

Package leaflet: Information for the user**ZICRON® 40 MG TABLETS
(Gliclazide)**

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 Zicron® Tablets are and what they are used for
2. What you need to know before you take Zicron® Tablets
3. How to take Zicron® Tablets
4. Possible Side Effects
5. How to Store Zicron® Tablets
6. Contents of the pack and other information

1. What Zicron® Tablets are and what they are used for

- Zicron® 40 mg Tablets contains the active substance gliclazide, one of a group of medicines sulfonylureas. It is an oral hypoglycaemic medicine (blood sugar lowering drug).
- Zicron® 40 mg Tablets are used to keep blood sugar at the correct level in adults with non-insulin dependent diabetes (type 2) when it is not controlled by diet, physical exercise and weight loss alone.

2. What you need to know before you take Zicron® Tablets**Do not take these Tablets if you:**

- are allergic to Gliclazide or any of the other ingredients of this medicine (listed in section 6), to other medicines of the same group (sulfonylureas), to other related medicines (hypoglycaemic sulphonamides)
- have insulin-dependent diabetes (type 1)
- suffer from severe kidney or liver disease
- have ketone bodies and sugar in your urine (this may mean you have keto-acidosis)
- suffer from a diabetic pre-coma and coma
- are taking miconazole (a treatment for fungal infections) (see section 'Other medicines and Zicron® Tablets')
- are breast-feeding (see Pregnancy, breast-feeding and fertility)

Zicron® Tablets are **not recommended** for use in children.

Warnings and precautions

Talk to your doctor or pharmacist before taking Zicron® Tablets.

You should observe the treatment plan prescribed by your doctor to achieve proper blood sugar levels.

This means, apart from regular tablet intake, you observe the dietary regimen, have physical exercise and, where necessary, reduce weight.

During gliclazide treatment regular monitoring of your blood (and possibly urine) sugar level and also your glycated haemoglobin (HbA1c) is necessary.

In the first few weeks of treatment the risk of having reduced blood sugar levels (hypoglycaemia) may be increased. So particularly close medical monitoring is necessary.

Low blood sugar (Hypoglycaemia) may occur if you:

- take meals irregularly or skip meals altogether, if you are fasting,
- are malnourished,
- change your diet,
- increase your physical activity and carbohydrate intake does not match this increase,
- drink alcohol, especially in combination with skipped meals,
- take other medicines or natural remedies at the same time,
- take too high doses of gliclazide,
- suffer from particular hormone-induced disorders (functional disorders of the thyroid gland, of the pituitary gland or adrenal cortex),
- severely decreased kidney function or liver function.

If you have low blood sugar you may have the following symptoms: headache, intense hunger, nausea, vomiting, weariness, sleep disorders, restlessness, aggressiveness, poor concentration, reduced alertness and reaction time, depression, confusion, speech or visual disorders, tremor, sensory disturbances, dizziness and helplessness.

The following signs and symptoms may also occur: sweating, clammy skin, anxiety, fast or irregular heart beat, high blood pressure, sudden strong pain in the chest that may radiate into nearby areas (angina pectoris).

If blood sugar levels continue to drop you may suffer from considerable confusion (delirium), develop convulsions, lose self control, your breathing may be shallow and your heart beat slowed down, you may become unconscious.

In most cases the symptoms of low blood sugar vanish very quickly when you consume some form of sugar, e.g. glucose tablets, sugar cubes, sweet juice, sweetened tea.

You should therefore always carry some form of sugar with you (glucose tablets, sugar cubes). Remember that artificial sweeteners are not effective.

Please contact your doctor or the nearest hospital if taking sugar does not help or if the symptoms recur.

Symptoms of low blood sugar may be absent, less obvious or develop very slowly or you are not aware in time that your blood sugar level has dropped. This may happen if you are an elderly patient taking certain medicines (e.g. those acting on the central nervous system and beta blockers).

If you are in stress-situations (e.g. accidents, surgical operations, fever etc.) your doctor may temporarily switch you to insulin therapy.

Symptoms of high blood sugar (hyperglycaemia) may occur when gliclazide has not yet sufficiently reduced the blood sugar, when you have not complied with the treatment plan prescribed by your doctor, if you take St John's Wort (*Hypericum*

perforatum) preparations (See section 'Other medicines and Zicron® Tablets'), or in special stress situations. These may include thirst, frequent urination, dry mouth, dry itchy skin, skin infections and reduced performance. If these symptoms occur, you must contact your doctor or pharmacist.

While taking Zicron® Tablets you should:

- follow a regular diet: it is important to eat regular meals, including breakfast and never to miss or delay a meal;
- take your medicine regularly (see **How to take Zicron® Tablets**);
- check your blood glucose regularly as recommended by your doctor.

