Package leaflet: Information for the patient

Icorvida SR 1.5 mg prolonged-release 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 Icorvida SR is and what it is used for

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. What you need to know before you take Icorvida SR

Do not take Icorvida SR
- if you are allergic to indapamide or any of the other ingredients of this medicine or to other drugs of the same type (called sulphonamides) (listed in section 6).
- if you have severe impairment of kidney function.
- if you have severe impairment of liver or suffer from a condition called hepatic encephalopathy (degenerative disease of the brain).
- if you have low level of potassium in your blood.

Warnings and precautions
Talk to your doctor or pharmacist before taking Icorvida SR.
- if you have impairment of liver function.
- if you have diabetes.
- if you have gout.
- if you have impairment of kidney function.
- if you have any heart rhythm problems.
- 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 weeks of taking Icorvida SR. 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.

You should tell your doctor if you had photosensitivity reactions.

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 Icorvida SR
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
You should not take Icorvida SR 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, neuroleptics),
- 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),
- vincamine 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 (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),
- potassium-sparing diuretics (amiloride, spironolactone, triamterene),
- allopurinol (for the treatment of gout),
- 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).

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

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, 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 low blood pressure such as dizziness or tiredness (see section 4). These side effects are more likely to occur at beginning of therapy or increasing the dose. If this occurs you should refrain from driving or other activities requiring alertness. However, under good control, these side effects are unlikely to occur.

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.

3. How to take Icorvida SR

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

The recommended 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. The tablets can be taken irrespective of meals. Do not crush or chew them. Treatment for high blood pressure is usually life-long.

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.
A very large dose of Icorvida SR 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 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
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 the medicinal product and see a doctor immediately, if you experience any of the following side effects:
- angioedema and/or urticaria. Angioedema is characterised by swelling of the skin extremities or face, 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 the breath or difficulty of swallowing. It this occurs, contact your doctor immediately. (Very rare) (*may affect up to 1 in 10,000 people*)
- 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 mucous membranes

(Steven Johnson syndrome) or other allergic reactions. (Very rare) (*may affect up to 1 in 10,000 people*)
- life-threatening irregular heartbeat. (Not known)
- inflamed pancreas which may cause severe abdominal and back pain accompanied with feeling very unwell. (Very rare) (*may affect up to 1 in 10,000 people*)
- disease of the brain caused by liver illness (hepatic encephalopathy). (Not known)
- inflammation of the liver (Hepatitis). (Not known)

The frequency of side effects listed below is defined according to the following categories:

Common (may affect up to 1 in 10 people):
- low potassium in the blood;
- red raised skin rash;
- allergic reactions, mainly dermatological, in subjects with a predisposition to allergic and asthmatic reactions.

Uncommon (may affect up to 1 in 100 people):
- low sodium in the blood that may lead to dehydration and low blood pressure;
- vomiting;
- red pinpoints on skin;
- impotence (inability to obtain or maintain an erection).

Rare (may affect up to 1 in 1,000 people):
- feeling of tiredness, headache, pins and needles (paraesthesia), vertigo;
- 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 (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 hepatic 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 vision;
- visual impairment;
- decrease in vision or pain in your eyes due to high pressure (possible signs of fluid accumulation in the vascular layer of the eye (choroidal effusion) or acute angle-closure glaucoma);
- 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,

- increased levels of liver enzymes;
- abnormal ECG heart tracing.

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 HPRA Pharmacovigilance, Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Icorvida SR

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 packaging after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other 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, macrogol 400 and titanium dioxide (E171).
  See section 2 "Icorvida SR contains lactose".

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, 60, 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, 8501 Novo mesto, Slovenia

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

Name of the Member State	Name of the medicinal product
Austria	Indapamid Krka
Hungary	Indapamid Pharma-Regist
Ireland	Icorvida SR
Slovak Republic	Indapamid SR Krka
France	INDAPAMIDE KRKA LP
United Kingdom	Indapres XL

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