

IRYS® 1 mg Film-coated Scored Tablets
IRYS® 2 mg Film-coated Scored Tablets
IRYS® 3 mg Film-coated Scored Tablets
IRYS® 4 mg Film-coated Scored Tablets
IRYS® 6 mg Film-coated Scored Tablets

Glimepiride

Read all of this leaflet carefully before you start taking this medicine.

- 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 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.

What is in this leaflet:

1. What Irys® Film-coated Scored Tablets is and what it is used for
2. What you need to know before you take Irys Film-coated Scored Tablets
3. How to take Irys® Film-coated Scored Tablets
4. Possible side effects
5. How to store Irys® Film-coated Scored Tablets
6. Contents of the pack and other information

1. What Irys® Film-Coated Scored Tablets is and what it is used for

Irys® is an orally active blood sugar lowering drug. This drug belongs to a blood sugar lowering group of medicines called sulfonylureas. Irys® works by increasing the amount of insulin released from your pancreas. The insulin then lowers your blood sugar levels.

Irys® Film-coated Scored Tablets is used to treat a certain form of diabetes (type 2 diabetes mellitus) when diet, physical exercise and weight reduction alone have not been able to control your blood sugar levels.

2. What you need to know before you take Irys® Film-coated Scored Tablets

Do not take Irys® Film-Coated Scored Tablets and tell your doctor if:

- You are allergic (hypersensitive) to Irys® or other sulfonylureas (medicines used to lower blood sugar such as glibenclamide) or sulfonamides (medicines for bacterial infections such as sulfamethoxazole) or any of the other ingredients of this medicine (listed in section 6 what Irys® Film-coated Scored Tablets contains).
- You have insulin dependent diabetes (type 1 diabetes mellitus)
- You have diabetic ketoacidosis (a complication of diabetes when your acid level is raised in your body and you may have some of the following signs: fatigue, feeling sick (nausea), frequent urination and muscular stiffness).
- You are in a diabetic coma.
- You have severe kidney disease.
- You have a severe liver disease

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Irys® Film-coated Scored Tablets.

Warnings and precautions

Talk to your doctor or pharmacist before taking Irys® Film-Coated Scored Tablets

If you are recovering from an injury, operation, infection with fever or from other forms of stress, inform your doctor that temporary change of treatment may be necessary.

If you have severe liver or kidney disorder

If you are not sure if any of these apply to you, talk to your doctor or pharmacist before taking Irys® Film-coated Scored Tablets lowering of the haemoglobin level and breakdown of red blood cells (haemolytic anemia) can occur in patients taking the enzyme glucose-6-phosphate dehydrogenase.

Important information about hypoglycaemia (low blood sugar)

When you take Irys® Film-Coated Scored Tablets, you may get hypoglycaemia (low blood sugar). Please see below for additional information about hypoglycaemia, its signs and treatment.

Following factors could increase the risk of you getting hypoglycaemia:

- Undernourishment, irregular meal time, missed or delayed meal or period of fasting
- Changes to your diet
- Taking more Irys® Film-coated Scored Tablets than needed
- Having kidneys that do not work properly
- Having severe liver disease
- If you suffer from particular hormone-induced disorders (disorders of the thyroid glands, of the pituitary gland or adrenal cortex)
- Drinking alcohol (especially when you skip a meal)
- Taking certain other medicines (See Taking other medicines below)
- If you increase the amount of exercise you do and you don't eat enough food or eat food containing less carbohydrate than usual.

Signs of hypoglycaemia include:

Hunger pangs, headache, nausea, vomiting, sluggishness, sleepiness, problems sleeping, restlessness, aggression, problems with concentration, reduced alertness and reaction time, depression, confusion, problems with your speech and sight, slurred speech, shakiness, partial paralysis, dizziness, helplessness. The following signs may also occur:
sweating, clammy skin, anxiety, fast or increased heart beat, high blood pressure, awareness of your heart beat, sudden sharp pain in the breast that may radiate into neighbouring areas (angina pectoris and cardiac arrhythmias)
If blood sugar levels continue to drop you may suffer from considerable confusion (delirium), develop fits, lose self control, breathing may be shallow and your heart beat slowed down, you may fall into unconsciousness. The clinical picture of a severe reduced blood sugar level may resemble that of a stroke.

