

# PACKAGE LEAFLET: INFORMATION FOR THE USER

## ISTIN™ 5mg & 10mg Tablets (amlodipine as amlodipine besilate)

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

### What is in this leaflet:

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

### 1. What Istin is and what it is used for

Istin contains the active substance amlodipine which belongs to a group of medicines called calcium antagonists.

Istin is used to treat high blood pressure (hypertension) or a certain type of chest pain called angina, a rare form of which is Prinzmetal's or variant angina.

In patients with high blood pressure this medicine works by relaxing blood vessels, so that blood passes through them more easily. In patients with angina Istin works by improving blood supply to the heart muscle which then receives more oxygen and as a result chest pain is prevented. This medicine does not provide immediate relief of chest pain from angina.

### 2. What you need to know before you take Istin

#### Do not take Istin

- if you are allergic (hypersensitive) to amlodipine, or any of the other ingredients of this medicine listed in section 6, or to any other calcium antagonists. This may be itching, reddening of the skin or difficulty in breathing.
- If you have severe low blood pressure (hypotension)
- If you have narrowing of the aortic heart valve (aortic stenosis), or cardiogenic shock (a condition where your heart is unable to supply enough blood to the body).
- If you suffer from heart failure after a heart attack

#### Warnings and precautions

Talk to your doctor or pharmacist before taking Istin.

You should inform your Doctor if you have or have had any of the following conditions:

- Recent heart attack
- Heart failure
- Severe increase in blood pressure (Hypertensive crisis)
- Liver disease
- You are elderly and your dose needs to be increased

#### Children and adolescents

Istin has not been studied in children under the age of 6 years. Istin should only be used for hypertension in children and adolescents from 6 years to 17 years of age (see section 3). For more information, talk to your doctor.

#### Other medicines and Istin

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Istin may affect or be affected by other medicines, such as:

- ketoconazole, itraconazole (anti-fungal medicines)
- ritonavir, indinavir, nelfinavir (so called protease inhibitors used to treat HIV)
- rifampicin, erythromycin, clarithromycin (antibiotics)
- hypericum perforatum (St John's Wort)
- verapamil, diltiazem (heart medicines)
- dantrolene (infusion for severe body temperature abnormalities)
- tacrolimus (medicine used to alter the way your immune system works)
- simvastatin (a cholesterol lowering medicine)
- cyclosporine (an immunosuppressant)

Istin may lower your blood pressure even more if you are already taking other medicines to treat your high blood pressure.

#### Istin with food and drink

Grapefruit juice and grapefruit should not be consumed by people who are taking Istin. This is because grapefruit and grapefruit juice can lead to an increase in the blood levels of the active ingredient amlodipine, which can cause an unpredictable increase in the blood pressure lowering effect of Istin.

#### Pregnancy and breastfeeding

##### Pregnancy

The safety of Amlodipine in human pregnancy has not been established. If you think you might be pregnant, or are planning to get pregnant, you must tell your doctor before you take Istin.

##### Breast-feeding

It is not known whether amlodipine is passed into breast milk. If you are breast-feeding or about to start breast-feeding you must tell your doctor before taking Istin.

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

#### Driving and using machines

Istin may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

#### Istin contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, which means it is essentially 'sodium-free'.

### 3. How to take Istin

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

The recommended initial dose is Istin 5 mg once daily. The dose can be increased to Istin 10 mg once daily.

This medicine can be used before or after food and drinks. You should take this medicine at the same time each day with a drink of water. Do not take Istin with grapefruit juice.

#### Use in children and adolescents

For children and adolescents (6 -17 years old), the recommended usual starting dose is 2.5 mg a day. The maximum recommended dose is 5 mg a day. Istin 5mg tablets can be divided into halves to provide a 2.5mg dose.

It is important to keep taking the tablets. Do not wait until your tablets are finished before seeing your doctor.

#### If you take more Istin than you should

Taking too many tablets may cause your blood pressure to become low or even dangerously low. You may feel dizzy, lightheaded, faint or weak. If blood pressure drop is severe enough shock can occur. Your skin could feel cool and clammy and you could lose consciousness. Seek immediate medical attention if you take too many Istin tablets.

#### If you forget to take Istin

Do not worry. If you forget to take a tablet, leave out that dose completely. Take your next dose at the right time. Do not take a double dose to make up for a forgotten dose.

#### If you stop taking Istin

Your doctor will advise you how long to take this medicine. Your condition may return if you stop using this medicine before you are advised.

If you have any 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.

Visit your doctor **immediately** if you experience any of the following side effects after taking this medicine.

- Sudden wheeziness, chest pain, shortness of breath or difficulty in breathing
- Swelling of eyelids, face or lips
- Swelling of the tongue and throat which causes great difficulty breathing

- Severe skin reactions including intense skin rash, hives, reddening of the skin over your whole body, severe itching, blistering, peeling and swelling of the skin, inflammation of mucous membranes (Stevens Johnson Syndrome) or other allergic reactions
- Heart attack, abnormal heart beat
- Inflamed pancreas which may cause severe abdominal and back pain accompanied with feeling very unwell

The following **very common side effect** has been reported. If this causes you problems or if it **lasts for more than one week**, you should **contact your doctor**.

