

**PACKAGE LEAFLET: INFORMATION FOR THE USER****ZICRON® 40mg 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, please ask your doctor or your 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.

**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**

- The name of your medicine is Zicron® 40 mg Tablets. The active ingredient is Gliclazide. Gliclazide belongs to a group of medicines called sulphonylureas that work by lowering the blood glucose (sugar) level.
- Zicron® Tablets are used in the treatment of diabetes mellitus when insulin is not necessary and when diet alone fails to lower blood glucose (sugar).

**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 (sulphonylureas), to other related medicines (hypoglycaemic sulphonamides)
- have insulin-dependant diabetes (type 1)
- suffer from severe kidney or liver problems
- suffer from diabetes complicated with ketosis or acidosis
- suffer from a diabetic pre-coma and coma
- are taking medicines to treat fungal infections (miconazole, see section "Other medicines and Zicron® Tablets")
- are breastfeeding (see Section Pregnancy, breast-feeding and fertility)
- you are diabetic and undergoing surgery, after trauma or during serious infections
- have porphyria (a hereditary disease affecting the liver or bone marrow).

This medicine should **NOT** be given to treat diabetes in children.

**Warnings and precautions**

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

Follow your doctor's advice about diet and treatment. This is to reduce the chances of very low blood sugar (hypoglycaemia).

**Make sure your doctor knows**

- if you have an operation, a serious injury, fever or infection, difficulty in eating,
  - if you plan a pregnancy or become pregnant,
  - if you are taking any of the medicines listed in Other medicines and Zicron® Tablets
  - take too high doses of gliclazide
- Tell your dentist about your treatment.

**Dietary advice**

This medicine may cause episodes of low blood sugar (hypoglycaemia). This is more likely if:

- you are on a strict diet,
- your diet is poorly balanced,
- you are taking prolonged or strenuous exercise,
- you drink alcohol,
- if you are taking several medicines for high blood sugar (See Other medicines and Zicron® Tablets).

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.

**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 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. sulphonamides, clarithromycin),
- medicines to treat high blood pressure or heart failure (beta blockers, Antiarrhythmics, 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.
- Sulphonamide antibiotics, e.g. sulfamethoxazole, co-trimoxazole.
- Antibacterials including clarithromycin, tetracycline compounds, oral forms of miconazole, trimethoprim and chloramphenicol
- Medicines used to reduce high blood fat levels (Lipid lowering agents e.g. clofibrate).
- Hormones such as testosterone or oestrolide
- Medicines used to treat gout (e.g. sulfinpyrazone).
- Medicines used to treat breast or prostate cancer (e.g. aminoglutethimide).
- Thyroid hormones used to treat thyroid problems e.g. thyroxine.

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).
- Medicines which increases urine flow (Diuretics, especially thiazide diuretics, e.g. bendroflumethiazide).
- Oral contraceptives e.g. oestrogens and progesterones.
- Rifamycins (antibacterial medicine)
- Laxatives used for constipation e.g. magnesium hydroxide.
- Adrenocorticotrophic hormones (ACTH) used in the treatment of adrenal insufficiency of central origin.e.g. tetracosactrin.

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

The effect of gliclazide may be diminished when taken along with Diazoxide (for high blood pressure).

The effect of gliclazide may be reduced when taken along with Lithium (to treat mental health problems) and nifedipine (to treat high blood pressure).

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

**Zicron® with food, drink and alcohol:**

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

You are advised **NOT** to drink alcohol with this medicine. Discuss this with your doctor if you have any questions.

**Pregnancy, breast-feeding and fertility:**

Do NOT take this medicine if you are pregnant, think you have become pregnant or intend to become pregnant whilst taking these tablets or are breast-feeding, inform your doctor so that he may prescribe a more suitable treatment for you.

**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.

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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 these tablets exactly as advised by your doctor. You should check with your doctor or pharmacist if you are not sure.
- Swallow the tablets with a glass of water.

#### Adults

- The total daily dose of Zicron® may vary from 40mg to 320mg and the dose required will be adjusted according to your response.
- Initially, a daily dose of 40-80mg will be prescribed. This dose will gradually be increased by your doctor until adequate control is achieved.
- A single dose should not exceed 160mg.
- When higher doses are required, the tablets should be taken twice a day with the main meals of the day.

#### Children

- Zicron® tablets are **NOT** recommended for use in children.

