

ODAPLIX SR

Sustained Release tablets containing indapamide (pronounced in-dap-a-mide)

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about ODAPLIX SR. It does not contain all the available information about this medicine. Reading this leaflet does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking ODAPLIX SR against the expected benefits for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What ODAPLIX SR is

The name of your medicine is ODAPLIX SR. The medicine releases the active ingredient indapamide progressively over 24 hours. Indapamide belongs to a group of medicines called chlorosulfamoyl diuretics (a type of "fluid" or "water" tablet).

What ODAPLIX SR is used for

You have been prescribed ODAPLIX SR for high blood pressure.

ODAPLIX SR is available only with a doctor's prescription.

There is no evidence that ODAPLIX SR is addictive.

Why ODAPLIX SR is used for high blood pressure

Everyone has blood pressure. This pressure helps to circulate blood all around the body. Your blood pressure may be different at different times of the day, depending on how busy or stressed you are.

You have high blood pressure (also known as hypertension) which is when your blood pressure stays higher than is needed, even when you are calm and relaxed.

If high blood pressure is not treated it can lead to serious health problems. You may feel fine and have no symptoms, but eventually it can cause stroke, heart disease and kidney failure.

ODAPLIX SR helps to lower your blood pressure.

Ask your doctor if you have any questions about why ODAPLIX SR has been prescribed for you.

Before you take ODAPLIX SR

There are some people who should not take ODAPLIX SR. Please read the lists below. If you think any of these situations apply to you, or you have any questions, please consult your doctor or pharmacist.

When you must not take ODAPLIX SR

Do not take ODAPLIX SR if:

- **You are allergic to indapamide, or any of the other ingredients of ODAPLIX SR listed at the end of this leaflet.**

- **You are allergic to sulfonamide (sulfa) antibiotics, or to thiazide diuretics (a type of "fluid" or "water" tablet).**
- **You are pregnant or trying to become pregnant.**
- **You are breastfeeding or plan to breast-feed.**
- **You have severe kidney disease.**
- **You have severe liver disease or suffer from a condition called hepatic encephalopathy (liver problems which affect the brain and central nervous system).**
- **You have low potassium levels in your blood.**
- **The packaging is torn or shows signs of tampering, or the tablets do not look quite right.**
- **The expiry date (EXP) on the pack has passed.**

Before you start to take it

Tell your doctor straight away if:

- You have an intolerance to lactose.
- You have or have had any other health problems, including:
 - High or low levels of potassium, sodium, or other problems with salt balance.
 - Gout.
 - Diabetes
 - Increased sensitivity to sunlight (photosensitivity reactions).
 - Systemic lupus erythematosus (a disease affecting the skin, joints and kidneys).
 - Heart rhythm problems.
 - Problems with your kidneys.

- If you experience a decrease in vision or eye pain. These could be symptoms of fluid accumulation in the vascular layer of the eye or an increase of pressure in your eye and can happen within hours to a week of taking ODAPLIX 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 have muscle disorders including muscle pain, tenderness, weakness or cramps.
- A test to check how well your parathyroid gland is working.
- Athletes should be aware that this medicine contains an active ingredient, which may give a positive reaction in doping tests.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from a pharmacy, supermarket or health food shop.

Taking ODAPLIX SR may change the effect of some medicines, and some medicines may affect how well ODAPLIX SR works. You may need different amounts of your medication or to take different medicines.

You should not take ODAPLIX SR with lithium medications (used to treat mood swings and some types of depression) due to the risk of increased levels of lithium in the blood.

The medicines that may interact with ODAPLIX SR include the following:

- Some steroid medicines.
- Diuretics (sometimes called "fluid" or "water" tablets, e.g. amiloride, spironolactone, triamterene).
- Medicines used for heart rhythm problems (e.g. disopyramide, amiodarone, sotalol, flecainide).
- Some medications used to treat high blood pressure (e.g. angiotensin converting enzyme

(ACE) inhibitors), a fast or irregular heartbeat and other heart conditions.