Treating hypoglycaemia:

In most cases the signs of reduced blood sugar vanish very quickly when you consume some form of sugar, e.g. sugar cubes, sweet juice, sweetened tea.
You should therefore always take some form of sugar with you (e.g. sugar cubes). Remember that artificial sweeteners are not effective. Please contact your doctor or go to the hospital if taking sugar does not help or if the symptoms recur.

Laboratory Tests

The level of sugar in your blood or urine should be checked regularly. Your doctor may also take blood tests to monitor your blood cell levels and liver function.

Children and adolescents

Irys® Film-coated Scored Tablets is not recommended for use in children under 18 years of age.

Other medicines and Irys® Film-coated Scored Tablets:

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

Your doctor may wish to change your dose of Irys® Film-Coated Scored Tablets if you are taking other medicines, which may weaken or strengthen the effect of Irys® Film-coated Scored Tablets on the level of sugar in your blood.

The following medicines can increase the blood sugar lowering effect of Irys® Film-coated Scored Tablets. This can lead to a risk of hypoglycaemia (low blood sugar):

- Medicines to treat pain and inflammation (phenylbutazone, azopropazone, oxyphenbutazone, aspirin/medicines)
- Medicines used to treat diabetes mellitus (such as insulin or metformin)
- Medicines supporting muscle build up (anabolic)
- Medicines to inhibit blood clotting (coumarin derivatives such as warfarin)
- Medicines used to reduce weight (fenfluramine)
- Medicines called anti-arhythmic agents used to control abnormal heart beat (disopyramide)
- Medicines lowering high cholesterol level (fibrates)
- Medicines lowering high blood pressure (ACE inhibitors)
- Medicines to treat depression (fluoxetine, MAO inhibitors)
- Medicines to treat gout (allopurinol, probenecid, sulfinpyrazole)
- Medicines to treat cancer (cytrophosphamide, ifosfamide, trofosfamide)
- Medicines to treat bacterial and fungal infections (tetracyclines, chloramphenicol, fluconazole, miconazole, quinolones, claritromycin)
- Medicines to treat nasal allergies such as hay fever (triquoalene)
- Medicines to increase circulation when given in a high dose intravenous infusion (pentoxifylline)
- Medicines to treat viral infections (such as interferon, including sulfonamides)
- Medicines used for male sex hormone replacement therapy
- Medicines called sympatholytics to treat high blood pressure, heart failure, or prostate symptoms

The following medicines may decrease the blood sugar lowering effect of Irys® Film-coated Scored Tablets. This can lead to a risk of hyperglycaemia (high blood sugar level):

- Medicines containing female sex hormones (oestrogens, progestogens)
- Medicines to treat high blood pressure called thiazide diuretics
- Medicines used to stimulate the thyroid gland (such as levothyroxine)
- Medicines to treat allergies and inflammation (glucocorticoids)
- Medicines to treat severe mental disorders (chlorpromazine and other phenothiazine derivatives)
- Medicines used to raise heart beat, to treat asthma or nasal congestion, coughs and colds, used to reduce weight, or used in life-threatening emergencies (adrenaline and sympathomimetics)
- Medicines to treat high cholesterol level (nicotinic acid)
- Medicines to treat constipation when they are used long term (laxatives)
- Medicines to treat fits (phenytoin)
- Medicines to treat high blood pressure or lowering blood sugar (diazoxide)
- Medicines to treat severe low blood sugar levels (glucagon)
- Medicines to treat nervousness and sleep problems (barbiturates)
- Medicines to treat infections, tuberculosis (rifampicine)
- Medicines to treat increased pressure in the eye (acetazolamide)

The following medicinal products can increase or decrease the blood sugar lowering effect of Irys® Film-coated Scored Tablets:

-Medicines to treat high blood pressure or heart failure such as beta-blockers, clonidine, guanethidine and reserpine. These can also hide the signs of hypoglycaemia, so special care is needed when taking these medicines.

-Medicines to treat stomach ulcers (called H2 antagonists)

Irys® Film-coated Scored Tablets may either increase or weaken the effects of the following medicines:
-Medicines inhibiting blood clotting (coumarin derivatives such as warfarin)
-Colestevlam, a medicine used to reduce cholesterol, has an effect on the absorption of Irys® Film-coated Scored Tablets. To avoid this effect, you should be advised to take Irys® Film-coated Scored Tablets at least 4 hours before colestevlam.

