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PACKAGE LEAFLET: INFORMATION FOR THE USER

Xaqua 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 symptoms are the same as yours.
- If you get any of the 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 Xaqua is and what it is used for
2. What you need to know before you take Xaqua
3. How to take Xaqua
4. Possible side effects
5. How to store Xaqua
6. Contents of the pack and other information

1. WHAT IS XAQUA AND WHAT IS IT USED FOR

Xaqua is a diuretic drug containing the active substance metolazone.

It is used for the treatment of:

- fluid retention (oedema) related to the heart and kidneys by increasing the flow of urine.
- high blood pressure, taken alone or with other medication.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE XAQUA

Do not take Xaqua

- if you are allergic (hypersensitive) to Metolazone, to thiazides, to sulfonamides or any of the other ingredients of this medicine (listed in section 6).
- if you are no longer able to urinate
- in case of coma or comatose conditions which is caused by liver cirrhosis
- in case of severe disturbances to the balance of salts or chemicals in the blood

Warning and precautions

Talk to your doctor or pharmacist before taking Xaqua:

- If you have severe kidney or liver disease.
- If you are elderly, your doctor may want to monitor you more closely.
- If you have a fluid or electrolyte imbalance in your blood (e.g. sodium, calcium or potassium), your doctor may want to monitor you more closely. Symptoms can include thirst, nausea, vomiting, disorientation, drowsiness, muscle cramps, low blood pressure and irregular heart rate.
- If you have Addison's disease (syndrome due to low level of corticosteroid hormones secretion, symptoms include weakness, loss of energy, low blood pressure and dark pigmentation of the skin).
- If you have diabetes. Blood sugar levels should be checked on a regular basis.
- If you have gout (high levels of uric acid in the blood)
- If you have systemic lupus erythematosus (an inflammatory disease of connective tissue causing large areas of red scaly patches on the face, hair loss, painful joints and fever).
- If you have brain or nervous system disorders (porphyria)
- 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. 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.
- If you have high cholesterol
- This product contains lactose. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. You should inform your doctor about all additional drugs you may have been using (herbal medicine included). This is especially important, if you are using the following medications:

- Other blood pressure treatments and diuretics.
- Muscle relaxants such as tubocurarine.
- Cyclosporine (a drug that affects the immune system).
- Alcohol, barbiturates and narcotics.
- Antidiabetic medicinal products.
- Corticosteroids and ACTH (a pituitary hormone) or drugs known to reduce the amount of potassium in the blood.
- Digoxin (used for treatment of heart insufficiency).
- Antiarrhythmic Drugs (e.g. sotalol used for treatment of heart diseases and hypertension).
- Non-steroidal anti-inflammatory drugs (used for treatment of pain, fever and inflammation).
- Medicines called 'pressor amines' such as noradrenaline.
- Medicines used in gout.
- Calcium salts.
- Lithium (used for treatment of a particular kind of depression).
- Anticoagulants (used to prevent blood clotting).
- Methenamine (is an antibiotic that stops the growth of bacteria in urine).

Xaqua with food, drink and alcohol

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

Pregnancy and breast-feeding

Xaqua tablets should not be used in pregnant or breast-feeding women. Speak to your doctor or pharmacist before taking any medicine.

Driving and using machines

Metolazone may cause adverse reactions affecting the ability to drive a vehicle or to operate machines, such as dizziness and fatigue. If you feel tired or drowsy, you should not drive or use machines.

Important information about some of the ingredients of Xaqua

Xaqua contains lactose monohydrate. 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 XAQUA

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

The tablets have a score-line on one side and can be divided into equal halves. You should take the tablet with the same meal each day, e.g. breakfast.

Adults

Initially the dosage should be 2.5 mg per day (half a tablet). Your doctor may adjust the dosage to 5mg per day (whole tablet)

according to your individual reaction if necessary.

Oedema (fluid retention): 2.5-5mg per day

Hypertension (high blood pressure): 2.5-5mg per day.

