors (a medication to treat heart failure) cannot be used or it may be used in addition to ACE cannot be used or it may be used in addition to ACE-inhibitors when other medications to treat heart failure cannot be used. Heart failure symptoms include shortness of breath, and swelling of the feet and legs due to fluid build-up. It is caused when the heart muscle cannot pump blood strongly enough to supply all the blood needed throughout the body.

2. What you need to know before you take Diovan

Do not take Diovan:

- if you are **allergic** (hypersensitive) to valsartan or any of the other ingredients of this medicine (listed in section 6).
- if you have **severe liver disease**.
- if you are **more than 3 months pregnant** (it is also better to avoid Diovan in early pregnancy – see pregnancy section).
- if you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.

If any of the above apply to you, tell your doctor and do not take Diovan.

Warnings and precautions:

Talk to your doctor

- if you have liver disease.
- if you have severe kidney disease or if you are undergoing dialysis.
- if you are suffering from a narrowing of the kidney artery.
- if you have recently undergone kidney transplantation (received a new kidney).
- if you have severe heart disease other than heart failure or heart attack.
- if you have ever experienced swelling of the tongue and face caused by an allergic reaction called angioedema when taking another drug (including ACE inhibitors), tell your doctor. If these symptoms occur when you are taking Diovan, stop taking Diovan immediately and never take it again. See also section 4, 'Possible side effects'.
- if you are taking medicines that increase the amount of potassium in your blood. These include potassium supplements or salt substitutes containing potassium, potassium-sparing medicines and heparin. It may be necessary to check the amount of potassium in your blood at regular intervals.
- if you suffer from aldosteronism. This is a disease in which your adrenal glands make too much of the hormone aldosterone. If this applies to you, the use of Diovan is not recommended.
- if you have lost a lot of fluid (dehydration) caused by diarrhoea, vomiting, or high doses of water tablets (diuretics).
- if you are taking any of the following medicines used to treat high blood pressure:
 - an ACE inhibitor (for example enalapril, lisinopril, ramipril), in particular if you have diabetes-related kidney problems.
 - aliskiren
 - if you are being treated with an ACE inhibitor together with certain other medicines to treat your heart failure, which are known as mineralocorticoid receptors antagonists (MRA) (for example spironolactone, eplerenone) or beta blockers (for example metoprolol).

Your doctor may check your kidney function, blood pressure, and the amount of electrolytes (e.g. potassium) in your blood at regular intervals.

See also information under the heading "Do not take Diovan."

You must tell your doctor if you think you are (or might become) pregnant. Diovan is not recommended in early pregnancy, and must not be taken if you are more than 3 months pregnant, as it may cause serious harm to your baby if used at that stage (see pregnancy section).

Other medicines and Diovan

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

The effect of the treatment can be influenced if Diovan is taken together with certain other medicines. It may be necessary to change the dose, to take other precautions, or in some cases to stop taking one of the medicines. This applies to both prescription and non-prescription medicines, especially:

- **other medicines that lower blood pressure**, especially **water tablets** (diuretics), ACE inhibitors (such as enalapril, lisinopril, etc.,) or aliskiren (see also information under the headings “Do not take Diovan” and “Warnings and precautions”).
- **medicines that increase the amount of potassium** in your blood. These include potassium supplements or salt substitutes containing potassium, potassium-sparing medicines and heparin.
- **certain type of pain killers** called non-steroidal anti-inflammatory medicines (**NSAIDs**).
- some antibiotics (rifamycin group), a drug used to protect against transplant rejection (cyclosporin) or an antiretroviral drug used to treat HIV/AIDS infection (ritonavir). These drugs may increase the effect of Diovan.
- **lithium**, a medicine used to treat some types of psychiatric illness.

In addition:

- if you are being **treated after a heart attack**, a combination with **ACE inhibitors** (a medication to treat heart attack) is not recommended.
- if you are being **treated for heart failure**, a triple combination with **ACE inhibitors and other medicines to treat your heart failure which are known as mineralocorticoid receptors antagonists (MRA) (for example spironolactone, eplerenone) or beta blockers** (for example metoprolol) is not recommended.

Pregnancy and breast-feeding

- **You must tell your doctor if you think that you are (or might become) pregnant.** Your doctor will normally advise you to stop taking Diovan before you become pregnant or as soon as you know you are pregnant, and will advise you to take another medicine instead of Diovan. Diovan is not recommended in early pregnancy, and must not be taken when more than 3 months pregnant, as it may cause serious harm to your baby if it is used after the third month of pregnancy.
- **Tell your doctor if you are breast-feeding or about to start breast-feeding.** Diovan is not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breast-feed, especially if your baby is newborn, or was born prematurely.

Driving and using machines

Before you drive a vehicle, use tools or operate machines, or carry out other activities that require concentration, make sure you know how Diovan affects you. Like many other medicines used to treat high blood pressure, Diovan may in rare cases cause dizziness and affect the ability to concentrate.

3. How to take Diovan

Always take this medicine exactly as your doctor has told you in order to get the best results and reduce the risk of side effects. Check with your doctor or pharmacist if you are not sure. People with high blood pressure often do not notice any signs of this problem. Many may feel quite normal. This makes it all the more important for you to keep your appointments with the doctor even if you are feeling well.