Irys® Film-coated Scored Tablets with food and drink:

Alcohol intake may increase or decrease the blood sugar lowering action of Irys® Film-coated Scored Tablets in an unpredictable way.

Pregnancy, breast-feeding and fertility:

Pregnancy

Irys® Film-coated Scored Tablets should not be taken during pregnancy. Tell your doctor if you are, you think you might be or are planning to become pregnant.

Breast feeding

Irys® may pass into breast milk. Irys® should not be taken during breast feeding.

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

Driving and using machines:

Your ability to concentrate or react may be reduced if your blood sugar is lowered (hypoglycaemia), or raised (hyperglycaemia) or if you develop visual problems as a result of such conditions. Bear in mind that you could endanger yourself or others (e.g. when driving a car or using machines). Please ask your doctor whether you can drive a car if you:
-have frequent episodes of hypoglycaemia
-have fewer or no warning signals of hypoglycaemia

Irys® Film-coated Scored Tablets contains lactose

If you have been told by your doctor that you cannot tolerate some sugars, contact your doctor before taking this medicinal product.

3. How to take Irys® Film-coated Scored Tablets

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

- Take this medicine by mouth just before or with the first main meal of the day (usually breakfast). If you do not have breakfast you should take the product on schedule as prescribed by your doctor. It is important not to leave out any meal when you are on Irys® Film-coated Scored Tablets
- Swallow the Tablets whole with at least half glass of water. Do not crush or chew the Tablets

How much to take

The dose of Irys® Film-coated Scored Tablets depends on your needs, condition and results of blood and urine sugar tests and is determined by your doctor. Do not take more Film-coated Scored Tablets than your doctor has prescribed.

The usual starting dose is one Irys® 1 mg tablet once a day.

If necessary, your doctor may increase the dose after each 1 - 2 weeks of treatment.

The maximum recommended dose is 6 mg Irys tablet per day.

- A combination therapy of Irys plus metformin or of Irys plus insulin may be started. In such a case your doctor will determine the proper doses of Irys, metformin or insulin individually for you.
- Your dose of Irys® Film-coated Scored Tablets may need to be adjusted if you change weight, change your lifestyle or if you are under a lot of stress. Please speak to your doctor if any of these situations apply to you

If you feel the effect of your medicine is too weak or too strong do not change the dose yourself, but ask your doctor.

If you take more Irys® Film-coated Scored Tablets than you should

If you happen to have taken too much Irys® Film-coated Scored Tablets or an additional dose there is a danger of hypoglycaemia and therefore you should instantly consume enough sugar (e.g. a small bar of sugar cubes, sweet juice, sweetened tea) and inform a doctor immediately. When treating hypoglycaemia due to accidental intake in children, the quantity of sugar given must be carefully controlled to avoid the possibility of producing dangerous hypoglycaemia. Persons in a state of unconsciousness must not be given food or drink. Since the state of hypoglycaemia may last for some time it is very important that the patient is carefully monitored until there is no more danger. Admission into hospital may be necessary, also as a measure of precaution. Show the doctor the package or remaining Tablets, so the doctor knows what has been taken.

Severe cases of hypoglycaemia accompanied by loss of consciousness and coma are cases of medical emergencies requiring immediate medical treatment and admission into hospital. It may be helpful to tell your family & friends to call a doctor immediately if this happens to you.

If you forget to take Irys® Film-coated Scored Tablets

If you forget to take a dose, do not take a double dose to make up for forgotten doses.

If you stop taking Irys® Film-coated Scored Tablets

If you interrupt or stop the treatment you should be aware that the desired blood sugar lowering effect is not achieved or that the disease will get worse again. Keep taking Irys® Film-coated Scored Tablets until your doctor tells you to stop.

