

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
5. How to store Tensaid XL
6. Contents of the pack and other information

1. What Tensaid XL is and what it is used for

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

It is a prolonged-release film-coated tablet containing indapamide as 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,
- 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.

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)
- medicines used to treat mental disorders such as depression, anxiety, schizophrenia (e.g. tricyclic antidepressants, antipsychotic drugs)
- bepridil (used to treat angina pectoris, a condition causing chest pain)
- cisapride, diphemanil (used to treat gastro-intestinal problems)
- sparfloxacin, moxifloxacin (antibiotics used to treat infections)
- halofantrine (antiparasitic drug used to treat certain types of malaria)
- pentamidine (used to treat certain types of pneumonia)
- mizolastine (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)
- 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)
- 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).
- amphotericin IV (to treat serious fungal infections)

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any 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 or if another blood pressure medicine is added. If this occurs, you should not driving or use machinery.

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 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.

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 for long-term, 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.

All medicines including this medicine can cause allergic reactions. You should contact your doctor immediately if you experience any of the following symptoms after taking Tensaid XL.

- *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. If this occurs, contact your doctor immediately.

- *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. In cases of liver failure, there is a

possibility of getting liver problems which affect the brain and central nervous system (hepatic encephalopathy)

- Life-threatening irregular heart beat (Torsade de Pointes)

Other side effects include:

- *Common (may affect up to 1 in 10 people):*
 - Low potassium in blood, which may cause muscle weakness
 - Skin rashes
- *Uncommon (may affect up to 1 in 100 people):*
 - Vomiting, allergic reactions, mainly dermatological, such as purpura (red pinpoint spots on skin) in subjects with a predisposition to allergic and asthmatic reactions.
- *Rare (may affect up to 1 in 1000 people):*
 - Feeling of tiredness, dizziness, headache, pins and needles (paraesthesia);
 - Gastro-intestinal disorders (such as nausea, constipation), dry mouth;
- *Very rare (may affect up to 1 in 10,000 people):*
 - Heart rhythm irregularities, low blood pressure;
 - Kidney disease;
 - Pancreatitis (inflammation of the pancreas which causes upper abdominal pain), abnormal liver function.
 - 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).
- *Not known (frequency cannot be estimated from the available data)*
 - Fainting,
 - Short-sightedness (myopia), blurred or decreased vision
 - Increased risk of dehydration in the elderly and in patients suffering from heart failure.

Cases of photosensitivity reactions (change in skin appearance) after exposure to the sun or artificial UVA have also been reported.

If you suffer from systemic lupus erythematosus (a type of collagen disease), this might get worse.

Some changes may occur in your laboratory parameters and your doctor may need to give you blood tests to check your condition. The following changes in laboratory parameters may occur:

- low potassium in the blood
- low sodium in the blood that may lead to dehydration and low blood pressure
- 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 of calcium in blood.
- increase in the level of enzymes produced by your liver

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.

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.

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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