Adult patients with high blood pressure:

The recommended dose is 80mg daily. In some cases your doctor may prescribe higher doses (e.g. 160mg or 320mg). He may also combine Diovan with an additional medicine (e.g. a diuretic).

Children and adolescents (6 to 18 years of age) with high blood pressure:

In patients who weigh less than 35kg the recommended dose is 40mg of valsartan once daily.

In patients who weigh 35kg or more the recommended starting dose is 80mg of valsartan once daily.

In some cases your doctor may prescribe higher doses (the dose can be increased to 160mg and to a maximum of 320mg).

Adult patients after a recent heart attack:

After a heart attack the treatment is generally started as early as after 12 hours, usually at a low dose of 20mg twice daily. You obtain the 20mg dose by dividing the 40mg tablet. Your doctor will increase this dose gradually over several weeks to a maximum of 160mg twice daily. The final dose depends on what you as an individual patient can tolerate. Diovan can be given together with other treatment for heart attack, and your doctor will decide which treatment is suitable for you.

Adult patients with heart failure:

Treatment starts generally with 40mg twice daily. Your doctor will increase the dose gradually over several weeks to a maximum of 160mg twice daily. The final dose depends on what you as an individual patient can tolerate. Diovan can be given together with other treatment for heart failure, and your doctor will decide which treatment is suitable for you.

You can take Diovan with or without food. Swallow Diovan with a glass of water. Take Diovan at about the same time each day.

If you take more Diovan than you should

If you experience severe dizziness and/or fainting, contact your doctor immediately and lie down. If you have accidentally taken too many tablets, contact your doctor, pharmacist, or hospital.

If you forget to take Diovan

If you forget to take a dose, take it as soon as you remember. However, if it is almost time for your next dose, skip the dose you missed. Do not take a double dose to make up for a forgotten dose.

If you stop taking Diovan

Stopping your treatment with Diovan may cause your disease to get worse. Do not stop taking your medicine unless your doctor tells you to.

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

4. Possible side effects

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

Some side effects can be serious and need immediate medical attention:

You may experience symptoms of angioedema (a specific allergic reaction), such as

- swollen face, lips, tongue or throat
- difficulty in breathing or swallowing
- hives, itching

If you get any of these symptoms, stop taking Diovan and contact your doctor straight away (see also section 2 ‘Warnings and precautions’).

Other side effects include:

Common (may affect up to 1 in 10 people):

- dizziness
- low blood pressure with or without symptoms such as dizziness and fainting when standing up
- decreased kidney function (signs of renal impairment)

Uncommon (may affect up to 1 in 100 people):

- angioedema (see section “Some symptoms need immediate medical attention”)
- sudden loss of consciousness (syncope)
- spinning sensation (vertigo)
- severely decreased kidney function (signs of acute renal failure)
- muscle spasms, abnormal heart rhythm (signs of hyperkalaemia)
- breathlessness, difficulty breathing when lying down, swelling of the feet or legs (signs of cardiac failure)
- headache
- cough
- abdominal pain
- nausea
- diarrhoea
- tiredness
- weakness

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

- blistering skin (sign of dermatitis bullous)
- allergic reactions with rash, itching and hives; symptoms of fever, swollen joints and joint pain, muscle pain, swollen lymph nodes and/or flu-like symptoms may occur (signs of serum sickness)
- purplish-red spots, fever, itching (signs of inflammation of blood vessels also called vasculitis)
- unusual bleeding or bruising (signs of thrombocytopenia)
- muscle pain (myalgia)
- fever, sore throat or mouth ulcers due to infections (symptoms of low level of white blood cells also called neutropenia)
- decrease of level of haemoglobin and decrease of the percentage of red blood cells in the blood (which can lead to anaemia in severe cases)
- increase of level of potassium in the blood (which can trigger muscle spasms and abnormal heart rhythm in severe cases)

- elevation of liver function values (which can indicate liver damage) including an increase of bilirubin in the blood (which can trigger yellow skin and eyes in severe cases)
- increase of level of blood urea nitrogen and increase of level of serum creatinine (which can indicate abnormal kidney function)
- low level of sodium in the blood (which can trigger tiredness, confusion, muscle twitching and/or convulsions in severe cases)

The frequency of some side effects may vary depending on your condition. For example, side effects such as dizziness, and decreased kidney function, were seen less frequently in adult patients treated with high blood pressure than in adult patients treated for heart failure or after a recent heart attack.

Side effects in children and adolescents are similar to those seen in adults.

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 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 Diovan

- Do not store above 30°C. Store in the original package in order to protect from moisture.
- Keep out of the sight and reach of children.
- Do not use Diovan after the expiry date which is stated on the pack. The expiry date refers to the last day of that month.
- If your medicine appears to be discoloured, damaged or shows any other signs of deterioration, please return it to your pharmacist who will advise you further.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Diovan contains

The active substance is valsartan.
Each film-coated tablet contains 160mg of valsartan.
The other ingredients are:
tablet core: microcrystalline cellulose, crospovidone type A, colloidal anhydrous silica, magnesium stearate.
film coat: hypromellose, titanium dioxide (E171), macrogol 8000, iron oxide red (E172), iron oxide yellow (E172), and iron oxide black (E172).