#### Kidney and Liver disorders:

The starting dose should be 40mg daily increasing until adequate control is achieved.

#### If you take more Zicron® tablets than you should

- Contact your nearest hospital casualty (A&E) or your doctor immediately.
- If you take too many tablets it may cause **hypoglycaemia** (too low a level of blood sugar): symptoms may include weakness, headache, sweating, feelings of hunger, raised pulse rate, breathlessness, tremor, problems with vision, loss of muscle co-ordination or anxiety.
- This condition can be improved by taking glucose or sweet drinks.
- Take your medicine in its original packaging with you in order to enable the doctor to identify your medication easily.

#### If you forget to take Zicron®

- If you miss a dose: Take the missed dose as soon as you remember and then take your next dose when it is due. Do not take a double dose to make up for the 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, Zicron® Tablets may sometimes 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.

#### Blood disorders:

Decrease in the number of cells in the blood has been reported (e.g. platelets, red and white blood cells).

This may cause:

- Paleness
- Prolonged bleeding
- Bruising
- Sore throat
- Fever
- tiredness, being short of breath,
- nose bleeds,
- mouth ulcers, severe chills

These symptoms usually vanish when the treatment is discontinued.

#### Liver disorders:

There have been isolated reports of abnormal liver function, which can cause yellow skin and eyes. If you get this, see your doctor immediately. The symptoms generally disappear if the medicine is stopped. Your doctor will decide whether to stop your treatment.

#### Skin disorders:

Skin reactions have been reported 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)
- skin reactions to sunlight.

The rash may progress to widespread blistering or peeling of the skin. (for example, the potentially fatal Stevens-Johnson syndrome or toxic epidermal necrolysis).

#### Digestive disorders:

- Stomach pain or discomfort
- Feeling or being sick
- Vomiting
- Indigestion
- Diarrhoea
- Constipation

#### 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. With sulphonylureas, cases of severe changes in the number of blood cells and allergic inflammation of the wall of blood vessels, reduction in blood sodium (hyponatraemia), have been described. Symptoms of liver impairment (e.g. jaundice) have

been observed which in most cases disappeared after withdrawal of the sulphonylureas, 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](http://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 reach and sight of children.
- Do not store above 25°C. Store in the original package.
- Do not use this medicine after the expiry date (EXP) which is stated in the carton. 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
- 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 Authorization 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  
Email: info@bristol-labs.co.uk

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 licence holder at the address (or telephone, fax, email) above.

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Back

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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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- Zicron® Tablets are used in the treatment of diabetes mellitus when insulin is not necessary and when diet alone fails to lower blood glucose (sugar).

**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 (sulphonylureas), to other related medicines (hypoglycaemic sulphonamides)
  - have insulin-dependant diabetes (type 1)
  - suffer from severe kidney or liver problems
  - suffer from diabetes complicated with ketosis or acidosis
  - suffer from a diabetic pre-coma and coma
  - are taking medicines to treat fungal infections (miconazole, see section "Other medicines and Zicron® Tablets")
  - are breastfeeding (see Section Pregnancy, breast-feeding and fertility)
  - you are diabetic and undergoing surgery, after trauma or during serious infections
  - have porphyria (a hereditary disease affecting the liver or bone marrow).
- This medicine should **NOT** be given to treat diabetes in children.

**Warnings and precautions**

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

Follow your doctor's advice about diet and treatment. This is to reduce the chances of very low blood sugar (hypoglycaemia).

**Make sure your doctor knows**

- if you have an operation, a serious injury, fever or infection, difficulty in eating,
- if you plan a pregnancy or become pregnant,
- if you are taking any of the medicines listed in Other medicines and Zicron® Tablets
- take too high doses of gliclazide

Tell your dentist about your treatment.

**Dietary advice**

This medicine may cause episodes of low blood sugar (hypoglycaemia). This is more likely if:

- you are on a strict diet,
- your diet is poorly balanced,
- you are taking prolonged or strenuous exercise,
- you drink alcohol,
- if you are taking several medicines for high blood sugar (See Other medicines and Zicron® Tablets).

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.

**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 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. sulphonamides, clarithromycin),
- medicines to treat high blood pressure or heart failure (beta blockers, Antiarrhythmics, 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 antirheumatics (phenylbutazone, ibuprofen),
- medicines containing alcohol.

