

Package leaflet: Information for the user

## **Diurexan 20 mg tablets**

Xipamide

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may have 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 Diurexan is and what it is used for
2. What you need to know before you take Diurexan
3. How to take Diurexan
4. Possible side effects
5. How to store Diurexan
6. Contents of the pack and other information

### **1. What Diurexan is and what it is used for**

Diurexan belongs to the group of medicines known as diuretics. Diuretics are often referred to as water tablets.

Diurexan removes excess water from the body by increasing how often you urinate. It is used to treat high blood pressure (hypertension) and too much fluid in the body (oedema), often caused by heart failure or problems with your liver or kidneys.

### **2. What you need to know before you take Diurexan**

#### **Do not take Diurexan if:**

- You are allergic to Xipamide
- You are allergic to any of the other ingredients of Diurexan (listed in section 6)
- You have low levels of salts in your blood sometimes caused by severe vomiting or diarrhoea
- You have liver disease that is causing you to become unconscious
- You have severe kidney disease
- You have untreated Addison's disease – a condition in which your adrenal glands do not produce sufficient levels of natural steroid in the blood
- You have symptomatic hyperuricaemia, for example gout or you have too much uric acid in your urine
- You have gallstones
- You have hypercalcaemia (high levels of calcium in your blood)
- You have pre-existing hypovolaemia (low blood volume sometimes caused by severe vomiting, dehydration, severe bleeding)
- You are pregnant or think you may be pregnant
- You are breast feeding.

### **Warnings and precautions**

**Talk to your doctor or pharmacist before taking Diurexan if:**

- You have diabetes
- You have kidney or liver disease
- You have an enlarged prostate gland or trouble urinating
- You suffer with coronary or cerebral arteriosclerosis (narrowing of the arteries in the heart or brain)
- Your body produces too much aldosterone, a hormone which controls salt and water balance (hyperaldosteronism)
- You have diarrhoea
- You are malnourished (a severe lack of food)
- You are being sick
- You are over 65 years
- You have an intolerance to some sugars
- You are alcohol dependent
- You experience a decrease in vision or eye pain. These could be symptoms of fluid accumulation in the vascular layer of the eye (choroidal effusion) or an increase of pressure in your eye and can happen within hours to a week of taking Diurexan. This can lead to permanent vision loss, if not treated. If you earlier have had a penicillin or sulfonamide allergy, you can be at higher risk of developing this.

**Other medicines and Diurexan**

- Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including: Any other diuretic medicines
- Medicines to treat high blood pressure
- Cardiac glycosides, such as digoxin, used to treat heart problems
- Anti-diabetics, such as insulin, used to treat diabetes
- Lithium (to treat mental problems)
- Antipsychotics (to treat schizophrenia)
- Anti-depressants (to treat depression)
- Medicines to treat an irregular or abnormally fast or slow heart beat
- Medicines or substances that affect your heart rate (check the patient information leaflet of your medicine)
- Non-steroidal anti-inflammatory drugs (NSAIDs) such as indomethacin
- Baclofen, a medicine used to treat muscle spasticity problems, i.e. for the treatment of multiple sclerosis (MS)
- Anti-epileptic medicines such as phenytoin and carbamazepine used to treat epilepsy and bipolar disorder
- Amifostine, a medicine used to protect against the effects of chemotherapy and radiotherapy
- Medicines for treating urological diseases
- Immunosuppressant's, such as cyclosporine and tacrolimus (to prevent transplanted organs being rejected)
- Chemotherapy medicines such as cytostatics, used to treat cancer
- Cholesterol lowering medicines such as colestipol and cholestyramine
- Halofantrine, used to treat malaria
- Mizolastine, an anti-histamine used to treat allergies

If you are taking any of these medicines at the same time as Diurexan, your doctor may adjust the dose you take.

Also tell your doctor if you are taking:

- Steroids used to treat many conditions including asthma, arthritis, eczema and dermatitis
- ACTH, a medicine used to test if your pituitary gland is working properly
- Carbenoxolone used to treat ulcers and inflammation of the oesophagus (gullet)
- Antibiotics used to treat fungal and bacterial infections
- Laxatives

These medicines may cause the level of potassium in your blood to fall when used at the same time as Diurexan.

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

### **Diurexan with food, drink and alcohol**

Avoid drinking alcohol while taking Diurexan.

### **Pregnancy and breast-feeding**

Do not take Diurexan if you are pregnant, trying to become pregnant or are breastfeeding.