What Diovan looks like and contents of the pack

Diovan are grey-orange, ovaloid, scored on one side, convex, debossed on one side with DX/DX and NVR on the other side. The tablet can be divided into equal halves.

Diovan is supplied in blister packs of 28 tablets.

Manufacturer

Manufactured by: Salutas Pharma GmbH,
Otto-von-Guericke-Allee 1, 39179 Barleben, Germany.

Procured from within the EU by the PPA holder: Imbat Ltd.,
Unit L2, North Ring Business Park, Santry, Dublin 9.

Repackaged by: Doncaster Pharmaceuticals Group Ltd.,
Kirk Sandall, Doncaster, DN3 1QR, UK.

Distributed by: Eurodrug Ltd., Santry, Dublin 9.

PPA No: 1151/67/2

POM

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

Austria, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Germany, Greece, Hungary, Iceland, Ireland, Latvia, Lithuania, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, United Kingdom	Diovan
Belgium, Luxembourg	Diovane
France, Italy	Tareg
Spain	Diovan Cardio

Leaflet issue and revision date (ref): 18.12.15

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Diovan® 160mg film-coated tablets
(valsartan)

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- ## What is in this leaflet:

- ## 1. What Diovan is and what it is used for

Diovan can be used for three different conditions:

- ## 2. What you need to know before you take Diovan

Do not take Diovan:

- if you are **allergic** (hypersensitive) to valsartan or any of the other ingredients of this medicine (listed in section 6).
- if you have **severe liver disease**.
- if you are **more than 3 months pregnant** (it is also better to avoid Diovan in early pregnancy – see pregnancy section).
- if you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.

If any of the above apply to you, tell your doctor and do not take Diovan.

Talk to your doctor

- Your doctor may check your kidney function, blood pressure, and the amount of electrolytes (e.g. potassium) in your blood at regular intervals.

See also information under the heading "Do not take Diovan."

You must tell your doctor if you think you are (or might become) pregnant. Diovan is not recommended in early pregnancy, and must not be taken if you are more than 3 months pregnant, as it may cause serious harm to your baby if used at that stage (see pregnancy section).

Other medicines and Diovan

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

The effect of the treatment can be influenced if Diovan is taken together with certain other medicines. It may be necessary to change the dose, to take other precautions, or in some cases to stop taking one of the medicines. This applies to both prescription and non-prescription medicines, especially:

- **other medicines that lower blood pressure**, especially **water tablets** (diuretics), ACE inhibitors (such as enalapril, lisinopril, etc.,) or aliskiren (see also information under the headings “Do not take Diovan” and “Warnings and precautions”).
- **medicines that increase the amount of potassium** in your blood. These include potassium supplements or salt substitutes containing potassium, potassium-sparing medicines and heparin.
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- **lithium**, a medicine used to treat some types of psychiatric illness.

- if you are being **treated after a heart attack**, a combination with **ACE inhibitors** (a medication to treat heart attack) is not recommended.
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Pregnancy and breast-feeding

- **You must tell your doctor if you think that you are (or might become) pregnant.** Your doctor will normally advise you to stop taking Diovan before you become pregnant or as soon as you know you are pregnant, and will advise you to take another medicine instead of Diovan. Diovan is not recommended in early pregnancy, and must not be taken when more than 3 months pregnant, as it may cause serious harm to your baby if it is used after the third month of pregnancy.
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Driving and using machines

Before you drive a vehicle, use tools or operate machines, or carry out other activities that require concentration, make sure you know how Diovan affects you. Like many other medicines used to treat high blood pressure, Diovan may in rare cases cause dizziness and affect the ability to concentrate.

3. How to take Diovan

Always take this medicine exactly as your doctor has told you in order to get the best results and reduce the risk of side effects. Check with your doctor or pharmacist if you are not sure. People with high blood pressure often do not notice any signs of this problem. Many may feel quite normal. This makes it all the more important for you to keep your appointments with the doctor even if you are feeling well.

Adult patients with high blood pressure:

The recommended dose is 80mg daily. In some cases your doctor may prescribe higher doses (e.g. 160mg or 320mg). He may also combine Diovan with an additional medicine (e.g. a diuretic).

Children and adolescents (6 to 18 years of age) with high blood pressure:

In patients who weigh less than 35kg the recommended dose is 40mg of valsartan once daily.
In patients who weigh 35kg or more the recommended starting dose is 80mg of valsartan once daily.
In some cases your doctor may prescribe higher doses (the dose can be increased to 160mg and to a maximum of 320mg).

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You can take Diovan with or without food. Swallow Diovan with a glass of water. Take Diovan at about the same time each day.

If you take more Diovan than you should

If you experience severe dizziness and/or fainting, contact your doctor immediately and lie down. If you have accidentally taken too many tablets, contact your doctor, pharmacist, or hospital.

If you forget to take Diovan

If you forget to take a dose, take it as soon as you remember. However, if it is almost time for your next dose, skip the dose you missed. Do not take a double dose to make up for a forgotten dose.

If you stop taking Diovan

Stopping your treatment with Diovan may cause your disease to get worse. Do not stop taking your medicine unless your doctor tells you to.