If you have a family history of or know you have the hereditary condition glucose-6-phosphate dehydrogenase (G6PD) deficiency (abnormality of red blood cells), contact your doctor before taking this medicinal product.

Other medicines and Zicron® Tablets

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

The blood sugar lowering effect of gliclazide may be strengthened and signs of low blood sugar levels may occur when one of the following medicines is taken:

- other medicines used to treat high blood sugar (oral antidiabetics, GLP-1 receptor inhibitors or insulin),
- antibiotics (e.g. sulfonamides, clarithromycin),
- medicines to treat high blood pressure or heart failure (beta blockers, ACE- inhibitors such as captopril or enalapril),
- medicines to treat fungal infections (miconazole, fluconazole),
- medicines to treat ulcers in the stomach or duodenum (H2 receptor antagonists),
- medicines to treat depression (monoamine oxidase inhibitors),
- painkiller or anti-rheumatics (phenylbutazone, ibuprofen),
- medicines containing alcohol.

The blood glucose lowering effect of gliclazide may be weakened and raised blood sugar levels may occur when one of the following medicines is taken:

- medicines to treat disorders of the central nervous system (chlorpromazine),
- medicines reducing inflammation (corticosteroids),
- medicines to treat asthma or used during labour (intravenous salbutamol, ritodrine and terbutaline),
- medicines to treat breast disorders, heavy menstrual bleeding and endometriosis (danazol),
- St John's Wort -*Hypericum perforatum*-preparations.

Blood glucose disturbance (low blood sugar and high blood sugar) can occur when a medicine belonging to a class of antibiotics called fluoroquinolones is taken at the same time as Zicron® Tablets, especially in elderly patients.

Zicron® Tablets may increase the effects of medicines which reduce blood clotting (e.g. warfarin).

Consult your doctor before you start taking another medicinal product, if you go into hospital tell the medical staff you are taking Zicron® Tablets.

Taking Zicron® with food, drink and alcohol

Zicron® Tablets can be taken with food and non-alcoholic drinks.

Drinking alcohol is not recommended as it can alter the control of your diabetes in an unpredictable manner.

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Pregnancy, breast-feeding and fertility

Zicron® Tablets are not recommended for use during pregnancy.

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

You must not take this medicine while you are breast-feeding.

Driving and using machines

Provided your blood glucose levels are satisfactorily controlled on Zicron® Tablets, your ability to drive or use machines should not be affected.

However, if your blood glucose levels become too low, this could adversely affect your concentration, and therefore your ability to perform these tasks.

Ask your doctor whether you can drive a car if you:

- have frequent episodes of low blood sugar (hypoglycaemia),
- have few or no warning signals of low blood sugar (hypoglycaemia).

Zicron® Tablets contain Lactose

If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Zicron® Tablets

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

Change in external factors (weight reduction, change in life style, stress) or improvements in the blood sugar control may require changed gliclazide doses.

The recommended daily dose is one to eight tablets. This depends on the response to treatment. When the total daily dose exceeds four tablets, it should be divided into two equal doses taken morning and evening.

Zicron® Tablets are for oral use. Take your tablet(s) with a glass of water (and preferably at the same time each day). Swallow your tablets whole. Do not chew them.

You must always eat a meal after taking your tablet(s).

If a combination therapy of Gliclazide tablets with metformin, an alpha glucosidase inhibitor, a thiazolidinedione, a dipeptidyl peptidase-4 inhibitor, a GLP-1 receptor agonist or insulin is initiated your doctor will determine the proper dose of each medicine individually for you. If you notice that your blood sugar levels are high although you are taking the medicine as prescribed, you should contact your doctor or pharmacist.

If you take more Zicron® tablets than you should

If you take too many tablets, contact your doctor or the nearest hospital Accident & Emergency department immediately.

The signs of overdose are those of low blood sugar (hypoglycaemia) described in Section 2.

The symptoms can be helped by taking sugar (4 to 6 lumps) or sugary drinks straight away, followed by a substantial snack or meal. If the patient is unconscious, immediately inform a doctor and call the emergency services.

If you forget to take Zicron® Tablets

It is important to take your medicine every day as regular treatment works better. However, if you forget to take a dose of Zicron® Tablets, take the next dose at the usual time. Do not take a double dose to make up for a forgotten dose.

If you stop taking Zicron® Tablets

As the treatment for diabetes is usually life long, you should discuss with your doctor before stopping this medicinal product. Stopping could cause high blood sugar (hyperglycaemia) which increases the risk of developing complications of diabetes.