### **Driving and using machines**

Diurexan may affect your reactions and therefore your road safety and ability to use machinery. Do not drive or operate machinery if you feel unwell.

## **3. How to take Diurexan**

Always take Diurexan exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

### **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.**

### **For high blood pressure:**

The usual dose is one tablet per day, taken early in the morning.

### **For excessive fluid retention:**

The usual starting dose is two tablets per day, taken early in the morning. Once your doctor has seen how the medicine is working, they may change your dose. They may reduce it to one tablet per day. If the medicine is not having much effect your doctor may increase your dose to 3 or 4 tablets per day.

### **Medical check-ups:**

Taking Diurexan for a long time can cause you to lose potassium from your blood. Your doctor will check for this and may prescribe you extra potassium especially if you are elderly or getting little potassium in your diet.

### **If you take more Diurexan than you should:**

If you accidentally take too much Diurexan, go immediately to the nearest hospital casualty department or your doctor. Taking too much of this medicine may cause you to lose too much fluid from your body. This can cause you to feel or be sick, feel faint, dizzy, or confused and

change the make-up of your blood. You may have your stomach washed out and an infusion into your vein to replace lost fluids.

**If you forget to take Diurexan:**

Do not take a double dose to make up for a missed dose. Simply take your dose as planned. If you have any further question on the use of this product, ask your doctor or pharmacist.

**4. Possible side effects**

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

**Seek immediate medical help if you have any of the following symptoms:**

- **You have difficulty breathing**
- **Your face or throat swells**
- **You have a severe rash that may blister**

**Tell your doctor if you have any of the following symptoms, they may need to stop your treatment with Diurexan:**

- **An allergic skin reaction which may cause redness, itching or a rash**
- **Severe stomach pains and feeling or being sick**
- **Muscle cramps or weakness**
- **Extreme tiredness**
- **Dizziness upon standing**
- **Decrease in vision or pain in your eyes due to high pressure (possible signs of fluid accumulation in the vascular layer of the eye (choroidal effusion) or acute angle-closure glaucoma)**

**Very common side effects** (affects more than 1 in 10 people):

- Low potassium levels in the blood (hypokalaemia) which may make cause headaches, muscles cramps, or weakness and make you feel or be sick.

**Common side effects** (affect less than 1 in 10 people):

- Tiredness or exhaustion
- Anxiety
- Agitation
- Headache
- Dizziness
- Dry mouth
- Sweating
- Palpitations (awareness of an abnormal beating of the heart)
- Dizziness or light-headedness upon standing which may cause you to collapse (you may have low blood pressure)
- Effects on your stomach or intestine such as stomach pain, constipation and diarrhoea
- Muscle spasms or cramps
- Dehydration
- Low sodium, magnesium or chloride levels in the blood (hyponatraemia, hypomagnesaemia and hypochloremia respectively) which may cause headaches, muscle cramps or weakness and make you feel or be sick

**Uncommon side effects** (affect less than 1 in 100 people):

- Photosensitivity (sensitivity to sunlight)

**Rare side effects (affect less than 1 in 1000 people):**

- Disturbed or blurred vision
- Pancreatitis (sudden inflammation of the pancreas)
- Inflammation of the gall bladder or gall stones
- Allergic skin reactions which may cause redness, itching or a rash
- Hyperlipidemia (raised lipid levels in your blood)

**Very rare side effects (affect less than 1 in 10,000 people):**

- Problems with your blood cells, such as a low white blood cell count or anemia
- Jaundice
- Problems with your kidneys

**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) or search for MHRA Yellow Card in 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 Diurexan**

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

Do not use Diurexan after the expiry date which is stated on 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 Diurexan contains**

The active substance is Xipamide. Each tablet contains 20 mg of Xipamide.

The other ingredients are maize starch, mannitol, cellulose powder, colloidal silicon dioxide, magnesium stearate and purified water.

**What Diurexan looks like**

Diurexan tablets are white and round with a notch on one side and an “A” on the other. They are about 6mm in diameter. They come in blister strips of 14 tablets with 10 blister strips in a box.

**Marketing Authorisation Holder is:**

Mylan Products Ltd. Station Close, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom

**Manufacturer is:**

Sidefarma, S.A., Rua da Guiné, nº 26, 2689-514 Prior Velho, PORTUGAL.

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**If this leaflet is difficult to see or read and you would like it in a different format, please contact Mylan Products Ltd. Station Close, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom.**