



### 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. Do not pass it on to others. It may harm them, even if their symptoms 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.

#### In this leaflet:

1. What Eudemine is for
2. Before you take Eudemine
3. How to take Eudemine
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## 1. What Eudemine is for

The name of your medicine is Eudemine 50mg tablets, called Eudemine in this leaflet. They contain the active ingredient diazoxide. Diazoxide belongs to a group of medicines called thiazides. These work by increasing levels of sugar in the blood. Diazoxide is used to treat a condition called 'intractable hypoglycaemia'. This is when the sugar level in your blood has been very low for a long time. A low sugar level in the blood is caused by an increase in the amount of the hormone insulin, being produced by the pancreas. It is important to take this medicine as very low blood sugar can result in unusual behaviour, (such as aggression), sweating, a fast pulse and can lead to a coma, which may occur quite suddenly.

## 2. Before you take Eudemine

### Do not take Eudemine if:

- You are allergic to diazoxide
- You are allergic to any of the other ingredients of Eudemine (see section 6)
- You are allergic to any other thiazide drugs such as bendrofluzide
- This is the first treatment you have been given for your low blood sugar.

If any of the above applies to you talk to your doctor or pharmacist.

### Check with your doctor before taking Eudemine if:

- You have heart problems
- You have kidney problems
- You have high levels of uric acid in your blood or have a history of gout
- You have been told you have low plasma proteins in your blood.

### Tell your doctor if you are taking any of the following medicines:

Eudemine can increase the effect of these medicines:

- Drugs to relieve water retention such as frusemide
- Drugs to lower your blood pressure such as propranolol, methyl dopa or captopril
- Drugs to thin your blood such as warfarin.

Eudemine can cause high blood sugar levels with these medicines:

- Any drugs known as steroids or corticosteroids, such as prednisolone or betamethasone
- An oral contraceptive (the 'Pill') containing oestrogen and progesterone.

Eudemine can reduce the effect of this medicine:

- A drug for epilepsy called phenytoin. Your doctor will regularly check the levels of phenytoin in your blood and may increase your dose.

### Tell your doctor immediately, if any of the following happens to your child taking Eudemine:

abdominal bloating, pain, swelling or discomfort, bloody stools, feeding intolerance (vomiting, poor feeding), lethargy as these may be signs of severe inflammation of the bowel (a condition called necrotising enterocolitis neonatal).

### Pregnancy and breast-feeding

If you are pregnant or trying to become pregnant ask your doctor or pharmacist for advice before taking Eudemine.

Your doctor will tell you if you need to take Eudemine.

If you take Eudemine for a long time whilst you are pregnant it may cause your newborn baby to lose its hair.

Do not take Eudemine if you are breastfeeding.

### Driving and using machines

Eudemine may cause you to feel faint, have difficulty moving, blurred vision and temporary cataracts. If any of these happens to you, do not drive or use machinery.

### Eudemine tablets contain lactose and sucrose

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 Eudemine

Always take Eudemine exactly as your doctor has told you.

### Important:

**Your doctor will choose the dose that is right for you. Your dose will be shown clearly on the label that your pharmacist puts on your medicine. If it does not, or you are not sure, ask your doctor or pharmacist.**

### How much to take

#### Adults and children

- The usual daily starting dose is 5 mg for every kilogram of body weight. The total amount is divided into 2 or 3 doses that are taken throughout the day
- Your doctor may increase your dose until it is right for you
- The usual daily maintenance dose is between 3 and 8 mg for every kilogram of body weight. This total is then divided into two or three doses taken throughout the day.

### People with Kidney problems

If you have kidney problems your doctor may choose a lower dose for you.

### Children with leucine-sensitive hypoglycaemia

For children with a certain type of hypoglycaemia known as 'leucine-sensitive hypoglycaemia', the usual dose is between 15 and 20 mg per kilogram per day.

### Adults with tumours of the pancreas

If you are an adult with tumours of the pancreas which produce large amounts of the hormone insulin you may require high doses of up to 1000 mg per day.

### Medical check-ups

While you are taking this medicine, your doctor may ask you to have checkups. These are to make sure that your medicine is working properly and that the dose you are taking is right for you.