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

4. Possible side effects

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

Some side effects can be serious and need immediate medical attention:

You may experience symptoms of angioedema (a specific allergic reaction), such as

- swollen face, lips, tongue or throat
- difficulty in breathing or swallowing
- hives, itching

If you get any of these symptoms, stop taking Diovan and contact your doctor straight away (see also section 2 ‘Warnings and precautions’).

Other side effects include:

Common (may affect up to 1 in 10 people):

- dizziness
- low blood pressure with or without symptoms such as dizziness and fainting when standing up
- decreased kidney function (signs of renal impairment)

Uncommon (may affect up to 1 in 100 people):

- angioedema (see section “Some symptoms need immediate medical attention”)
- sudden loss of consciousness (syncope)
- spinning sensation (vertigo)
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- breathlessness, difficulty breathing when lying down, swelling of the feet or legs (signs of cardiac failure)
- headache
- cough
- abdominal pain
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- tiredness
- weakness

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

- blistering skin (sign of dermatitis bullous)
- allergic reactions with rash, itching and hives; symptoms of fever, swollen joints and joint pain, muscle pain, swollen lymph nodes and/or flu-like symptoms may occur (signs of serum sickness)
- purplish-red spots, fever, itching (signs of inflammation of blood vessels also called vasculitis)
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Manufacturer

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or
Novartis Pharma GmbH, Ronnestrasse, 25 Numberg, Germany.

Procured from within the EU by the PPA holder: Imbat Ltd., Unit L2, North Ring Business Park, Santry, Dublin 9.

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If any of the above apply to you, tell your doctor and do not take Diovan.

Talk to your doctor

- Your doctor may check your kidney function, blood pressure, and the amount of electrolytes (e.g. potassium) in your blood at regular intervals.

See also information under the heading "Do not take Diovan."

You must tell your doctor if you think you are (or might become) pregnant. Diovan is not recommended in early pregnancy, and must not be taken if you are more than 3 months pregnant, as it may cause serious harm to your baby if used at that stage (see pregnancy section).

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Other Medicines and Diet:
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Always take this medicine exactly as your doctor has told you in order to get the best results and reduce the risk of side effects. Check with your doctor or pharmacist if you are not sure. People with high blood pressure often do not notice any signs of this problem. Many may feel quite normal. This makes it all the more important for you to keep your appointments with the doctor even if you are feeling well.

Adult patients with high blood pressure:

The recommended dose is 80mg daily. In some cases your doctor may prescribe higher doses (e.g. 160mg or 320mg). He may also combine Diovan with an additional medicine (e.g. a diuretic).

Children and adolescents (6 to 18 years of age) with high blood pressure:

In patients who weigh less than 35kg the recommended dose is 40mg of valsartan once daily.
In patients who weigh 35kg or more the recommended starting dose is 80mg of valsartan once daily.
In some cases your doctor may prescribe higher doses (the dose can be increased to 160mg and to a maximum of 320mg).

Adult patients after a recent heart attack:

After a heart attack the treatment is generally started as early as after 12 hours, usually at a low dose of 20mg twice daily. You obtain the 20mg dose by dividing the 40mg tablet. Your doctor will increase this dose gradually over several weeks to a maximum of 160mg twice daily. The final dose depends on what you as an individual patient can tolerate. Diovan can be given together with other treatment for heart attack, and your doctor will decide which treatment is suitable for you.

Adult patients with heart failure:

Treatment starts generally with 40mg twice daily. Your doctor will increase the dose gradually over several weeks to a maximum of 160mg twice daily. The final dose depends on what you as an individual patient can tolerate. Diovan can be given together with other treatment for heart failure, and your doctor will decide which treatment is suitable for you.

You can take Diovan with or without food. Swallow Diovan with a glass of water. Take Diovan at about the same time each day.

If you take more Diovan than you should

If you experience severe dizziness and/or fainting, contact your doctor immediately and lie down. If you have accidentally taken too many tablets, contact your doctor, pharmacist, or hospital.

If you forget to take Diovan

If you forget to take a dose, take it as soon as you remember. However, if it is almost time for your next dose, skip the dose you missed. Do not take a double dose to make up for a forgotten dose.

If you stop taking Diovan

Stopping your treatment with Diovan may cause your disease to get worse. Do not stop taking your medicine unless your doctor tells you to.

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

4. Possible side effects

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

Some side effects can be serious and need immediate medical attention:

You may experience symptoms of angioedema (a specific allergic reaction), such as

- swollen face, lips, tongue or throat
- difficulty in breathing or swallowing
- hives, itching

If you get any of these symptoms, stop taking Diovan and contact your doctor straight away (see also section 2 ‘Warnings and precautions’).

