

EDEMID FORTE

500mg tablets

FUROSEMIDE

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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 •

What is in this leaflet?

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1. WHAT EDEMID FORTE TABLETS ARE AND WHAT THEY ARE USED FOR

Edemid Forte tablets is one of a group of medicines called diuretics (water tablets). They are used to treat the abnormally low production of urine caused by kidney disorders.

2. BEFORE YOU TAKE

Do not take Edemid Forte tablets if you:

- are allergic (hypersensitive) to furosemide, other sulphonamide related drugs or any of the other ingredients in Edemid Forte tablets
- have severe kidney damage which has stopped them working properly and producing urine
- have very low levels of potassium, sodium or other electrolytes in your blood or low blood volume (your doctor will be able to advise you)
- are dehydrated
- have low blood pressure
- take potassium supplements or potassium sparing diuretics for high blood pressure (e.g. amiloride or spironolactone)

- have liver cirrhosis (tiredness, weakness, water retention, feeling or being sick, loss of weight or appetite, yellowing skin or eyes, itch) or liver encephalopathy (confusion, altered levels of consciousness and coma as a result of liver failure)
- have Addison's disease (low levels of corticosteroid hormones secreted)
- have digitalis poisoning (feeling or being sick, high levels of potassium in the blood, slow, fast or irregular heart beats).
- are breast-feeding

Check with your doctor or pharmacist before taking Edemid Forte tablets if you have:

- low blood volume (hypovolaemia) or are at risk of developing low blood pressure
- low levels of protein in the blood (hypoproteinaemia) as a result of kidney damage
- liver congestion (slowed blood flow through the vessels) or other liver problems
- kidney problems
- or may have diabetes. If you are taking insulin, your doctor may need to adjust your insulin dosage
- are an elderly patient
- prostate trouble or difficulty passing urine
- or have had gout
- have an abnormal blood condition
- are about to undergo any blood or urine tests

Your doctor will want to monitor you, and may take blood for testing while you are taking 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. Especially:

- drugs to lower blood pressure, such as ACE inhibitors, alpha blockers, calcium channel blockers, diuretics
- drugs to treat mental illness (e.g. pimozide, amisulpride)
- drugs for arrhythmias (e.g. sotalol, amiodarone, flecainide)
- digoxin for your heart
- moxisylyte for Raynaud's syndrome
- nitrates (for angina)
- lithium for depression or mania
- colestyramine or colestipol for high cholesterol
- non-steroidal anti-inflammatory drugs (NSAIDs) e.g. ibuprofen or naproxen
- aspirin for pain
- antibiotics for infections that affect your kidneys or ears (e.g. cefaclor, colistin, gentamicin, vancomycin)
- amphoterecin (to treat fungal infections)
- chloral hydrate (to treat insomnia)
- antidepressants (e.g. monoamine oxidase inhibitors (MAOIs))
- medicines to control diabetes such as insulin or tablets
- antiepileptics e.g. phenytoin or carbamazepine
- corticosteroids or antihistamines (to treat allergic reactions)
- drugs for ADHD
- drugs treating cancer
- levodopa (for Parkinson's disease)
- oral contraceptives
- alprostadil for erectile dysfunction
- certain treatments for asthma such as theophylline or salbutamol
- probenecid to prevent gout
- laxatives used over a long period of time

- medicines or foods containing liquorice
- if you are about to undergo a procedure where curariform muscle relaxants (e.g. vecuronium) or anaesthetics may be used, tell your anaesthetist/dentist or healthcare professional

Pregnancy and breast-feeding

Speak to your doctor before you take Edemid Forte tablets if you are pregnant, thinking of getting pregnant, or breast-feeding.

Driving and using machines

Do not drive or operate machinery if you feel less alert after taking Edemid Forte tablets.

Sugar intolerance

If you have been told you have an intolerance to some sugars, contact your doctor before taking this medicine, as it contains a type of sugar called lactose.

3. HOW TO TAKE

Always take Edemid Forte tablets exactly as your doctor has told you. If you are not sure, check with your doctor or pharmacist.

Swallow the tablets with a glass of water.