**Very common: may affect more than 1 in 10 people**

- Oedema (fluid retention)

The following **common side-effects** have been reported. If any of these cause you problems or if they **last for more than one week**, you should **contact your doctor**.

**Common: may affect up to 1 in 10 people**

- Headache, dizziness, sleepiness (especially at the beginning of treatment)
- Palpitations (awareness of your heart beat), flushing.
- Abdominal pain, feeling sick (nausea).
- Altered bowel habits, diarrhea, constipation, indigestion
- Tiredness, weakness
- Visual disturbances, double vision
- Muscle cramps
- Ankle swelling

Other side-effects that have been reported include the following list. If any of these get serious, or if you notice any side-effects not listed in this leaflet, please tell your doctor or pharmacist.

**Uncommon: may affect up to 1 in 100 people**

- Mood changes, anxiety, depression, sleeplessness.
- Trembling, taste abnormalities, fainting.
- Numbness or tingling sensation in your limbs; loss of pain sensation
- Ringing in the ears.
- Low blood pressure.
- Sneezing/running nose caused by inflammation of the lining of the nose (rhinitis)
- Cough
- Dry mouth, vomiting (being sick)
- Hair loss, increased sweating, itchy skin, red patches on skin, skin discoloration
- Disorder in passing urine, increased need to urinate at night, increased number of times of passing urine.
- Inability to obtain an erection; discomfort or enlargement of the breasts in men
- Pain, feeling unwell
- Joint or muscle pain, back pain
- Weight increase or decrease.

**Rare: may affect up to 1 in 1000 people**

- confusion

**Very rare: may affect up to 1 in 10000 people**

- Decreased numbers of white blood cells, decrease in blood platelets which may result in unusual bruising or easy bleeding
- Excess sugar in blood (hyperglycaemia)
- A disorder of the nerves which can cause muscular weakness, tingling or numbness
- Swelling of the gums
- Abdominal bloating (gastritis)
- Abnormal liver function, inflammation of the liver (hepatitis), yellowing of the skin (jaundice), liver enzyme increase which may have an effect on some medical tests
- Increased muscle tension
- Inflammation of blood vessels, often with skin rash
- Sensitivity to light
- Disorders combining rigidity, tremor, and/or movement disorders

**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 HPRC Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); email: [medsafety@hpra.ie](mailto:medsafety@hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

**5. How to store Istin**

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

Do not use this medicine after the expiry date which is stated on the carton and tablet blister after Exp. The expiry date refers to the last day of that month.

Do not store above 25°C.

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 Istin contains**

The active substance in Istin 5 mg tablets is amlodipine (as besilate). The active substance in Istin 10 mg tablets is amlodipine (as besilate).

The other ingredients are calcium hydrogen phosphate anhydrous, magnesium stearate, microcrystalline cellulose and sodium starch glycollate.

**What Istin looks like and contents of the pack**

5mg tablets: white to off white, emerald shaped tablets engraved AML 5 and breaker score-on one side and the Pfizer logo on the other side.

10mg tablets: white to off white, emerald shaped tablets engraved AML 10 on one side and the Pfizer logo on the other side.

Istin comes in packs of 28 tablets.

**Product procured from within the EU by the Parallel Product**

**Authorisation Holder:**

**iMed Healthcare Ltd.  
Unit 625 Kilshane Avenue,  
Northwest Business Park  
Ballycoolin, Dublin 15  
Ireland**

**Manufacturer:**

**R-Pharm Germany GmbH,  
Heinrich-Mack-Strasse 35,  
89257 Illertissen,  
Germany.**

**Repackaged by:**

**Cast Healthcare Ltd,  
Unit B6 The Business Centre,  
5-7 Tobermore Road, Draperstown,  
Northern Ireland,  
BT45 7AG.  
UK**

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

Tablets

Austria, Bulgaria, Denmark, Estonia, Finland, Germany, Hungary, Iceland, Italy, Latvia, Lithuania, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Sweden: Norvasc.

Czech Republic: Zorem

Denmark: Amlodipin Pfizer Ireland, Malta, United Kingdom: Istin

Ireland: Amlodipine Pfizer 5 mg tablets, Amlodipine Pfizer 10 mg tablets

Italy: Amlodipina Pfizer Italia

Spain: Norvas 5 mg comprimidos, Norvas 10 mg comprimidos

United Kingdom: Amlodipine 5 mg tablets, Amlodipine 10 mg tablets

**Date of last revision: April 2016**

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- Severe increase in blood pressure (Hypertensive crisis)
- Liver disease
- You are elderly and your dose needs to be increased

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Istin may affect or be affected by other medicines, such as:

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#### If you take more Istin than you should

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Do not worry. If you forget to take a tablet, leave out that dose completely. Take your next dose at the right time. Do not take a double dose to make up for a forgotten dose.

