

Package leaflet: Information for the patient

TENSAID XL 1.5 mg prolonged-release film-coated tablets indapamide

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 Tensaid XL is and what it is used for
2. What you need to know before you take Tensaid XL
3. How to take Tensaid XL
4. Possible side effects
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1. What Tensaid XL is and what it is used for

This medicine is intended to reduce high blood pressure (hypertension) in adults.

It is a prolonged-release film-coated tablet containing indapamide as the active ingredient. Tensaid XL is a diuretic. Most diuretics increase the amount of urine produced by the kidneys. However, Tensaid XL is different from other diuretics, as it only causes a slight increase in the amount of urine produced.

2. What you need to know before you take Tensaid XL

Do not take Tensaid XL:

- if you are allergic to indapamide or any other sulphonamide or to any of the other ingredients of this medicine (listed in section 6),
- if you have severe kidney disease,
- if you have severe liver disease, or suffer from a condition called hepatic encephalopathy (degenerative disease of the brain),
- if you have low potassium levels in your blood.

Warnings and precautions

Talk to your doctor or pharmacist before taking Tensaid XL:

- if you have liver problems
- if you have diabetes
- if you suffer from gout
- if you have any heart rhythm problems or problems with your kidneys
- if you need to have a test to check how well your parathyroid gland is working.

- 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 a week of taking INDAPAMIDE. 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 muscle disorders including muscle pain, tenderness, weakness or cramps.

You should tell your doctor if you have had sensitivity to sunlight.

Your doctor may give you blood tests to check for low sodium or potassium levels or high calcium levels.

If you think any of these situations may apply to you or you have any questions or doubts about taking your medicine, you should consult your doctor or pharmacist.

Athletes should be aware that this medicine contains an active ingredient, which may give a positive reaction in doping tests.

Other medicines and Tensaid XL

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

You should not take Tensaid XL with lithium (used to treat depression) due to the risk of increased levels of lithium in the blood.

Make sure to tell your doctor if you are taking any of the following medicines, as special care may be required:

- medicines used for heart rhythm problems (e.g. quinidine, hydroquinidine, disopyramide, amiodarone, sotalol, ibutilide, dofetilide, digitalis, bretylium)
- medicines used to treat mental disorders such as depression, anxiety, schizophrenia (e.g. tricyclic antidepressants, neuroleptics), other antipsychotic drugs (e.e. pimozide)
- bepridil (used to treat angina pectoris, a condition causing chest pain)
- cisapride, diphemanil (used to treat gastro-intestinal problems)
- sparfloxacin, moxifloxacin, erythromycin by injection (antibiotics used to treat infections)
- vincamycin by injection (used to treat symptomatic cognitive disorders in elderly including memory loss)
- halofantrine (antiparasitic drug used to treat certain types of malaria)
- pentamidine (used to treat certain types of pneumonia)
- mizolastine, astemizole, terfenadine (used to treat allergic reactions, such as hay fever)
- non-steroidal anti-inflammatory drugs for pain relief (e.g. ibuprofen) or high doses of acetylsalicylic acid
- angiotensin converting enzyme (ACE) inhibitors (used to treat high blood pressure and heart failure)
- amphotericin B by injection (anti-fungal medicines)
- oral corticosteroids used to treat various conditions including severe asthma and rheumatoid arthritis
- stimulant laxatives
- baclofen (to treat muscle stiffness occurring in diseases such as multiple sclerosis)
- allopurinol (for the treatment of gout)
- potassium-sparing diuretics (amiloride, spironolactone, triamterene)
- metformin (to treat diabetes)
- iodinated contrast media (used for tests involving X-rays)
- calcium tablets or other calcium supplements

- ciclosporin, tacrolimus or other medicines to depress the immune system after organ transplantation, to treat autoimmune diseases, or severe rheumatic or dermatological diseases
- tetracosactide (to treat Crohn's disease).
- methadone (used to treat addiction).

Pregnancy and breast-feeding

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

This medicine is not recommended during pregnancy. When a pregnancy is planned or confirmed, the switch to an alternative treatment should be initiated as soon as possible. Please tell your doctor if you are pregnant or wish to become pregnant.

The active ingredient is excreted in milk. Breast-feeding is not advisable if you are taking this medicine.

Driving and using machines

This medicine can cause side effects due to lowering of the blood pressure such as dizziness or tiredness (see Section 4). These side effects are more likely when treatment is first started and after doses increases. If this occurs, you should not drive or use machinery. However, under good control, these side effects are unlikely to occur.

Tensaid XL 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 medicine.

3. How to take Tensaid XL

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

The recommended dose is one tablet each day, preferably in the morning.

The tablets can be taken with or without meals. They should be swallowed whole with water. Do not crush or chew them.

Use in children and adolescents

Tensaid XL is not recommended for use in children or adolescents.

Treatment for high blood pressure is usually life-long.

If you take more Tensaid XL than you should

If you have taken too many tablets, contact your doctor or pharmacist immediately.