Other side effects include:

Common (may affect up to 1 in 10 people):

- dizziness
- low blood pressure with or without symptoms such as dizziness and fainting when standing up
- decreased kidney function (signs of renal impairment)

Uncommon (may affect up to 1 in 100 people):

- angioedema (see section “Some symptoms need immediate medical attention”)
- sudden loss of consciousness (syncope)
- spinning sensation (vertigo)
- severely decreased kidney function (signs of acute renal failure)
- muscle spasms, abnormal heart rhythm (signs of hyperkalaemia)
- breathlessness, difficulty breathing when lying down, swelling of the feet or legs (signs of cardiac failure)
- headache
- cough
- abdominal pain
- nausea
- diarrhoea
- tiredness
- weakness

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

- blistering skin (sign of dermatitis bullous)
- allergic reactions with rash, itching and hives; symptoms of fever, swollen joints and joint pain, muscle pain, swollen lymph nodes and/or flu-like symptoms may occur (signs of serum sickness)
- purplish-red spots, fever, itching (signs of inflammation of blood vessels also called vasculitis)
- unusual bleeding or bruising (signs of thrombocytopenia)
- muscle pain (myalgia)
- fever, sore throat or mouth ulcers due to infections (symptoms of low level of white blood cells also called neutropenia)
- decrease of level of haemoglobin and decrease of the percentage of red blood cells in the blood (which can lead to anaemia in severe cases)
- increase of level of potassium in the blood (which can trigger muscle spasms and abnormal heart rhythm in severe cases)

- elevation of liver function values (which can indicate liver damage) including an increase of bilirubin in the blood (which can trigger yellow skin and eyes in severe cases)
- increase of level of blood urea nitrogen and increase of level of serum creatinine (which can indicate abnormal kidney function)
- low level of sodium in the blood (which can trigger tiredness, confusion, muscle twitching and/or convulsions in severe cases)

The frequency of some side effects may vary depending on your condition. For example, side effects such as dizziness, and decreased kidney function, were seen less frequently in adult patients treated with high blood pressure than in adult patients treated for heart failure or after a recent heart attack.

Side effects in children and adolescents are similar to those seen in adults.

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 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 Diovan

- Do not store above 30°C. Store in the original package in order to protect from moisture.
- Keep out of the sight and reach of children.
- Do not use Diovan after the expiry date which is stated on the pack. The expiry date refers to the last day of that month.
- If your medicine appears to be discoloured, damaged or shows any other signs of deterioration, please return it to your pharmacist who will advise you further.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Diovan contains

The active substance is valsartan.
Each film-coated tablet contains 160mg of valsartan.
The other ingredients are:
tablet core: microcrystalline cellulose, crospovidone type A, colloidal anhydrous silica, magnesium stearate.
film coat: hypromellose, titanium dioxide (E171), macrogol 8000, iron oxide red (E172), iron oxide yellow (E172), and iron oxide black (E172).

What Diovan looks like and contents of the pack

Diovan are grey-orange, ovaloid, scored on one side, convex, debossed on one side with DX/DX and NVR on the other side. The tablet can be divided into equal halves.

Diovan is supplied in blister packs of 28 tablets.

Manufacturer

Manufactured by: Novartis Farmaceutica S.A.
Gran Via de les Corts Catalanes, 764, 08013 Barcelona, Spain.

Procured from within the EU by the PPA holder: Imbat Ltd., Unit L2, North Ring Business Park, Santry, Dublin 9.

Repackaged by: Doncaster Pharmaceuticals Group Ltd., Kirk Sandall, Doncaster, DN3 1QR, UK.

Distributed by: Eurodrug Ltd., Santry, Dublin 9.

PPA No: 1151/67/2

POM

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

Austria, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Germany, Greece, Hungary, Iceland, Ireland, Latvia, Lithuania, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, United Kingdom	Diovan
Belgium, Luxembourg	Diovane
France, Italy	Tareg
Spain	Diovan Cardio

Leaflet issue and revision date (ref): 18.12.15

Diovan® is a registered trademark of Novartis AG

Diovan® 160mg film-coated tablets
(valsartan)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- ## What is in this leaflet:

- ## 1. What Diovan is and what it is used for

Diovan can be used for three different conditions:

- ## 2. What you need to know before you take Diovan

Do not take Diovan:

- if you are **allergic** (hypersensitive) to valsartan or any of the other ingredients of this medicine (listed in section 6).
- if you have **severe liver disease**.
- if you are **more than 3 months pregnant** (it is also better to avoid Diovan in early pregnancy – see pregnancy section).
- if you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.

If any of the above apply to you, tell your doctor and do not take Diovan.

Talk to your doctor

- Your doctor may check your kidney function, blood pressure, and the amount of electrolytes (e.g. potassium) in your blood at regular intervals.

See also information under the heading "Do not take Diovan."

You must tell your doctor if you think you are (or might become) pregnant. Diovan is not recommended in early pregnancy, and must not be taken if you are more than 3 months pregnant, as it may cause serious harm to your baby if used at that stage (see pregnancy section).

Other medicines and Diovan

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

The effect of the treatment can be influenced if Diovan is taken together with certain other medicines. It may be necessary to change the dose, to take other precautions, or in some cases to stop taking one of the medicines. This applies to both prescription and non-prescription medicines, especially:

- **other medicines that lower blood pressure**, especially **water tablets** (diuretics), ACE inhibitors (such as enalapril, lisinopril, etc.,) or aliskiren (see also information under the headings “Do not take Diovan” and “Warnings and precautions”).
- **medicines that increase the amount of potassium** in your blood. These include potassium supplements or salt substitutes containing potassium, potassium-sparing medicines and heparin.
- **certain type of pain killers** called non-steroidal anti-inflammatory medicines (**NSAIDs**).
- some antibiotics (rifamycin group), a drug used to protect against transplant rejection (cyclosporin) or an antiretroviral drug used to treat HIV/AIDS infection (ritonavir). These drugs may increase the effect of Diovan.
- **lithium**, a medicine used to treat some types of psychiatric illness.