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Your doctor will advise you how long to take this medicine. Your condition may return if you stop using this medicine before you are advised.

If you have any 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.

Visit your doctor **immediately** if you experience any of the following side effects after taking this medicine.

- Sudden wheeziness, chest pain, shortness of breath or difficulty in breathing
- Swelling of eyelids, face or lips
- Swelling of the tongue and throat which causes great difficulty breathing

- Severe skin reactions including intense skin rash, hives, reddening of the skin over your whole body, severe itching, blistering, peeling and swelling of the skin, inflammation of mucous membranes (Stevens Johnson Syndrome) or other allergic reactions
- Heart attack, abnormal heart beat
- Inflamed pancreas which may cause severe abdominal and back pain accompanied with feeling very unwell.

The following **very common side effect** has been reported. If this causes you problems or if it **lasts for more than one week**, you should **contact your doctor**.

**Very common: may affect more than 1 in 10 people**

- Oedema (fluid retention)

The following **common side-effects** have been reported. If any of these cause you problems or if they **last for more than one week**, you should **contact your doctor**.

**Common: may affect up to 1 in 10 people**

- Headache, dizziness, sleepiness (especially at the beginning of treatment)
- Palpitations (awareness of your heart beat), flushing.
- Abdominal pain, feeling sick (nausea).
- Altered bowel habits, diarrhea, constipation, indigestion
- Tiredness, weakness
- Visual disturbances, double vision
- Muscle cramps
- Ankle swelling

Other side-effects that have been reported include the following list. If any of these get serious, or if you notice any side-effects not listed in this leaflet, please tell your doctor or pharmacist.

**Uncommon: may affect up to 1 in 100 people**

- Mood changes, anxiety, depression, sleeplessness.
- Trembling, taste abnormalities, fainting.
- Numbness or tingling sensation in your limbs; loss of pain sensation
- Ringing in the ears.
- Low blood pressure.
- Sneezing/running nose caused by inflammation of the lining of the nose (rhinitis)
- Cough
- Dry mouth, vomiting (being sick)
- Hair loss, increased sweating, itchy skin, red patches on skin, skin discoloration
- Disorder in passing urine, increased need to urinate at night, increased number of times of passing urine.
- Inability to obtain an erection; discomfort or enlargement of the breasts in men
- Pain, feeling unwell
- Joint or muscle pain, back pain
- Weight increase or decrease.

**Rare: may affect up to 1 in 1000 people**

- confusion

**Very rare: may affect up to 1 in 10000 people**

- Decreased numbers of white blood cells, decrease in blood platelets which may result in unusual bruising or easy bleeding
- Excess sugar in blood (hyperglycaemia)
- A disorder of the nerves which can cause muscular weakness, tingling or numbness
- Swelling of the gums
- Abdominal bloating (gastritis)
- Abnormal liver function, inflammation of the liver (hepatitis), yellowing of the skin (jaundice), liver enzyme increase which may have an effect on some medical tests
- Increased muscle tension
- Inflammation of blood vessels, often with skin rash
- Sensitivity to light
- Disorders combining rigidity, tremor, and/or movement disorders

**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](http://www.hpra.ie); email: [medsafety@hpra.ie](mailto:medsafety@hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

**5. How to store Istin**

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

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Do not store above 25°C.

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**

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The other ingredients are calcium hydrogen phosphate anhydrous, magnesium stearate, microcrystalline cellulose and sodium starch glycollate.

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10mg tablets: white to off white, emerald shaped tablets engraved AML 10 on one side and the Pfizer logo on the other side.

Istin comes in packs of 28 tablets.

**Product procured from within the EU by the Parallel Product**

**Authorisation Holder:**

**iMed Healthcare Ltd.  
Unit 625 Kilshane Avenue,  
Northwest Business Park  
Ballycoolin, Dublin 15  
Ireland**

**Manufacturer:**

**R-Pharm Germany GmbH,  
Heinrich-Mack-Strasse 35,  
89257 Illertissen,  
Germany.**

**Repackaged by:**

**IMED Pharma Ltd  
Unit 625 Kilshane Avenue  
Northwest Business Park  
Ballycoolin  
Dublin 15  
Ireland**

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

Tablets

Austria, Bulgaria, Denmark, Estonia, Finland, Germany, Hungary, Iceland, Italy, Latvia, Lithuania, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Sweden: Norvasc.

Czech Republic: Zorem

Denmark: Amlodipin Pfizer Ireland, Malta, United Kingdom: Istin

Ireland: Amlodipine Pfizer 5 mg tablets, Amlodipine Pfizer 10 mg tablets

Italy: Amlodipina Pfizer Italia

Spain: Norvas 5 mg comprimidos, Norvas 10 mg comprimidos

United Kingdom: Amlodipine 5 mg tablets, Amlodipine 10 mg tablets

**Date of last revision: April 2016**