Elderly

Xaqua should be used with caution in elderly patients.

Children

Xaqua in children aged under 18 years is not recommended.

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

If you take more Xaqua than you should

If you (or someone else) swallow a lot of tablets at the same time, or you think a child may have swallowed any, contact your nearest hospital casualty department or tell your doctor immediately.

An overdose of Xaqua might lead to dehydration and electrolyte disturbances and as a consequence you may experience thirst, nausea, vomiting, disorientation, drowsiness, muscle cramps and low blood pressure. In severe cases an overdose may result in irregular heart rate. Treatment for overdosing involves fluid and electrolyte replacement.

If you forget to take Xaqua

If you forget to take a dose, take it as soon as you remember it and then take the next dose at the right time. Do not take a double dose to make up for a forgotten dose.

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

4. POSSIBLE SIDE EFFECTS

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

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please contact your doctor or pharmacist.

The following side effects may occur in connection with the use of Xaqua:

Common (occurring in more than 1 out of 100 patients)

- Nausea, vomiting, constipation and diarrhoea
- Muscle pain and cramps
- Headache, dizziness and fatigue
- Low blood pressure and dizziness on standing due to low blood pressure (orthostatic hypotension)
- Low levels of potassium, sodium, magnesium and chloride in the blood
- High levels of uric acid, urea and creatinine and sugar in the blood
- Glucose in the urine.

Uncommon (occurring in less than 1 out of 100 patients)

- Reduced number of white blood cells
- Skin rash, Hives
- Inflammation of the blood vessels
- Joint pain, Gout

Rare (occurring in less than 1 out of 1000 patients)

- Reduced number of red blood cells
- Reduced number of white blood cells (agranulocytosis)
- Reduced number of platelets in the blood
- High levels of calcium in the blood
- Low level of phosphates in the blood
- Low levels of magnesium in the blood
- Allergic reactions, including anaphylactic shock
- Psychotic depression, confusion
- A disturbance in the function of the brain or spinal cord that may affect the nerves and muscles of the body (Neuropathy), vertigo, Tingling of the skin, sleepiness, drowsiness, weakness, apathy, restlessness, seizures, liver related brain disease
- Temporarily blurred vision
- Fast heartbeat, chest pain, palpitation
- Fainting spell, dehydration, concentrated blood, blood clot in a vein
- Abdominal pain, anorexia, abdominal bloating
- Inflammation of the liver (Hepatitis) and potential liver disorder that can develop in pregnancy (intrahepatic cholestasis), inflammation of the pancreas
- Renal insufficiency, decreased amount of urine
- Erectile dysfunction
- Chills
- Increased LDL cholesterol, increased triglycerides
- A severe skin reaction, starting with a painful red area, developing into large blisters then peeling of layers of skin (*toxic epidermal necrolysis*). A less severe skin reaction, starting with a painful red area, developing into large blisters then peeling of layers of skin (Stevens-Johnsons Syndrome, Small purple-red marks in skin or other tissue caused by bleeding, skin inflammation (sensitivity to light)

Reporting of side effect:

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 Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for the MHRA Yellow Card in the Google Play or Apple App Store.

5. HOW TO STORE XAQUA

This medicinal product does not require any special temperature storage conditions.

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

Keep out of the reach and sight of children.

Do not use Xaqua after the expiry date which is stated on the carton after "EXP." The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Xaqua contains

- The active substance (the ingredient that makes the tablet work) is Metolazone 5 mg.
- The other ingredients are microcrystalline cellulose, lactose monohydrate, croscarmellose sodium and sodium stearyl fumarate.

What Xaqua looks like and contents of the pack

Xaqua 5mg tablets are round, biplanar, white to off-white tablets with beveled-edges and score-line.

Xaqua is supplied in blister packs with 20, 60 or 100 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder

Renascience Pharma Limited, 11 George street West, Luton, LU1 2BJ, United Kingdom

Manufacturer

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

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