In addition:

- if you are being **treated after a heart attack**, a combination with **ACE inhibitors** (a medication to treat heart attack) is not recommended.
- if you are being **treated for heart failure**, a triple combination with **ACE inhibitors and other medicines to treat your heart failure which are known as mineralocorticoid receptors antagonists (MRA) (for example spironolactone, eplerenone) or beta blockers** (for example metoprolol) is not recommended.

Pregnancy and breast-feeding

- **You must tell your doctor if you think that you are (or might become) pregnant.** Your doctor will normally advise you to stop taking Diovan before you become pregnant or as soon as you know you are pregnant, and will advise you to take another medicine instead of Diovan. Diovan is not recommended in early pregnancy, and must not be taken when more than 3 months pregnant, as it may cause serious harm to your baby if it is used after the third month of pregnancy.
- **Tell your doctor if you are breast-feeding or about to start breast-feeding.** Diovan is not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breast-feed, especially if your baby is newborn, or was born prematurely.

Driving and using machines

Before you drive a vehicle, use tools or operate machines, or carry out other activities that require concentration, make sure you know how Diovan affects you. Like many other medicines used to treat high blood pressure, Diovan may in rare cases cause dizziness and affect the ability to concentrate.

3. How to take Diovan

Always take this medicine exactly as your doctor has told you in order to get the best results and reduce the risk of side effects. Check with your doctor or pharmacist if you are not sure. People with high blood pressure often do not notice any signs of this problem. Many may feel quite normal. This makes it all the more important for you to keep your appointments with the doctor even if you are feeling well.

Adult patients with high blood pressure:

The recommended dose is 80mg daily. In some cases your doctor may prescribe higher doses (e.g. 160mg or 320mg). He may also combine Diovan with an additional medicine (e.g. a diuretic).

Children and adolescents (6 to 18 years of age) with high blood pressure:

In patients who weigh less than 35kg the recommended dose is 40mg of valsartan once daily.
In patients who weigh 35kg or more the recommended starting dose is 80mg of valsartan once daily.
In some cases your doctor may prescribe higher doses (the dose can be increased to 160mg and to a maximum of 320mg).

Adult patients after a recent heart attack:

After a heart attack the treatment is generally started as early as after 12 hours, usually at a low dose of 20mg twice daily. You obtain the 20mg dose by dividing the 40mg tablet. Your doctor will increase this dose gradually over several weeks to a maximum of 160mg twice daily. The final dose depends on what you as an individual patient can tolerate. Diovan can be given together with other treatment for heart attack, and your doctor will decide which treatment is suitable for you.

Adult patients with heart failure:

Treatment starts generally with 40mg twice daily. Your doctor will increase the dose gradually over several weeks to a maximum of 160mg twice daily. The final dose depends on what you as an individual patient can tolerate. Diovan can be given together with other treatment for heart failure, and your doctor will decide which treatment is suitable for you.

You can take Diovan with or without food. Swallow Diovan with a glass of water. Take Diovan at about the same time each day.

If you take more Diovan than you should

If you experience severe dizziness and/or fainting, contact your doctor immediately and lie down. If you have accidentally taken too many tablets, contact your doctor, pharmacist, or hospital.

If you forget to take Diovan

If you forget to take a dose, take it as soon as you remember. However, if it is almost time for your next dose, skip the dose you missed. Do not take a double dose to make up for a forgotten dose.

If you stop taking Diovan

Stopping your treatment with Diovan may cause your disease to get worse. Do not stop taking your medicine unless your doctor tells you to.

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

4. Possible side effects

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

Some side effects can be serious and need immediate medical attention:

You may experience symptoms of angioedema (a specific allergic reaction), such as

- swollen face, lips, tongue or throat
- difficulty in breathing or swallowing
- hives, itching

If you get any of these symptoms, stop taking Diovan and contact your doctor straight away (see also section 2 ‘Warnings and precautions’).

Other side effects include:

Common (may affect up to 1 in 10 people):

- dizziness
- low blood pressure with or without symptoms such as dizziness and fainting when standing up
- decreased kidney function (signs of renal impairment)

Uncommon (may affect up to 1 in 100 people):

- angioedema (see section “Some symptoms need immediate medical attention”)
- sudden loss of consciousness (syncope)
- spinning sensation (vertigo)
- severely decreased kidney function (signs of acute renal failure)
- muscle spasms, abnormal heart rhythm (signs of hyperkalaemia)
- breathlessness, difficulty breathing when lying down, swelling of the feet or legs (signs of cardiac failure)
- headache
- cough
- abdominal pain
- nausea
- diarrhoea
- tiredness
- weakness

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

- blistering skin (sign of dermatitis bullous)
- allergic reactions with rash, itching and hives; symptoms of fever, swollen joints and joint pain, muscle pain, swollen lymph nodes and/or flu-like symptoms may occur (signs of serum sickness)
- purplish-red spots, fever, itching (signs of inflammation of blood vessels also called vasculitis)
- unusual bleeding or bruising (signs of thrombocytopenia)
- muscle pain (myalgia)
- fever, sore throat or mouth ulcers due to infections (symptoms of low level of white blood cells also called neutropenia)
- decrease of level of haemoglobin and decrease of the percentage of red blood cells in the blood (which can lead to anaemia in severe cases)
- increase of level of potassium in the blood (which can trigger muscle spasms and abnormal heart rhythm in severe cases)