A very large dose of Tensaid XL could cause nausea, vomiting, low blood pressure, cramps, dizziness, drowsiness, confusion and changes in the amount of urine produced by the kidneys.

If you forget to take Tensaid XL

If you forget to take a dose of your medicine, take the next dose at the usual time.

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

If you stop taking Tensaid XL

As the treatment for high blood pressure is usually life-long, you should discuss with your doctor before stopping this medicinal product.

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 this medicine and see a doctor immediately if you experience any of the following side effects:

- *Very rare (may affect up to 1 in 10,000 people):*
 - Angioedema and/or urticaria, severe skin manifestations. Angioedema is characterised by swelling of the skin of extremities or face, swelling of the lips or tongue, swelling of the mucous membranes of the throat or airways resulting in shortness of breath or difficulty of swallowing.
 - Severe skin reactions including intense skin rash, reddening of the skin over your whole body, severe itching, blistering, peeling and swelling of the skin, inflammation of the mucous membranes (Stevens-Johnson syndrome).
 - Inflamed pancreas which may cause severe abdominal and back pain accompanied by feeling very unwell.
- *Not known (frequency cannot be estimated from the available data)*
 - Inflammation of the liver (hepatitis), with symptoms such as tiredness, loss of appetite, feeling or being sick, swollen extremities, yellow skin.
 - Disease of the brain caused by liver illness (hepatic encephalopathy)
 - Life-threatening irregular heart beat (Torsade de Pointes)
 - Decrease in vision or pain in your eyes are possible signs of fluid accumulation in the vascular layer of the eye (choroidal effusion).

Other side effects include:

- *Common (may affect up to 1 in 10 people):*
 - Red, raised skin rashes
 - Allergic reactions, mainly dermatological, in subjects with a predisposition to allergic and asthmatic reactions.
 - Low potassium in the blood
- *Uncommon (may affect up to 1 in 100 people):*
 - Vomiting.
 - Red pinpoint spots on the skin (purpura)
 - Low sodium in the blood that may lead to dehydration and low blood pressure
 - Impotence (inability to obtain or maintain an erection).
- *Rare (may affect up to 1 in 1000 people):*
 - Feeling of tiredness, vertigo (dizziness), headache, pins and needles (paraesthesia);
 - Gastro-intestinal disorders (such as nausea, constipation), dry mouth;
 - Low chloride in the blood
 - Low magnesium in the blood
- *Very rare (may affect up to 1 in 10,000 people):*
 - Changes in blood cells, such as thrombocytopenia (decrease in the number of platelets which causes easy bruising and nasal bleeding), leucopenia and agranulocytosis (decrease

of white blood cells which may cause unexplained fever, soreness of the throat or other flu-like symptoms – if this occurs, contact your doctor) and anaemia (decrease in red blood cells).

- High level of calcium in blood
 - Heart rhythm irregularities (causing palpitations, feeling of the heart pounding), low blood pressure
 - Kidney disease (causing symptoms of tiredness, increased need to urinate, itchy skin, feeling sick, swollen extremities)
 - Abnormal liver function
- *Not known (frequency cannot be estimated from the available data)*
 - Fainting
 - If you suffer from ‘systemic lupus erythematosus’ (a disorder of the immune system leading to inflammation and damage to the joints, tendons and organs with symptoms including skin rashes, tiredness, loss of appetite, weight gain and joint pain), this might get worse.
 - Cases of photosensitivity reactions (change in skin appearance) after exposure to the sun or artificial UVA have also been reported.
 - Short-sightedness (myopia), blurred or decreased vision
 - Changes may occur in your blood and your doctor may need to give you blood tests to check your condition. The following changes in laboratory parameters may occur:
 - increase in uric acid, a substance which may cause or worsen gout (painful joint(s) especially in the feet),
 - increase in blood glucose levels in diabetic patients,
 - increase in the level of enzymes produced by your liver.
 - Abnormal ECG heart tracing
 - Muscle weakness, cramps, tenderness or pain and particularly, if at the same time, you feel unwell or have a high temperature it may be caused by an abnormal muscle breakdown

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 - Website: 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 Tensaid XL

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

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 the month.

Do not throw 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 Tensaid XL contains

- The active substance is indapamide
- The other ingredients are:

lactose monohydrate, hypromellose, anhydrous colloidal silica, magnesium stearate, titanium dioxide (E171), macrogol 6000, pregelatinized starch. See section 2, 'Tensaid XL contains lactose monohydrate'.

What Tensaid XL looks like and contents of the pack

Tensaid XL prolonged-release film-coated tablets are white, round film-coated tablets. They are available in blister packs containing 10, 30, 90 or 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder is:

Mylan, Potters Bar, Hertfordshire,
EN6 1TL, United Kingdom.

Manufacturer:

Gerard Laboratories, 35-36 Industrial Estate, Grange Road, Dublin 13, Ireland.

Mylan Hungary Kft, H-2900 Komarom, Mylan utca 1, Hungary.

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