Icorvida SR is a drug that reduces blood pressure by promoting the excretion of urine and by dilating blood vessels. Icorvida SR is used to treat increased blood pressure.

2. Before you take Icorvida SR

Do not take Icorvida SR:

- If you are allergic (hypersensitive) to indapamide or any of the other ingredients of Icorvida SR or to other drugs of the same type (called sulphonamides).
- If you have severe impairment of kidney function.
- If you have severe impairment of liver function.
- If you have low level of potassium in your blood.

Take special care with Icorvida SR:

- If you have impairment of liver function.
- If you have disorders of blood electrolyte levels or body water depletion.
- If you have diabetes.
- If you have gout.
- If you have impairment of kidney function.
- If you have a skin reaction when exposed to sunlight.
- If you are an athlete. Icorvida SR can interfere with results of doping tests.
- You should monitor your blood pressure and heart rate regularly during treatment.
- If you are an elderly person, your doctor will check your kidney function before the start of therapy.
- If you are a child or an adolescent, this medicine is not recommended for you.

Your doctor will give you a detailed explanation and instructions.

Taking other medicines

Concomitant use of Icorvida SR and some other drugs may increase the effect of one or the other drug and cause side effects. Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. In particular, tell your doctor if you are taking any of the following:

- Drugs containing lithium.
- Drugs for treating heart rhythm disorders (e.g. quinidine, amiodarone).
- Drugs for treating cardiovascular diseases (e.g. ACE inhibitors).
- Drugs for treating infections (e.g. erythromycin).
- Backache, a drug for treating muscular spasms.
- Metformin, a drug for treating diabetes mellitus.
- Drugs for treating mental disorders (e.g. some antipsychotics, some antidepressants).
- Drugs for treating rheumatic diseases (non-steroid anti-inflammatory drugs, acetylsalicylic acid).
- Drugs that may decrease potassium levels in the body (corticosteroids, tetrahydrozoline, certain laxatives).

Taking Icorvida SR with food and drink

Food and drink have no influence on the effect of Icorvida SR.

3. How to take Icorvida SR

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

The dose of Icorvida SR is one tablet a day. Take the drug every day at the same time, preferably in the morning, swallow it whole with some liquid. It is important that you take the drug regularly, as it may help you to keep feeling well.

If you have the impression that the effect of the drug is too strong or too weak, consult your physician or pharmacist.

If you take more Icorvida SR than you should

If you have taken a higher dose of the drug than you should, consult your doctor or pharmacist immediately.

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. Breastfeeding is not advisable if you are taking this medicine.

Driving and using machines

Icorvida SR does not affect vigilance; however different reactions in relation with the decrease in blood pressure may occur. This is more likely at the start of the treatment or when another drug for lowering blood pressure is added. In such cases the ability to drive and use machines may be impaired.

Important information about some of the ingredients of Icorvida SR

Icorvida SR contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Pregnancy and breast-feeding

Icorvida SR 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.

This medicine is not recommended for nursing mothers. If using Icorvida SR while you are nursing, the drug from passing into the blood.

If you forget to take Icorvida SR

If you forget to take Icorvida SR at the right time, follow your usual dosing schedule by taking your next dose at the scheduled time. Do not take a double dose to make up for a forgotten tablet.

If you stop taking Icorvida SR

If you stop taking the drug for a short period of time, there is no immediate danger. However, after a longer period of time, different forms of cardiovascular disease may develop or recur due to unregulated high blood pressure.

If you want to stop taking this drug, consult your doctor or pharmacist.
4. Possible side effects

Like all medicines, Icorvida SR can cause side effects, although not everybody gets them. The following side effects are important and require immediate action in case of occurrence. You should stop taking Icorvida SR tablets and immediately consult your doctor if following symptoms appear:

- unexplained fever, soreness of the throat or other flu-like symptoms;
- severe skin manifestations;
- allergic reactions, mainly dermatological, such as skin rashes in subjects with a predisposition to allergic and asthmatic reactions.

Uncommon (less than 1 patient per 100 but more than 1 per 1000):

- vomiting;
- feeling of tiredness, dizziness, headache, pins and needles (paresthesia);
- nausea (feeling sick), constipation, dry mouth;
- increased risk of dehydration in the elderly and in patients suffering from heart failure.

Very rare (less than 1 patient per 10,000):

- kidney disease (causing symptoms of tiredness, increased need to urinate, itchy skin, feeling sick, swollen extremities);
- pancreatitis (inflammation of the pancreas which causes upper abdominal pain), abnormal liver function (with symptoms such as tiredness, loss of appetite, feeling or being sick, swollen extremities, yellow skin);
- changes in blood cells, such as thrombocytopenia (decrease in the number of platelets which causes easy bruising and nasal bleeding) and anaemia (decrease in red blood cells).

Not known (frequency cannot be estimated from the available data):

- feeling of tiredness,
- dizziness,
- headache,
- pins and needles (paresthesia);
- changes in blood cells, such as thrombocytopenia (decrease in the number of platelets which causes easy bruising and nasal bleeding) and anaemia (decrease in red blood cells).

Very rare (less than 1 patient per 10,000):

- 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 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, increased levels of liver enzymes.
- in cases of liver failure, there is a possibility of getting hepatic encephalopathy (liver problems which affect the brain and central nervous system);
- 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 UV A have also been reported;
- abnormal ECG heart tracing;
- hepatitis;
- jaundice.

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

5. How to store Icorvida SR

Keep out of the reach and sight of children. This medicinal product does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the blister and 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. Further information

What Icorvida SR contains

- The active substance is indapamide. Each prolonged-release tablet contains 1.5 mg indapamide.
- The other ingredients are hypromellose, powdered cellulose, lactose monohydrate, colloidal anhydrous silica, magnesium stearate, croscarmellose sodium, titanium dioxide (E171).

What Icorvida SR looks like and contents of the pack

Prolonged-release tablets are white, round, slightly biconvex film-coated tablets. The tablets are available in boxes of 10, 14, 15, 20, 30, 50, 90 and 100 tablets in blister packs.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8051 Nova mesto, Slovenia

Prescribing information

On physician’s prescription only.

For any information about this medicinal product, please contact the local representative of the Marketing Authorisation Holder.

This medicinal product is authorised in the Member States of the EEA under the following names:

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<thead>
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<th>Name of the Member State</th>
<th>Name of the medicinal product</th>
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<tbody>
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<td>Indapamid Krka</td>
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<tr>
<td>Hungary</td>
<td>Indapamid Billev</td>
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<tr>
<td>Ireland</td>
<td>Icorvida SR</td>
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This leaflet was last approved in