- elevation of liver function values (which can indicate liver damage) including an increase of bilirubin in the blood (which can trigger yellow skin and eyes in severe cases)
- increase of level of blood urea nitrogen and increase of level of serum creatinine (which can indicate abnormal kidney function)
- low level of sodium in the blood (which can trigger tiredness, confusion, muscle twitching and/or convulsions in severe cases)

The frequency of some side effects may vary depending on your condition. For example, side effects such as dizziness, and decreased kidney function, were seen less frequently in adult patients treated with high blood pressure than in adult patients treated for heart failure or after a recent heart attack.

Side effects in children and adolescents are similar to those seen in adults.

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 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 Diovan

- Do not store above 30°C. Store in the original package in order to protect from moisture.
- Keep out of the sight and reach of children.
- Do not use Diovan after the expiry date which is stated on the pack. The expiry date refers to the last day of that month.
- If your medicine appears to be discoloured, damaged or shows any other signs of deterioration, please return it to your pharmacist who will advise you further.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Diovan contains

The active substance is valsartan.
Each film-coated tablet contains 160mg of valsartan.
The other ingredients are:
tablet core: microcrystalline cellulose, crospovidone type A, colloidal anhydrous silica, magnesium stearate.
film coat: hypromellose, titanium dioxide (E171), macrogol 8000, iron oxide red (E172), iron oxide yellow E172), and iron oxide black (E172).

What Diovan looks like and contents of the pack

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Diovan is supplied in blister packs of 28 tablets.

Manufacturer

Manufactured by: Novartis Pharma B.V.,
Postbus 241, 6800 LZ ARNHEM, Netherlands.

Procured from within the EU by the PPA holder: Imbat Ltd.,
Unit L2, North Ring Business Park, Santry, Dublin 9.

Repackaged by: Doncaster Pharmaceuticals Group Ltd.,
Kirk Sandall, Doncaster, DN3 1QR, UK.

Distributed by: Eurodrug Ltd., Santry, Dublin 9.

PPA No: 1151/67/2

POM

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Austria, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Germany, Greece, Hungary, Iceland, Ireland, Latvia, Lithuania, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, United Kingdom	Diovan
Belgium, Luxembourg	Diovane
France, Italy	Tareg
Spain	Diovan Cardio

Leaflet issue and revision date (ref): 18.12.15

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Diovan® 160mg film-coated tablets
(valsartan)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- ## What is in this leaflet:

- ## 1. What Diovan is and what it is used for

Diovan can be used for three different conditions:

- ## 2. What you need to know before you take Diovan

Do not take Diovan:

- if you are **allergic** (hypersensitive) to valsartan or any of the other ingredients of this medicine (listed in section 6).
- if you have **severe liver disease**.
- if you are **more than 3 months pregnant** (it is also better to avoid Diovan in early pregnancy – see pregnancy section).
- if you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.

If any of the above apply to you, tell your doctor and do not take Diovan.

Talk to your doctor

- Your doctor may check your kidney function, blood pressure, and the amount of electrolytes (e.g. potassium) in your blood at regular intervals.

See also information under the heading "Do not take Diovan."

You must tell your doctor if you think you are (or might become) pregnant. Diovan is not recommended in early pregnancy, and must not be taken if you are more than 3 months pregnant, as it may cause serious harm to your baby if used at that stage (see pregnancy section).

Other medicines and Diovan

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

The effect of the treatment can be influenced if Diovan is taken together with certain other medicines. It may be necessary to change the dose, to take other precautions, or in some cases to stop taking one of the medicines. This applies to both prescription and non-prescription medicines, especially:

- **other medicines that lower blood pressure**, especially **water tablets** (diuretics), ACE inhibitors (such as enalapril, lisinopril, etc.,) or aliskiren (see also information under the headings “Do not take Diovan” and “Warnings and precautions”).
- **medicines that increase the amount of potassium** in your blood. These include potassium supplements or salt substitutes containing potassium, potassium-sparing medicines and heparin.
- **certain type of pain killers** called non-steroidal anti-inflammatory medicines (**NSAIDs**).
- some antibiotics (rifamycin group), a drug used to protect against transplant rejection (cyclosporin) or an antiretroviral drug used to treat HIV/AIDS infection (ritonavir). These drugs may increase the effect of Diovan.
- **lithium**, a medicine used to treat some types of psychiatric illness.

- if you are being **treated after a heart attack**, a combination with **ACE inhibitors** (a medication to treat heart attack) is not recommended.
- if you are being **treated for heart failure**, a triple combination with **ACE inhibitors and other medicines to treat your heart failure which are known as mineralocorticoid receptors antagonists (MRA) (for example spironolactone, eplerenone) or beta blockers** (for example metoprolol) is not recommended.