- Medicines to treat mental illnesses such as some medicines for epilepsy, anxiety, schizophrenia and some other antidepressants (e.g. tricyclic antidepressants, antipsychotic drugs, neuroleptics such as: droperidol, haloperidol, chlorpromazine, trifluoperazine, amisulpride, sulpiride, psychoanaleptics).
- Antiparasitic medicines used to treat certain types of malaria (e.g. chloroquine).
- Pentamidine (a medicine used to treat certain types of pneumonia).
- Antihistamines used to treat allergic reactions, such as hay fever.
- Medicines used to treat nausea and vomiting (e.g. ondansetron, domperidone)
- Medicines used to treat cancer (e.g. vandetanib, oxaliplatin).
- Anagrelide (used to reduce elevated blood platelet counts).
- Non-steroidal anti-inflammatory drugs for pain relief (e.g. ibuprofen) or high doses of aspirin.
- Calcium supplements.
- Stimulant laxatives.
- Baclofen (a medicine used to treat muscle stiffness occurring in diseases such as multiple sclerosis).
- Metformin (a medicine used to treat diabetes).
- Cyclosporin, tacrolimus (medicines used to treat certain problems with the immune system).
- Medicines used to treat fungal infections (e.g. Amphotericin B (amphotericin) by IV, fluconazole).
- Medicines used during scans to see the images of your body.

- Medicines used to treat gastrointestinal problems (e.g. cisapride, papaverine).
- Medicines used to treat bacterial infections (e.g. Moxifloxacin, ciprofloxacin, clarithromycin, erythromycin by IV).
- Allopurinol (a medicine used to treat gout).
- Tetracosactide (tetracosactrin) (to treat Crohn's disease).
- Methadone (used to treat addiction).
- Cilostazol (used to treat cramp-like pain in the legs when you walk).

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking ODAPLIX SR.

For older people or children

- Elderly people can generally use ODAPLIX SR safely. However, some older people have reduced kidney function - in which case additional care may be required.
- **ODAPLIX SR is not recommended for use in children.**

How to take ODAPLIX SR

Follow all directions given to you by your doctor and pharmacist carefully. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

Your doctor will select a dose when they prescribe ODAPLIX SR for you. The usual dose is one tablet once daily.

Swallow your tablet with water, preferably in the morning. Do not crush or break them.

How long to take ODAPLIX SR for

ODAPLIX SR can help to control your blood pressure but cannot cure it. ODAPLIX SR treatment is usually for life - so you should keep taking the tablets regularly unless advised otherwise by your doctor.

If you forget to take ODAPLIX SR

If your next usual dose is less than 6 hours away, just leave out the dose that you missed. Take the next dose at the usual time and continue as normal.

If your next dose is more than 6 hours away, take the dose you have missed as soon as you realise. Then take the next dose at the usual time and continue as normal.

Do not try to make up for missed doses by taking more than one dose at a time.

If you take too much ODAPLIX SR

Taking too much ODAPLIX SR (an overdose) may cause low blood pressure (also known as hypotension). Other effects like sickness, cramps, sleepiness, confusion, kidney problems, salt and water disturbances are possible. You may require urgent medical attention.

If you think that you or anyone else may have taken too much ODAPLIX SR then act immediately

- Telephone your doctor or the Poisons Information Centre (13 11 26 in Australia), or go to the Accident and Emergency department at your nearest hospital. Do this even if there are no signs of discomfort or poisoning.

While you are taking ODAPLIX SR

Things you must do

Take ODAPLIX SR exactly as your doctor has prescribed. Otherwise you may not get the benefits from treatment.

Tell all doctors, dentists and pharmacists who are involved with your treatment that you are taking ODAPLIX SR.

Make sure you drink enough water during exercise and hot weather especially if you sweat a lot. This will help you avoid any dizziness or light-headedness caused by a sudden drop in blood pressure.

Tell your doctor straight away if you have excessive vomiting or diarrhoea while taking ODAPLIX SR as these may affect how ODAPLIX SR is processed by your body. If you experience any of the following symptoms, you may be dehydrated because you are losing too much water:

- Dry mouth or thirst
- Fainting
- Weakness,
- Tiredness or drowsiness
- Muscle pain or cramps
- Fast heartbeat
- Passing less urine than normal.

Things you must not do

Do not give this medicine to anyone else, even if they have the same condition as you.

Do not use ODAPLIX SR to treat any other complaints unless your doctor tells you to.

Do not stop taking ODAPLIX SR or change the dose, without checking with your doctor.

Things to be careful of

Be careful when driving or operating machinery until you know how ODAPLIX SR affects you.

You may feel light-headed or dizzy when you begin to take ODAPLIX SR. This is because your blood pressure is falling. Symptoms are likely to be made worse if you drink alcohol or take strong pain killers.