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

4. Possible side effects

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

Tell your doctor immediately if you experience any of the following symptoms :

- Allergic reactions (including inflammation of blood vessels, often with skin rash) which may develop into serious reactions with difficulty in breathing, fall in blood pressure and sometimes progressing to shock
- Abnormal liver function including yellowing of the skin and eyes (jaundice), problems with the bile flow (cholestasis), inflammation of the liver (hepatitis) or liver failure
- Allergy (hypersensitivity) of the skin such as itching, rash, hives and increased sensitivity to sun. Some mild allergic reactions may develop into serious reactions
- Severe hypoglycaemia including loss of consciousness, seizure or coma

Other possible side effects with Irys® Film-coated Scored Tablets:

Rare side effects (may affect up to 1 in 1000 people)

- Lower blood sugar than normal (hypoglycaemia) (See Section 2)
 - Decrease in the number of blood cells:
 - Blood platelets (which increases risk of bleeding or bruising)
 - White blood cells (which makes infections more likely)
 - Red blood cells (which can make the skin pale and cause weakness or breathlessness)
- These problems generally get better after you stop taking Irys® Film-coated Scored Tablets
- Very rare side effects (may affect up to 1 in 10,000 people):**
- Allergic reactions (including inflammation of blood vessels, often with skin rash) which may develop into serious reactions with difficulty in breathing, fall in blood pressure and sometimes progressing to shock. If you experience any of these symptoms, tell your doctor immediately.
 - Abnormal liver function including yellowing of the skin and eyes (jaundice), impairment of the bile flow (cholestasis), inflammation of the liver (hepatitis) or liver failure. If you experience any of

these symptoms, tell your doctor immediately.

-Feeling or being sick, diarrhoea, feeling full or bloated, and abdominal pain

-Decrease in the amount of sodium level in your blood (shown by blood tests)

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

- Allergy (hypersensitivity) of the skin may occur such as itching, rash, hives and increased sensitivity to sun. Some mild allergic reactions may develop into serious reactions with swallowing or breathing problems, swelling of your lips, throat or tongue.

Therefore in the event of one of these side effects, tell your doctor immediately.

- Allergic reactions with sulfonylureas, sulfonamides, or related drugs may occur
- Problems with your sight may occur when beginning treatment with Irys® Film-coated Scored Tablets. This is due to changes in blood sugar levels and should soon improve
- Increased liver enzymes
- Severe unusual bleeding or bruising under the skin

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Irys® Film-coated Scored Tablets

- 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 (EXP). The expiry date refers to the last day of that month.
- Do not use this medicine if you notice visible signs of deterioration.
- 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.
- Store at a temperature not exceeding 25 °C.
- Store in the original package in order to protect from moisture.

6. Contents of the pack and other information

For one film-coated Scored Tablet IRYs®	Active substance: Glimepiride	Excipients :
IRYS® 1 mg	1mg	Lactose monohydrate, Cellulose microcrystalline, sodium starch glycolate, magnesium stearate and Opadry II.
IRYS® 2 mg	2mg	
IRYS® 3 mg	3mg	
IRYS® 4 mg	4mg	
		Cellulose microcrystalline, lactose monohydrate, sodium starch glycolate, croscarmellose sodium, polyvinylpyrrolidone, magnesium stearate and Opadry II orange.
IRYS® 6 mg	6mg	

What IRYs looks like and contents of the pack:

Irys Film-coated Scored Tablets.

Product	contents of the pack	AMM N°
	pack size of 30	923 335 1
	pack size of 60	923 335 5
IRYS® 1 mg	pack size of 90	923 335 9
	pack size of 30	923 335 2
IRYS® 2 mg	pack size of 60	923 335 6
	pack size of 90	923 335 10
	pack size of 30	923 335 3
IRYS® 3 mg	pack size of 60	923 335 7
	pack size of 90	923 335 11
	pack size of 30	923 335 4
IRYS® 4 mg	pack size of 60	923 335 8
	pack size of 90	923 335 12
IRYS® 6 mg	pack size of 30	
	pack size of 90	

Marketing authorisation holder and manufacturer:

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Delivery conditions: list I

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THIS IS MEDICATION

- A medication is a product but not like the others.
- A medication is a product that affects your health and its consumption without compliance to the prescription exposes you to danger.
- Strictly follow your doctor's prescription and directions for use, follow the advice of your pharmacist.
- Your doctor and pharmacist are familiar with the medication, its indications and contraindications.
- Do not stop treatment on your own during the prescribed period.
- Do not resume, do not increase doses without consulting your doctor.

Keep medicines out of the reach of children