Pregnancy and breast-feeding

- **You must tell your doctor if you think that you are (or might become) pregnant.** Your doctor will normally advise you to stop taking Diovan before you become pregnant or as soon as you know you are pregnant, and will advise you to take another medicine instead of Diovan. Diovan is not recommended in early pregnancy, and must not be taken when more than 3 months pregnant, as it may cause serious harm to your baby if it is used after the third month of pregnancy.
- **Tell your doctor if you are breast-feeding or about to start breast-feeding.** Diovan is not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breast-feed, especially if your baby is newborn, or was born prematurely.

Driving and using machines

Before you drive a vehicle, use tools or operate machines, or carry out other activities that require concentration, make sure you know how Diovan affects you. Like many other medicines used to treat high blood pressure, Diovan may in rare cases cause dizziness and affect the ability to concentrate.

3. How to take Diovan

Always take this medicine exactly as your doctor has told you in order to get the best results and reduce the risk of side effects. Check with your doctor or pharmacist if you are not sure. People with high blood pressure often do not notice any signs of this problem. Many may feel quite normal. This makes it all the more important for you to keep your appointments with the doctor even if you are feeling well.

Adult patients with high blood pressure:

The recommended dose is 80mg daily. In some cases your doctor may prescribe higher doses (e.g. 160mg or 320mg). He may also combine Diovan with an additional medicine (e.g. a diuretic).

Children and adolescents (6 to 18 years of age) with high blood pressure:

In patients who weigh less than 35kg the recommended dose is 40mg of valsartan once daily.
In patients who weigh 35kg or more the recommended starting dose is 80mg of valsartan once daily.
In some cases your doctor may prescribe higher doses (the dose can be increased to 160mg and to a maximum of 320mg).

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Adult patients with heart failure:

Treatment starts generally with 40mg twice daily. Your doctor will increase the dose gradually over several weeks to a maximum of 160mg twice daily. The final dose depends on what you as an individual patient can tolerate. Diovan can be given together with other treatment for heart failure, and your doctor will decide which treatment is suitable for you.

You can take Diovan with or without food. Swallow Diovan with a glass of water. Take Diovan at about the same time each day.

If you take more Diovan than you should

If you experience severe dizziness and/or fainting, contact your doctor immediately and lie down. If you have accidentally taken too many tablets, contact your doctor, pharmacist, or hospital.

If you forget to take Diovan

If you forget to take a dose, take it as soon as you remember. However, if it is almost time for your next dose, skip the dose you missed. Do not take a double dose to make up for a forgotten dose.

If you stop taking Diovan

Stopping your treatment with Diovan may cause your disease to get worse. Do not stop taking your medicine unless your doctor tells you to.

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

4. Possible side effects

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

Some side effects can be serious and need immediate medical attention:

You may experience symptoms of angioedema (a specific allergic reaction), such as

- swollen face, lips, tongue or throat
- difficulty in breathing or swallowing
- hives, itching

If you get any of these symptoms, stop taking Diovan and contact your doctor straight away (see also section 2 ‘Warnings and precautions’).

Other side effects include:

Common (may affect up to 1 in 10 people):

- dizziness
- low blood pressure with or without symptoms such as dizziness and fainting when standing up
- decreased kidney function (signs of renal impairment)

Uncommon (may affect up to 1 in 100 people):

- angioedema (see section “Some symptoms need immediate medical attention”)
- sudden loss of consciousness (syncope)
- spinning sensation (vertigo)
- severely decreased kidney function (signs of acute renal failure)
- muscle spasms, abnormal heart rhythm (signs of hyperkalaemia)
- breathlessness, difficulty breathing when lying down, swelling of the feet or legs (signs of cardiac failure)
- headache
- cough
- abdominal pain
- nausea
- diarrhoea
- tiredness
- weakness

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

- blistering skin (sign of dermatitis bullous)
- allergic reactions with rash, itching and hives; symptoms of fever, swollen joints and joint pain, muscle pain, swollen lymph nodes and/or flu-like symptoms may occur (signs of serum sickness)
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- muscle pain (myalgia)
- fever, sore throat or mouth ulcers due to infections (symptoms of low level of white blood cells also called neutropenia)
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- increase of level of potassium in the blood (which can trigger muscle spasms and abnormal heart rhythm in severe cases)

- elevation of liver function values (which can indicate liver damage) including an increase of bilirubin in the blood (which can trigger yellow skin and eyes in severe cases)
- increase of level of blood urea nitrogen and increase of level of serum creatinine (which can indicate abnormal kidney function)
- low level of sodium in the blood (which can trigger tiredness, confusion, muscle twitching and/or convulsions in severe cases)

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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 Diovan

- Do not store above 30°C. Store in the original package in order to protect from moisture.
- Keep out of the sight and reach of children.
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6. Contents of the pack and other information

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Diovan is supplied in blister packs of 28 tablets.

Diovan are marketed in the The Netherlands as Valsartan. The blister strip may state both names.

Manufacturer

Manufactured by: Lek Pharmaceuticals d.d., Verovškova 57, 1526 Ljubljana, Slovenia.

Procured from within the EU by the PPA holder: Imbat Ltd., Unit L2, North Ring Business Park, Santry, Dublin 9.

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Austria, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Germany, Greece, Hungary, Iceland, Ireland, Latvia, Lithuania, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, United Kingdom	Diovan
Belgium, Luxembourg	Diovane
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