- Sulphonamide antibiotics, e.g. sulfamethoxazole, co-trimoxazole.
- Antibacterials including clarithromycin, tetracycline compounds, oral forms of miconazole, trimethoprim and chloramphenicol
- Medicines used to reduce high blood fat levels (Lipid lowering agents e.g. clofibrate).
- Hormones such as testosterone or octreotide
- Medicines used to treat gout (e.g. sulfinpyrazone).
- Medicines used to treat breast or prostate cancer (e.g. aminoglutethimide).
- Thyroid hormones used to treat thyroid problems e.g. thyroxine.

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:

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- medicines reducing inflammation (corticosteroids),
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- Medicines which increases urine flow (Diuretics, especially thiazide diuretics, e.g. bendroflumethiazide).
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The effect of gliclazide may be diminished when taken along with Diazoxide (for high blood pressure).

The effect of gliclazide may be reduced when taken along with Lithium (to treat mental health problems) and nifedipine (to treat high blood pressure).

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

**Zicron® with food, drink and alcohol:**

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

You are advised **NOT** to drink alcohol with this medicine. Discuss this with your doctor if you have any questions.

**Pregnancy, breast-feeding and fertility:**

Do NOT take this medicine if you are pregnant, think you have become pregnant or intend to become pregnant whilst taking these tablets or are breast-feeding, inform your doctor so that he may prescribe a more suitable treatment for you.

**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).

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Front

**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 these tablets exactly as advised by your doctor. You should check with your doctor or pharmacist if you are not sure.
- Swallow the tablets with a glass of water.

**Adults**

- The total daily dose of Zicron® may vary from 40mg to 320mg and the dose required will be adjusted according to your response.
- Initially, a daily dose of 40-80mg will be prescribed. This dose will gradually be increased by your doctor until adequate control is achieved.
- A single dose should not exceed 160mg.
- When higher doses are required, the tablets should be taken twice a day with the main meals of the day.

**Children**

- Zicron® tablets are **NOT** recommended for use in children.

**Kidney and Liver disorders:**

The starting dose should be 40mg daily increasing until adequate control is achieved.

**If you take more Zicron® tablets than you should**

- Contact your nearest hospital casualty (A&E) or your doctor immediately.
- If you take too many tablets it may cause **hypoglycaemia** (too low a level of blood sugar): symptoms may include weakness, headache, sweating, feelings of hunger, raised pulse rate, breathlessness, tremor, problems with vision, loss of muscle co-ordination or anxiety.
- This condition can be improved by taking glucose or sweet drinks.
- Take your medicine in its original packaging with you in order to enable the doctor to identify your medication easily.

**If you forget to take Zicron®**

- If you miss a dose: Take the missed dose as soon as you remember and then take your next dose when it is due. Do not take a double dose to make up for the 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, Zicron® Tablets may sometimes 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.

**Blood disorders:**

Decrease in the number of cells in the blood has been reported (e.g. platelets, red and white blood cells).

This may cause:

- Paleness
- Prolonged bleeding
- Bruising
- Sore throat
- Fever
- tiredness, being short of breath,
- nose bleeds,
- mouth ulcers, severe chills

These symptoms usually vanish when the treatment is discontinued.

**Liver disorders:**

There have been isolated reports of abnormal liver function, which can cause yellow skin and eyes. If you get this, see your doctor immediately. The symptoms generally disappear if the medicine is stopped. Your doctor will decide whether to stop your treatment.

**Skin disorders:**

Skin reactions have been reported such as:

- Rash
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The rash may progress to widespread blistering or peeling of the skin. (for example, the potentially fatal Stevens-Johnson syndrome or toxic epidermal necrolysis).

**Digestive disorders:**

- Stomach pain or discomfort
- Feeling or being sick
- Vomiting
- Indigestion
- Diarrhoea
- Constipation

**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.

With sulphonylureas, cases of severe changes in the number of blood cells and allergic inflammation of the wall of blood vessels, reduction in blood sodium (hyponatraemia), have been described. Symptoms of liver impairment (e.g. jaundice) have been observed which in most cases disappeared after withdrawal of the sulphonylureas, but may lead to life threatening liver failure in isolated cases.

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**6. Contents of the pack and other information****What Zicron® Tablets contain**

- The active substance is 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**

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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 Authorization 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  
Email: [info@bristol-labs.co.uk](mailto:info@bristol-labs.co.uk)

**Zicron® 40mg Tablets: PL 17907/0067**

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