Indipam XL 1.5mg Prolonged-Release Tablets
Indications

Read all of this leaflet carefully before starting treatment. If you have any further questions, ask your doctor or pharmacist.

You have been prescribed this medicine. Do not start this treatment unless you have read this leaflet and understood it. Ask your doctor or pharmacist if you have any questions.

Your doctor has prescribed this medicine to reduce high blood pressure.

The medicine is used to treat high blood pressure (essential hypertension) which may be caused by the kidneys producing too much sodium and water, and/or acute kidney failure when treatment with diuretics is essential. Blood pressure is lowered in a similar manner whether renal function is normal or impaired.

Possible side effects

- pictures, scaly skin, peeling skin, rash, redness of skin
- increased sweating
- skin ulcers
- blisters
- skin reaction to the sun
- swelling of the face, lips, tongue or throat

If you think any of the above side effects are mild and you want further advice, talk to your doctor or pharmacist.

Contraindications

- if you are allergic to the active substance or any of the inactive ingredients of this medicine
- if you have a severe allergy to sulphonamides

Before you take Indipam XL 1.5mg Prolonged-Release Tablets

1. What Indipam XL 1.5mg Prolonged-Release Tablets are and what they are used for

Indipam tablets contain the active substance Indapamide, which is a diuretic. Indipam XL 1.5mg Prolonged-Release Tablets are used for the treatment of high blood pressure (essential hypertension).

2. How to take Indipam XL 1.5mg Prolonged-Release Tablets

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3. HOW TO TAKE INDIPAM XL 1.5MG PROLONGED-RELEASE TABLETS

Shake the bottle before you take the tablet. It is not recommended to eat food before taking your tablet or take any other medicines at the same time. Do not take any other medicines at the same time.

4. Why Indipam XL 1.5mg Prolonged-Release Tablets are and what they are not

Indipam XL 1.5mg tablets contain the active substance Indapamide, which is a diuretic. Indipam XL 1.5mg Prolonged-Release Tablets are used for the treatment of high blood pressure (essential hypertension).

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4. POSSIBLE SIDE EFFECTS

Side-effects are common during the first few days of treatment. They are usually mild and can be controlled by taking your medicine with a sufficient amount of water (such as a glass of water). Do not stop your medicine without discussing it with your doctor or pharmacist.

Common: affecting fewer than one person in 100,000:
• Allergic reaction (especially in people who are allergic to aspirin and other nonsteroidal anti-inflammatory drugs), including rash, itch, swelling of the lips, mouth or throat leading to difficulty in breathing, angioedema, asthma, anaphylaxis. These symptoms may occur after taking your medicine but they are very rare.

Rare: affecting fewer than one person in 10,000:
• Blood dyscrasias (a bone marrow depression), resulting in bruising or make infections more likely (Agranulocytosis).
• Inflammation of the brain and nerves which can occur as a complication of use (Encephalopathy).
• Reduction in levels of certain blood components, which may lead to anaemia (Anaemia), infections, weakness, tiredness or easy bruising.

Uncommon: affecting fewer than one person in 1,000:
• Headaches
• Nausea
• Diarrhoea
• Fever
• Abdominal pain
• Loss of appetite
• Vomiting
• Constipation
• Fever
• Irritable bowel syndrome
• Blood dyscrasias causing low levels of blood cells, which can cause weakness, tiredness or easy bruising.

Very rare: affecting fewer than one person in 1,000,000:
• Reduced blood platelets, which increases the risk of bleeding or bruising
• Reduced kidney function
• Reduced liver function
• Other very rare side effects may include:• raised blood sugar levels.

Serious side effects: If you notice any of the following side effects or any other symptoms not listed in this leaflet, please tell your doctor.

Stomatitis (swelling of the mouth, tongue, lips and gums), which may lead to difficulty in swallowing, contact your doctor immediately.

Indapamide may cause increased blood sugar levels.

If you notice any problems, taking Indapamide may cause high blood sugar levels. Contact your doctor immediately.

If you suffer from a condition that means you cannot absorb your food properly, the way in which Indapamide is taken, may cause diarrhoea or vomiting.

If you notice any side effects or symptoms which you are not sure about, contact your doctor immediately.

If you notice any other side effects, however mild, contact your doctor or pharmacist.

5. HOW TO STORE INDIPAM XL 1.5MG Prolonged-Release Tablets

Keep out of the reach and sight of children. This medicine should not be used by anyone under the age of 18.

Do not use this medicine after the expiry date which appears on the pack or on individual tablets or blister packs. This medicine may be ineffective if used after the expiry date.

Special Instructions

If you or someone else takes too much of this product, contact a doctor or your local Poisons centre immediately.

6. FURTHER INFORMATION

What Indipam XL 1.5 Prolonged-Release Tablets look like and contents of pack.

Each prolonged-release tablet contains:

- The active substance is: indapamide (1.5 mg).
- The excipients are: lactose, microcrystalline cellulose, sodium starch glycolate, magnesium stearate.
- Indipam XL 1.5 mg tablets look like a capsule or a white, hard, smooth, round tablet with a white outer coating and the following symbols on the coating: "ACTAPAM 1.5 mg" and "1.5 mg Indapamide SR".

Medicines should not be disposed of via household waste. Please inform your local waste disposal service on how to dispose of any unused medicines.