- Your doctor will check your blood sugar levels regularly in the first few days of treatment to see how the drug is working
- Your doctor will regularly check your blood pressure
- Eudemine causes the body to retain water so you may need to take another medicine called a diuretic to

help your body get rid of this water. If you have to take a diuretic (water pill) your doctor may reduce your dose of Eudemine

- Your doctor may prescribe a potassium supplement for you to stop your potassium levels going too low
- Your doctor may check the level of uric acid in your blood if you have a history of high uric acid levels or gout
- If you take Eudemine for a long time your doctor will monitor the levels of your blood cells
- In children the doctor will check the rate they are growing and developing.

#### **If you take more Eudemine than you should**

If you accidentally take too much, immediately go to the nearest hospital casualty department or your doctor.

Too much Eudemine can cause very high levels of sugar in your blood. This will be treated with other drugs to bring your blood sugar back to normal. Too much Eudemine may also cause your blood pressure to fall and again, you may be given other medicines to bring this back to normal.

#### **If you forget to take Eudemine**

Do not take a double dose to make up for

a missed dose. Simply take the next dose as planned.

#### **If you stop taking Eudemine**

Do not stop taking Eudemine without first talking to your doctor.

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

### **4. Possible side effects**

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

**Seek immediate medical help if you feel faint or dizzy, especially when you stand up.**

#### **Effects on your heart and circulation**

- Fast or irregular heartbeat (palpitations)
- Chest pains
- Collapse
- Anaemia (which may make you feel tired)
- Reduced blood platelets (which increases the chances of bleeding or bruising)
- Changes to white blood cells (which may cause a sore throat and fever)
- Pericardial effusion (fluid around the heart) (you may experience shortness of breath, trouble breathing when lying down, chest pressure or pain, light-headedness and swelling of the abdomen or legs).

#### **Effects on the nervous system**

- Coma
- Symptoms similar to those seen in Parkinson's disease, such as shaking of the hands, difficulty moving and rolling of the eyes. Your doctor may treat these with an anti-Parkinson's drug

- Headache

#### **Effects on liver or kidneys**

- Weight gain
- Feeling bloated and swollen
- Changes in the way the liver and kidney's work, seen from blood or urine test results.

#### **Effects on stomach and bowels**

- Feeling and being sick, especially during the first 2-3 weeks of taking Eudemine. Your doctor may give you another medicine to stop this.
- Stomach pain
- Loss of appetite
- Diarrhoea
- Constipation
- Necrotising enterocolitis (tissue areas of the intestine become inflamed and start to die which can lead to serious infections). Symptoms can include trouble digesting food, bloated or swollen abdomen, swelling, diarrhea, constipation.

#### **Not known**

Intestinal inflammation with bloody stools and tissue death in newborn babies (necrotising enterocolitis neonatal).

#### **Effects on the eyes and skin**

- Sensitivity reactions such as rash or fever
- Blurred vision
- Cataracts which are temporary
- Increased growth of body hair.

#### **Other effects**

- Breathlessness
- Muscle pain
- High levels of uric acid in the blood (which may cause joint pain)
- Changes to voice and abnormal facial features in children
- Hyperglycaemia (high sugar levels in the blood) which may cause you to pass large amounts of urine and/or make you thirsty.

#### **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. You can also report side effects directly via Yellow Card Scheme on the MHRA website ([www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)) or search for MHRA Yellow Card in the Google

Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

### **5. How to store Eudemine Tablets**

Store below 25°C

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

Do not use Eudemine after the expiry date on the label. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Return any medicine you no longer need to your pharmacist.

### **6. Further information**

#### **What Eudemine contains**

The active substance is diazoxide 50 mg. The other ingredients are lactose, maize starch pre-gelatinised, magnesium stearate, purified water.

The tablet coating consists of sugar, gelatin coarse powder 200 bloom, purified water, carnauba wax (E903), beeswax, white (E901), polysorbate 20 (E432) and sorbic acid (E200).

#### **What Eudemine looks like?**

Eudemine tablets are white to off white, round, biconvex, sugar-coated tablets. Eudemine comes in plastic containers containing 100 tablets.

#### **Marketing Authorisation holder**

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#### **Manufacturer**

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**If this leaflet is difficult to see or read or you would like it in a different format, please contact RPH Pharmaceuticals AB Box 603, 101 32 Stockholm, Sweden**