If you have these symptoms when standing up or getting out of bed then getting up more slowly can help. This allows your body to get used to the change in position and blood pressure.

ODAPLIX SR may cause your skin to become more sensitive to the sun. If this happens you should stop taking ODAPLIX SR and contact your doctor.

If you have these symptoms and they don't get better in a short time then talk to your doctor.

Unwanted effects potentially due to treatment

If you do not feel well while you are taking ODAPLIX SR then tell your doctor or pharmacist as soon as possible.

All medicines can have side effects. Most of the time they are not serious but sometimes they can be.

ODAPLIX SR helps most people with high blood pressure, but it may sometimes have unwanted side effects. These can include:

- Headache.
- Feeling tired or as if you have less energy, difficulty sleeping.
- Feeling faint, light-headed, or dizzy.
- Feeling nervous or anxious.
- Feeling sick or having an upset stomach, having an uncomfortable feeling after eating, vomiting or constipation.
- Muscle weakness, pain, tenderness, cramp, tingling or numbness of the hands or feet (and particularly if at the same time you feel unwell or have a

high temperature it may be caused by an abnormal muscle breakdown (not known)).

- Skin rashes or other allergic reactions.
- Gout.
- Increased sensitivity to sunlight.
- An increased risk of becoming dehydrated (in elderly patients and in patients with heart failure)
- Kidney disease.
- Inflammation of the pancreas.
- Hepatic encephalopathy (liver problems which affect the brain and central nervous system).
- Abnormal liver function.
- If you suffer from systemic lupus erythematosus (a type of collagen disease), this might get worse.
- Changes in blood cells, such as thrombocytopenia (a decrease in the number of platelets which causes easy bruising and nasal bleeding), leucopenia (a decrease of white blood cells which may cause unexplained fever, soreness of the throat or other flu-like symptoms) and anaemia (a decrease in red blood cells).
- Low blood pressure, unusual heartbeat.
- High level of calcium in blood
- Blurred or changed vision, short sightedness (myopia).
- Decrease in vision or pain in your eyes due to high pressure (possible signs of fluid accumulation in the vascular layer of the eye or acute angle-closure glaucoma).
- Dry mouth.
- Cystitis.
- Erectile dysfunction.

Most of these side effects are mild when they occur. Do not be alarmed by this list of possible side effects. You may not experience any of them. However, if you do - or if you notice anything else that is making you feel

unwell - you should consult your doctor or pharmacist.

Changes may occur in your laboratory parameters (blood tests) and your doctor may need to give you blood tests to check your condition. The following changes in laboratory tests may occur: low potassium, magnesium, chloride or sodium in the blood. Low sodium may lead to dehydration and low blood pressure. Increase in uric acid (a substance which may cause or worsen gout), increase in blood glucose levels in diabetic patients, increased levels of liver enzymes.

If any of the signs below occur then tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital:

- Swelling of your lips, face, mouth, tongue or throat.
- Purple spots with occasional blisters on the front of your arms and legs and/or around your neck and ears (a rare condition known as Stevens-Johnson Syndrome).
- Toxic epidermal necrolysis.
- A fast and irregular heartbeat.
- Severe blisters, skin rash, itching or other allergic reactions.
- These side effects are extremely rare but can become serious.

After taking ODAPLIX SR

Storage

Keep your tablets in the pack until it is time to take them. Keep them in a cool, dry place where it stays below 25°C. Keep them where children cannot reach them.

Disposal

If your doctor tells you to stop taking ODAPLIX SR, or the tablets have passed their expiry date, return any leftover tablets to your pharmacist for disposal.

What ODAPLIX SR looks like

ODAPLIX SR tablets are white and round.

ODAPLIX SR tablets come in a blister strip. Each box contains 90 tablets.

Ingredients

Each tablet of ODAPLIX SR contains 1.5 mg of indapamide hemihydrate as the active ingredient and a number of inactive ingredients.

The inactive ingredients in ODAPLIX SR tablets include colloidal anhydrous silica, glycerol, hypromellose, lactose monohydrate, macrogol 6000, magnesium stearate, povidone, and titanium dioxide.

The tablets are gluten free.

Distributor

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond
30-34 Hickson Road
Millers Point NSW 2000
www.viatris.com.au

ODAPLIX SR is registered on the Australian Register of Therapeutic Goods and has the Australian Register Number: AUST R 139608

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