Doses:

Adults and children over 12 years: 250mg (half a tablet) once a day up to a maximum of 1.5g (3 tablets) once a day. 2g (4 tablets) a day may be given in exceptional cases.

Elderly: may be reduced in this age group.

Children under 12 years: use a more suitable dosage form.

Dosage adjustment may be necessary in patients with:

- hypoproteinaemia
- liver congestion/dysfunction

If you take more than you should

If you take more medicine than your doctor has told you to, contact a doctor or your nearest hospital casualty department immediately and take your Edemid Forte tablets with you. Signs of an overdose include dehydration, changes in the levels of certain chemicals in the blood and low blood pressure.

If you forget to take the tablets

If you forget to take a dose, take another as soon as you remember. Then take your next dose at the normal time. Do not take double the amount to make up for a forgotten dose.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Edemid Forte tablets can cause side effects, although not everybody gets them.

If you have any of the following side effects while taking your medicine tell your doctor immediately or go to hospital straight away:

- severe allergic reaction which may include a skin rash, itching, dermatitis, peeling skin, sensitivity to sunlight or sun lamps or fever, swelling of the face, lips, tongue or throat, or difficulty breathing or swallowing
- inflammation of blood vessels (vasculitis, which may cause rash, fever and joint or muscle pains) or kidney inflammation, this may change the number of times you pass urine or you may see blood in your urine. You may have a fever, feel drowsy, or notice swelling e.g. of the ankles

- blood clot (causing pain, swelling or tenderness in the legs)

Tell your doctor or pharmacist if you notice any of the following side effects:

Very common: may affect more than 1 in 10 people

- dehydration
- Altered balance of fluid or chemicals in the body (e.g. sodium, potassium, chlorine, calcium and magnesium) causing a dry mouth, weakness, tiredness or drowsiness, restlessness, fits, muscle pain fatigue or cramps, low blood pressure, difficulty passing water, fast or irregular heart rate and feeling and being sick

Common: may affect up to 1 in 10 people

- Low blood volume (hypovolaemia)
- Increased creatinine and blood urea (seen in blood tests)

Uncommon: may affect up to 1 in 100 people

- Anaemia causing tiredness, breathlessness, unusual bleeding or bruising,
- Changes in the body seen in tests such as levels of cholesterol, glucose, uric acid
- Gout
- Changes in vision including blurred or yellow vision
- Low blood pressure causing loss of concentration and slowed reactions, light-headedness, sensations of pressure in the head, headache, dizziness, drowsiness, weakness, changes in vision, dry mouth, dizziness when standing.
- Irregular heartbeat
- Muscle cramps or weakness
- Changes in the amount or need to urinate
- Tiredness
- Dry mouth, thirst
- Feeling or being sick
- Changes in bowel movements including diarrhoea and constipation

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

- Changes in blood cells such as amount of white blood cells, reduction of platelets causing a rash fever, sweating, tiredness, and weight loss. Your doctor will perform regular blood tests to ensure no changes have occurred.
- Psychiatric disorder NOC causing delusions, hallucinations, disorganized speech
- Feeling 'pins and needles' or tingling sensation
- Confusion
- Headache, dizziness
- 'Ringing' in the ears, loss of hearing usually reversible
- Symptoms of shock such as changes in heart rate, breathlessness, cool clammy skin
- Inflammation of the pancreas causing pains in your abdomen or back and nausea
- Changes in the liver causing yellowing of the skin or whites of the eyes)
- Skin rashes
- Inflammation or failure of the kidney which may cause back pain or changes in the amount or need to urinate
- Tiredness, generally feeling unwell
- Fever

Very rare: may affect up to 1 in 10,000 people

- Involuntary movements of the muscle

Not known: frequency cannot be estimated from the available data

- Worsening of conditions where there is already balances of fluid or chemicals in the body
- Increased levels of glucose in the body

Additional side effects in children

- increased risk or persistence of patent ductus arteriosus in premature infants.
- kidney stones in premature babies

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

5. HOW TO STORE

Keep out of the reach and sight of children.

Store below 25°C in a dry place. Protect from light.

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

Ask your pharmacist how to dispose of medicines no longer required.

This leaflet was last revised in August 2013.