

## **Package leaflet: Information for the user**

### **Metolazon Abcur 5 mg tablets**

metolazone

**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 Metolazon Abcur is and what it is used for
2. What you need to know before you take Metolazon Abcur
3. How to take Metolazon Abcur
4. Possible side effects
5. How to store Metolazon Abcur
6. Contents of the pack and other information

#### **1. What Metolazon Abcur is and what it is used for**

Metolazon Abcur is a diuretic drug containing the active substance metolazone. It is used in the treatment of oedema (liquid accumulations in the tissues) of kidney diseases resistant to other therapy.

#### **2. What you need to know before your take Metolazon Abcur**

##### **Do not take Metolazon Abcur**

- if you are allergic to metolazone or any of the other ingredients of this medicine (listed in section 6)
- if you ever have had an allergic reaction to diuretics belonging to a group called sulphonamides or thiazides
- if you are no longer able to urinate
- in case of coma or comatose conditions which is caused by liver cirrhosis
- if you have a serious disorder of the electrolyte balance in your blood

##### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Metolazon Abcur

- if you suffer from any additional disease, especially kidney disease, diabetes or rheumatism. Inform your doctor about your disease.
- if you experience an infection with symptoms such as fever and serious deterioration of your general condition, or fever with local infection symptoms such as sore throat/pharynx/mouth or urinary problems. Then you should see your doctor immediately. Metolazon Abcur may cause a reduction in the number of white blood cells and your resistance to infection may be decreased. A blood test will be taken to check possible reduction of white blood cells (agranulocytosis). It is important to inform your doctor about your medicine.
- if you will undergo surgery. Then your dose of Metolazon Abcur must be carefully adjusted. Inform your doctor about the surgery.
- if 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 weeks of taking Metolazon Abcur. 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 Metolazon Abcur**

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

You should inform your doctor about all additional medicines you may have been using (herbal medicine included). This is especially important, if you are using the following medicines:

- Lithium (used for treatment of a particular kind of depression)
- Digoxin (used for treatment of heart insufficiency)
- NSAIDs (used for treatment of pain, fever and inflammation)
- Ciclosporin (a drug that affects the immune system)
- Diuretics (other than Metolazon Abcur; used for treatment of kidney diseases, high blood pressure, heart failure and liver cirrhosis)
- ACE inhibitors (used for treatment of high blood pressure and heart failure)
- Warfarin (used to prevent blood clotting)
- Insulin or oral antidiabetics
- Corticosteroids
- ACTH (a pituitary hormone)
- Sotalol (used for treatment of heart diseases and hypertension)
- Barbiturates (used for treatment of insomnia, anxiety and epilepsy)
- Angiotension-II-antagonists (used for treatment of high blood pressure, heart failure and kidney damage due to diabetes)

### **Metolazon Abcur with food, drink and alcohol**

If you take Metolazon Abcur in combination with alcohol, your blood pressure may decrease and result in dizziness, debility and fatigue.

You should take the tablet with the same meal each day, eg breakfast.

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

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

You should not use Metolazon Abcur during pregnancy and the lactation period.

### **Driving and using machines**

No studies on the effects on the ability to drive and use machines have been performed. However, treatment with Metolazon Abcur may cause adverse reactions affecting the ability to drive a vehicle or to operate machines, such as tiredness and dizziness. If you feel tired or drowsy, you should not drive or use machines.

### **Metolazon Abcur contains lactose monohydrate and sodium**

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

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

## **3. How to take Metolazon Abcur**

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

Initially the dose should be 2.5 mg per day. The tablets have a break notch on one side and can be divided into equal doses. Your doctor may adjust the dose according to your individual reaction on the medicine and increase the dose if necessary.

You should take the tablet with the same meal each day, eg breakfast.

You should not change the prescribed dose on your own initiative. If you believe, you are not getting the adequate dose, please contact your doctor or pharmacist.

#### **If you take more Metolazon Abcur than you should**

Contact a doctor or hospital for risk assessment and advice if you have taken too large a dose of the medicine, or if for example, a child has ingested the medicine by mistake.

An overdose of Metolazon Abcur might lead to thirst, nausea, vomiting, disorientation, drowsiness, muscle cramps and low blood pressure. In severe cases an overdose may result in irregular heart rate.

#### **If you forget to take Metolazon Abcur**

Do not take a double dose to make up for a forgotten tablet.

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.

Stop taking Metolazon Abcur and contact a doctor or go to your nearest emergency department immediately if you experience any of the following symptoms:

Rare: may affect up to 1 in 1,000 people

- Flu-like symptoms, sore throat/pharynx/mouth, fatigue or urinary problems. This may be caused by a decrease in your white blood cells (agranulocytosis)
- A severe skin reaction, starting with a painful red area, developing into large blisters then peeling of layers of skin (toxic epidermal necrolysis)

Other side effects that may occur in connection with the use of Metolazon Abcur:

Common: may affect up to 1 in 10 people

- Nausea, vomiting, congestion and diarrhoea
- Muscle cramps
- Headache, dizziness and tiredness
- Low levels of potassium, sodium and chloride in the blood
- High levels of uric acid, urea and creatinine and sugar in the blood
- Glucose in the urine

Uncommon: may affect up to 1 in 100 people

- Reduced number of white blood cells (leukopenia)
- Skin rash
- Inflammation in the blood vessels
- Gout

Rare: may affect up to 1 in 1,000 people

- Reduced number of red blood cells
- Reduced number of platelets in the blood
- High levels of calcium in the blood
- Low levels of magnesium in the blood
- Hepatitis and intrahepatic cholestasis
- Renal failure

Not known: frequency cannot be estimated from the available data

- 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).

#### **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 [the national reporting system listed in Appendix V\\*](#). By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Metolazon Abcur**

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

Store in the original package in order to protect from light.

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 to protect the environment.

## **6. Contents of the pack and other information**

### **What Metolazon Abcur contains**

- The active substance is metolazone 5 mg.
- The other ingredients are croscarmellose sodium, microcrystalline cellulose, lactose monohydrate and sodium stearyl fumarate.

### **What Metolazon Abcur looks like and contents of the pack**

Metolazon Abcur tablets are round, biplanar and white to off-white with bevelled edges and a single break notch. The tablets can be divided into equal doses.

Metolazon Abcur is supplied in blister packs with 20, 28, 30, 50, 56, 60, 98 or 100 tablets. Not all pack sizes may be marketed.

### **Marketing Authorisation Holder**

To be completed nationally

### **Manufacturer**

Formula Pharmazeutische und chemische Entwicklungs GmbH  
Goerzallee 305 b  
14167 Berlin  
Germany

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