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.

Low blood sugar (Hypoglycaemia)

The most commonly observed side effect is low blood sugar (hypoglycaemia). For symptoms and signs see section

Warnings and Precautions.

If left untreated, these symptoms could progress to drowsiness, loss of consciousness or possibly coma. If an episode of low blood sugar is severe or prolonged, even if it is temporarily controlled by eating sugar, you should seek immediate medical attention.

If you experience any of below mentioned side effects, stop taking the tablets and contact your doctor immediately. The symptoms generally disappear if the medicine is stopped. Your doctor will decide whether to stop your treatment.

- Skin reactions such as rash, redness, itching, hives, angioedema (rapid swelling of tissues such as eyelids, face, lips, mouth, tongue or throat that may result in breathing difficulty) have been reported. The rash may progress to widespread blistering or peeling of the skin. Exceptionally, signs of severe hypersensitivity reactions (DRESS) have been reported: initially as flu-like symptoms and a rash on the face then an extended rash with a high temperature.
- Decrease in the number of cells in the blood (for instance platelets, red and white blood cells) which may cause paleness, prolonged bleeding, bruising, sore throat and fever.
- There have been isolated reports of abnormal liver function which can cause yellow skin and eyes. If you get this, see your doctor immediately.

Other side effects

Digestive disorders: Abdominal pain, nausea, vomiting, indigestion, diarrhoea and constipation. These effects are reduced when Gliclazide is taken with a meal as recommended.

Eye disorders: Your vision may be affected for a short time, especially at the start of treatment. This effect is due to changes in blood sugar levels.

As for other sulfonylureas, the following adverse events have been observed: cases of severe changes in the number of blood cells and allergic inflammation of the wall of blood vessels, reduction in blood sodium (hyponatraemia), symptoms of liver impairment (for instance jaundice) which in most cases disappeared after withdrawal of the sulfonylurea, but may lead to life threatening liver failure in isolated cases.

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Zicron® Tablets

- Keep this medicine out of the sight and reach of children.
- Do not store above 25°C. Store in the original package.
- Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.
- 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 Zicron® Tablets contain**

- The active substance is Gliclazide. Each tablet contains 40mg of gliclazide.
- The other ingredients are Lactose monohydrate, microcrystalline cellulose, magnesium stearate, purified talc, croscarmellose sodium and povidone.

What Zicron® Tablets look like and contents of the pack

- Zicron® 40mg Tablets are white to off white, circular, flat, bevelled edged, uncoated tablets with '40' on one side, plain on reverse.
- These tablets are available in packs of 20, 28, 56, 60, 84, 100 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Name and address: Bristol Laboratories Ltd,
Unit 3, Canalside, Northbridge Road, Berkhamsted,
Hertfordshire, HP4 1EG, United Kingdom

Telephone: 0044 (0)1442 200922
Fax: 0044 (0)1442 873717
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Zicron® 40mg Tablets: PL 17907/0067

This leaflet was last revised in May 2017

To request a copy of this leaflet in Braille, large print or audio format, please contact the marketing authorisation holder at the address (or telephone, fax, email) above.

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6. Contents of the pack and other information

1. What Zicron® Tablets are and what they are used for

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2. What you need to know before you take Zicron® Tablets**Do not take these Tablets if you:**

- are allergic to Gliclazide or any of the other ingredients of this medicine (listed in section 6), to other medicines of the same group (sulfonylureas), to other related medicines (hypoglycaemic sulphonamides)
- have insulin-dependent diabetes (type 1)
- suffer from severe kidney or liver disease
- have ketone bodies and sugar in your urine (this may mean you have keto-acidosis)
- suffer from a diabetic pre-coma and coma
- are taking miconazole (a treatment for fungal infections) (see section 'Other medicines and Zicron® Tablets')
- are breast-feeding (see Pregnancy, breast-feeding and fertility)

Zicron® Tablets are **not recommended** for use in children.

Warnings and precautions

Talk to your doctor or pharmacist before taking Zicron® Tablets.

You should observe the treatment plan prescribed by your doctor to achieve proper blood sugar levels.

This means, apart from regular tablet intake, you observe the dietary regimen, have physical exercise and, where necessary, reduce weight. During gliclazide treatment regular monitoring of your blood (and possibly urine) sugar level and also your glycated haemoglobin (HbA1c) is necessary.

In the first few weeks of treatment the risk of having reduced blood sugar levels (hypoglycaemia) may be increased. So particularly close medical monitoring is necessary.