Bulgaria
• Balkanpharma-Dupnitsa AD
Dobrich, Bulgaria
• Dupnitsa 2600, Bulgaria

UK
• Indapamide Actavis
• Indapamide Actavis 1.5 mg
• Indapamide Actavis 1.5 mg SR
• Indapamide Actavis 1.5 mg SR Retardtabletten
• Indapamide Actavis 1,5 mg Retardtabletten

SK
• Indapamida Akter
• Indapamide Actavis
• Indapamide Actavis 1.5 mg
• Indapamide Actavis 1,5 mg SR

ACT
• Indapamide Actavis
• Indapamide Actavis 1.5 mg
• Indapamide Actavis 1,5 mg SR

AT
• Indapamide Actavis
• Indapamide Actavis 1.5 mg
• Indapamide Actavis 1,5 mg SR

HUN
• Indapamid Actavis
• Indapamide Actavis 1.5 mg
• Indapamide Actavis 1,5 mg SR

CMS
• Indapamide Actavis 1.5 mg SR

Reykjavíkurvegur 76-78, 220 Hafnarfjordur, Iceland
Batum
• Indipam XL 1.5 mg Tablets
• Indapamide Actavis

Handmade (the product is available in the Member States of the EU on the following terms.

If you would like a leaflet with larger text, please contact 01271 311257.
Indapamide XL 1.5mg Prolonged-Release Tablets

1. WHAT INDIPAM XL 1.5MG PROLONGED-RELEASE TABLETS IS AND WHAT IT IS USED FOR

Indapamide belongs to a class of medicines called thiazide-like diuretics, used to lower blood pressure.

2. HOW TO TAKE INDIPAM XL 1.5MG PROLONGED-RELEASE TABLETS

Take your tablets with or without food. Take 1 tablet daily, in the evening and before bedtime.

3. HOW MUCH INDIPLAM XL 1.5MG PROLONGED-RELEASE TABLETS SHOULD I TAKE?

1 tablet daily of Indipam XL 1.5mg Prolonged-Release Tablets if:

• Allergic (Reactions to) medicines, including medicines obtained over the counter, or if you have an allergy to any of the ingredients of this product.

• Allergic (Reactions to) aspirin, ibuprofen, or other non-steroidal anti-inflammatory medicines, or if you have an allergy to any of the ingredients of this product.

• Have been told by your Doctor or Pharmacist to avoid medicines, including medicines obtained over the counter, or to avoid the active substance of this product.

• Are taking medicines that interact with Indapamide: Amisulpride, Sulpiride, Sultopride, Amoxapine, Chlorpromazine, Haloperidol, Haldol, Paroxetin, Proxeron, Risperidone, Sertibrine, Sertil, Zyprexa.

• Are taking medicines that are possible to increase the risk of increased levels of Indapamide: Amoxicillin, Omeprazole, Fluconazole, Amlodipine, Lisinopril, Manadyl, Nifedipine, Propranolol, Metoprolol, carvedilol, Bupropion.

• Are taking medicines that are possible to make you feel light-headed and dizzy: Amoxapine, Sulpiride, Haloperidol, Haldol, Paroxetin, Proxeron, Risperidone, Sertibrine, Sertil, Zyprexa.

• Are taking medicines that interact with Indapamide: Fluzase, Metformin, Ibuprofen, Diclofenac, Indometacin, Naproxen, Anaprox.

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• Are taking a lithium (lithium carbonate) treatment, or are taking medicines that interact with lithium (lithium carbonate).

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Like all medicines, Indapamide can cause side effects, although many people do not experience any.

The most common side effects are:
• Headache
• Tiredness
• Nausea (feeling sick)

Some rare side effects may affect fewer than one person in 10,000:
• Asthmatic reactions (leading to difficulty of breathing or resulting in anaphylactic shock)
• Inflammation of the pancreas, which may cause abnormal levels of certain blood fats (leading to pancreatitis)
• Irregular heart beat
• Inflammation of the skin, which can cause weakness, or make infections more likely to occur

Symptoms of an overdose may include:
• A lack of urine, which may lead to dehydration and fall
• Low blood pressure, which may lead to fainting
• Hypotension)

The duration of treatment will be decided by your treating Doctor. If you have the impression that the effect of Indapamide is not as good as before, talk to your Pharmacist or Doctor.

Duration of Treatment
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If you forget to take Indipam XL 1.5mg Prolonged-Release Tablets:
If you forget to take a tablet then take it as soon as you remember. However, do not take a double dose to make up for a forgotten dose.

If you stop taking Indipam XL 1.5mg Prolonged-Release Tablets:
Treatment for high blood pressure is normally life-long. If you stop taking Indapamide as directed by your treating Doctor, your blood pressure will rise again.

If you have any further questions or require advice, please contact your Pharmacist.

The following side effects may also occur:
• Indapamide may cause increased levels of cholesterol in the blood.
• Indapamide may cause high levels of bilirubin in the blood which may lead to jaundice. Metabolic (related to activity of liver)

If you have any further questions or require advice, please contact your Pharmacist.

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Do not use this medicine if you are pregnant or likely to become pregnant. If you think you may be pregnant, stop taking this medicine and talk to your Pharmacist or Doctor.

If you have any further questions or require advice, please contact your Pharmacist.

6. POSSIBILITY OF SIDE EFFECTS
• Indapamide may cause decreased levels of magnesium in the blood.

If you have any further questions or require advice, please contact your Pharmacist.

7. APPROVALS

IF YOU WOULD LIKE A LEAFLET, PLEASE CONTACT...: 01271 311257.

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