Low blood sugar (Hypoglycaemia) may occur if you:

- take meals irregularly or skip meals altogether, if you are fasting,
- are malnourished,
- change your diet ,
- increase your physical activity and carbohydrate intake does not match this increase,
- drink alcohol, especially in combination with skipped meals,
- take other medicines or natural remedies at the same time,
- take too high doses of gliclazide,
- suffer from particular hormone-induced disorders (functional disorders of the thyroid gland, of the pituitary gland or adrenal cortex),
- severely decreased kidney function or liver function.

If you have low blood sugar you may have the following symptoms: headache, intense hunger, nausea, vomiting, weariness, sleep disorders, restlessness, aggressiveness, poor concentration, reduced alertness and reaction time, depression, confusion, speech or visual disorders, tremor, sensory disturbances, dizziness and helplessness.

The following signs and symptoms may also occur: sweating, clammy skin, anxiety, fast or irregular heart beat, high blood pressure, sudden strong pain in the chest that may radiate into nearby areas (angina pectoris).

If blood sugar levels continue to drop you may suffer from considerable confusion (delirium), develop convulsions, lose self control, your breathing may be shallow and your heart beat slowed down, you may become unconscious. In most cases the symptoms of low blood sugar vanish very quickly when you consume some form of sugar, e.g. glucose tablets, sugar cubes, sweet juice, sweetened tea.

You should therefore always carry some form of sugar with you (glucose tablets, sugar cubes). Remember that artificial sweeteners are not effective.

Please contact your doctor or the nearest hospital if taking sugar does not help or if the symptoms recur.

Symptoms of low blood sugar may be absent, less obvious or develop very slowly or you are not aware in time that your blood sugar level has dropped. This may happen if you are an elderly patient taking certain medicines (e.g. those acting on the central nervous system and beta blockers).

If you are in stress-situations (e.g. accidents, surgical operations, fever etc.) your doctor may temporarily switch you to insulin therapy.

Symptoms of high blood sugar (hyperglycaemia) may occur when gliclazide has not yet sufficiently reduced the blood sugar, when you have not complied with the treatment plan prescribed by your doctor, if you take St John's Wort (*Hypericum perforatum*) preparations (See section 'Other medicines and Zicron® Tablets'), or in special

stress situations. These may include thirst, frequent urination, dry mouth, dry itchy skin, skin infections and reduced performance.

If these symptoms occur, you must contact your doctor or pharmacist.

While taking Zicron® Tablets you should:

- follow a regular diet: it is important to eat regular meals, including breakfast and never to miss or delay a meal;
- take your medicine regularly (see **How to take Zicron® Tablets**);
- check your blood glucose regularly as recommended by your doctor.

Blood glucose disturbance (low blood sugar and high blood sugar) can occur when gliclazide is prescribed at the same time as medicines belonging to a class of antibiotics called fluoroquinolones, especially in elderly patients. In this case, your doctor will remind you the importance of monitoring your blood glucose.

If you have a family history of or know you have the hereditary condition glucose-6-phosphate dehydrogenase (G6PD) deficiency (abnormality of red blood cells), contact your doctor before taking this medicinal product.

Other medicines and Zicron® Tablets

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

The blood sugar lowering effect of gliclazide may be strengthened and signs of low blood sugar levels may occur when one of the following medicines is taken:

- other medicines used to treat high blood sugar (oral antidiabetics, GLP-1 receptor inhibitors or insulin),
- antibiotics (e.g. sulfonamides, clarithromycin),
- medicines to treat high blood pressure or heart failure (beta blockers, ACE- inhibitors such as captopril or enalapril),
- medicines to treat fungal infections (miconazole, fluconazole),
- medicines to treat ulcers in the stomach or duodenum (H2 receptor antagonists),
- medicines to treat depression (monoamine oxidase inhibitors),
- painkiller or anti-rheumatics (phenylbutazone, ibuprofen),
- medicines containing alcohol.

The blood glucose lowering effect of gliclazide may be weakened and raised blood sugar levels may occur when one of the following medicines is taken:

- medicines to treat disorders of the central nervous system (chlorpromazine),
- medicines reducing inflammation (corticosteroids),
- medicines to treat asthma or used during labour (intravenous salbutamol, ritodrine and terbutaline),
- medicines to treat breast disorders, heavy menstrual bleeding and endometriosis (danazol).
- St John's Wort -*Hypericum perforatum*- preparations.

Blood glucose disturbance (low blood sugar and high blood sugar) can occur when a medicine belonging to a class of antibiotics called fluoroquinolones is taken at the same time as Zicron® Tablets, especially in elderly patients.

Zicron® Tablets may increase the effects of medicines which reduce blood clotting (e.g. warfarin).

Consult your doctor before you start taking another medicinal product, if you go into hospital tell the medical staff you are taking Zicron® Tablets.

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Taking Zicron® with food, drink and alcohol

Zicron® Tablets can be taken with food and non-alcoholic drinks.

Drinking alcohol is not recommended as it can alter the control of your diabetes in an unpredictable manner.

Pregnancy, breast-feeding and fertility

Zicron® Tablets are not recommended for use during pregnancy.

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

You must not take this medicine while you are breast-feeding.

Driving and using machines

Provided your blood glucose levels are satisfactorily controlled on Zicron® Tablets, your ability to drive or use machines should not be affected.

However, if your blood glucose levels become too low, this could adversely affect your concentration, and therefore your ability to perform these tasks.

Ask your doctor whether you can drive a car if you:

- have frequent episodes of low blood sugar (hypoglycaemia),
- have few or no warning signals of low blood sugar (hypoglycaemia).

Zicron® Tablets contain Lactose

If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Zicron® Tablets

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

Change in external factors (weight reduction, change in life style, stress) or improvements in the blood sugar control may require change in gliclazide doses.

The recommended daily dose is one to eight tablets. This depends on the response to treatment. When the total daily dose exceeds four tablets, it should be divided into two equal doses taken morning and evening.

Zicron® Tablets are for oral use. Take your tablet(s) with a glass of water (and preferably at the same time each day). Swallow your tablets whole. Do not chew them.

You must always eat a meal after taking your tablet(s).

If a combination therapy of Gliclazide tablets with metformin, an alpha glucosidase inhibitor, a thiazolidinedione, a dipeptidyl peptidase-4 inhibitor, a GLP-1 receptor agonist or insulin is initiated your doctor will determine the proper dose of each medicine individually for you. If you notice that your blood sugar levels are high although you are taking the medicine as prescribed, you should contact your doctor or pharmacist.

If you take more Zicron® tablets than you should

If you take too many tablets, contact your doctor or the nearest hospital Accident & Emergency department immediately.

The signs of overdose are those of low blood sugar (hypoglycaemia) described in Section 2.

The symptoms can be helped by taking sugar (4 to 6 lumps) or sugary drinks straight away, followed by a

substantial snack or meal. If the patient is unconscious, immediately inform a doctor and call the emergency services.

If you forget to take Zicron® Tablets

It is important to take your medicine every day as regular treatment works better. However, if you forget to take a dose of Zicron® Tablets, take the next dose at the usual time. Do not take a double dose to make up for a forgotten dose.

If you stop taking Zicron® Tablets

As the treatment for diabetes is usually life long, you should discuss with your doctor before stopping this medicinal product. Stopping could cause high blood sugar (hyperglycaemia) which increases the risk of developing complications of diabetes.

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.

Low blood sugar (Hypoglycaemia)

The most commonly observed side effect is low blood sugar (hypoglycaemia). For symptoms and signs see section **Warnings and Precautions**.

If left untreated, these symptoms could progress to drowsiness, loss of consciousness or possibly coma. If an episode of low blood sugar is severe or prolonged, even if it is temporarily controlled by eating sugar, you should seek immediate medical attention.

If you experience any of below mentioned side effects, stop taking the tablets and contact your doctor immediately. The symptoms generally disappear if the medicine is stopped. Your doctor will decide whether to stop your treatment.

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Digestive disorders: Abdominal pain, nausea, vomiting, indigestion, diarrhoea and constipation. These effects are reduced when Gliclazide is taken with a meal as recommended.

Eye disorders: Your vision may be affected for a short time, especially at the start of treatment. This effect is due to changes in blood sugar levels.

As for other sulfonylureas, the following adverse events have been observed: cases of severe changes in the number of blood cells and allergic inflammation of the wall of blood vessels, reduction in blood sodium (hyponatraemia), symptoms of liver impairment (for instance jaundice) which in most cases disappeared

after withdrawal of the sulfonylurea, but may lead to life threatening liver failure in isolated cases.

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- The other ingredients are Lactose monohydrate, microcrystalline cellulose, magnesium stearate, purified talc, croscarmellose sodium and povidone.

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- These tablets are available in packs of 20, 28, 56, 60, 84, 100 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Name and address: Bristol Laboratories Ltd,
Unit 3, Canalside, Northbridge Road, Berkhamsted,
Hertfordshire, HP4 1EG, United Kingdom
Telephone: 0044 (0)1442 200922
Fax: 0044 (0)1442 873717
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Zicron® 40mg Tablets: PL 17907/0067

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To request a copy of this leaflet in Braille, large print or audio format, please contact the marketing authorisation holder at the address (or telephone, fax, email) above.

V18 05-05-17 D0

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