PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

# Odrik 0.5 mg Hard Capsules
# Odrik 1 mg Hard Capsules
# Odrik 2 mg Hard Capsules

Trandolapril

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**
- Keep this leaflet as you may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet**



## 1. What Odrik is and what it is used for

Odrik capsules contain the active ingredient trandolapril which belongs to a group of medicines called angiotensin-converting enzyme inhibitors (ACE inhibitors). They work by relaxing the blood vessels, making it easier for the heart to pump blood around the body and lowering blood pressure.
Odrik Capsules are used to treat hypertension (high blood pressure). The capsules may also be prescribed to protect the heart after a heart attack.

## 2. What you need to know before you take Odrik

**Do not take Odrik:**
- if you are **allergic** (hypersensitive) to trandolapril or any of the other ingredients in this medicine.
- if you have ever had an **allergic reaction** to any ACE inhibitors such as swelling of the face, lips, tongue or throat with difficulty swallowing or breathing.
- if you have ever had the condition known as angioedema or Quincke's oedema involving a skin condition and swelling mainly affecting the face, extremities, tongue, mouth and throat.
- if you are more than 3 months **pregnant**. (It is also better to avoid Odrik in early pregnancy - see section 'Pregnancy and Breast-feeding').
- if you suffer from any obstruction that slows the flow of blood to the heart, such as narrowing of one of the valves in the heart (**aortic stenosis**).
- if you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.
- if you have taken or are currently taking sacubitril/valsartan, a medicine used to treat a type of long-term (chronic) heart failure in adults, as the risk of angioedema (rapid swelling under the skin in an area such as the throat) is increased.

**Warnings and precautions**
Talk to your doctor or pharmacist before taking Odrik if you:
- suffer from kidney problems such as narrowing of the artery that supplies blood to the kidneys.

- have a condition where there is ineffective pumping of the heart leading to an accumulation of fluid in the lungs (congestive heart failure).
- have been taking diuretics (water tablets) for a long time or you have been on a low salt diet.
- have any liver problems.
- have cerebrovascular disease (disease of the arteries of the brain)
- have ischaemic heart disease (heart disease caused by reduced blood flow to the heart muscle or if you have ever had or are at risk of heart attack)
- recently had severe or prolonged sickness or diarrhoea.
- are to undergo LDL apheresis (a procedure used to remove harmful cholesterol from your blood)
- are going to have desensitisation treatment to reduce the effects of an allergy to bee or wasp stings.
- have a history of angioedema or if you have ever had an allergic reaction to any ACE inhibitor such as swelling of the face, tongue, throat, hands or feet)
- if you are taking any of the following medicines used to treat high blood pressure:
    - an angiotensin II receptor blocker (ARBs) (also known as sartans - for example valsartan, telmisartan, irbesartan), in particular if you have diabetes-related kidney problems.
    - aliskiren
- if you are taking any of the following medicines, the risk of angioedema may be increased:
    - racecadotril, a medicine used to treat diarrhoea;
    - medicines used to prevent organ transplant rejection and for cancer (e.g. temsirolimus, sirolimus, everolimus);
    - vildagliptin, a medicine used to treat diabetes.

Your doctor may check your kidney function, blood pressure, and the amount of electrolytes (e.g. potassium) in your blood at regular intervals.
See also information under the heading “Do not take Odrik if you:”

If you need to have an **operation** it is important to tell the surgeon or dentist as Odrik may affect the anesthetics or other treatments used.
If you are on **kidney dialysis**, tell the nurse or doctor that you are taking Odrik. Some kinds of dialysis membrane may not be suitable as allergic reactions may occur. The signs include:

- a red or lumpy skin rash or inflamed itchy skin
- swelling of your face, lips, tongue or neck
- a drop in your blood pressure
- loss of consciousness
- difficulty swallowing.

Your doctor may need to monitor you more closely or change the dose of Odrik if you have any of the following conditions: liver or kidney problems; diabetes mellitus; heart failure, or the condition known as collagen vascular disease (this is sometimes called connective tissue disease, for example lupus or scleroderma); or if you are taking diuretics or potassium supplements at the same time as taking your Odrik.
Tell your doctor if you develop a dry and non-productive cough. Your doctor may choose another medicine for you. Remember to tell the doctor or nurse if you have any **blood or urine tests** as Odrik may affect the results.

**Children**
Odrik is not suitable for use in children.

**Other medicines and Odrik**
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including those obtained without a prescription. Your doctor may need to change your dose and/or to take other precautions:
If you are taking an angiotensin II receptor blocker (ARB) or aliskiren (see also information under the headings “Do not take Odrik if you:” and “Warnings and Precautions:”)

It is especially important to tell your doctor if you are taking:

- any other medicines for high blood pressure
- potassium supplements (including salt substitutes), potassium-sparing diuretics and other medicines that can increase the amount of potassium in your blood (e.g. trimethoprim and co-trimoxazole for infections caused by bacteria; ciclosporin, an immunosuppressant medicine used to prevent organ transplant rejection; and heparin, a medicine used to thin blood to prevent clots)
- thiazide-type diuretics (e.g. bendroflumethiazide, indapamide)
- any anti-inflammatory pain killers (e.g. ibuprofen, diclofenac, indomethacin, acetylsalicylic acid)
- any medicines to control diabetes (e.g. insulin, metformin or any sulphonamides)
- any tricyclic antidepressants (e.g. amitriptylline, dothiepin) or lithium
- any medicine known as sympathomimetics - these include ephedrine, pseudoephedrine and salbutamol and may be found in some decongestants, cough/cold remedies and asthma medicines.
- any antacids (use to treat indigestion and/or heartburn)
- any antipsychotics (e.g. chlorpromazine, thioridazine, flupenthixol)
- any narcotic drugs (e.g. morphine)
- systemic corticosteroid medication (e.g., prednisolone, hydrocortisone)
- anticancer agents
- allopurinol (used to treat gout)
- procainamide (used to treat abnormal heart rhythms)
- sodium aurothiomalate (used to treat rheumatoid arthritis)
- high doses of other ACE inhibitors (used to treat high blood pressure, or to help treat heart failure)
- medicines which are most often used to avoid rejection of transplanted organs (sirolimus, everolimus and other medicines belonging to the class of mTOR inhibitors). See section “Warnings and Precautions”
- NEP inhibitors such as sacubitril (available in combination with valsartan to treat long-term heart failure, see subsection “Do not take Odrik”) and racecadotril (used to treat diarrhoea)
- vildagliptin (used for treatment of type II diabetes)

**Pregnancy and breast-feeding**

Pregnancy

Please tell your doctor if you are, or think you are (or might become) pregnant. Your doctor will normally advise you to stop taking Odrik before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Odrik.
Odrik is not recommended in early pregnancy, and must not be taken when more than 3 months pregnant, as it may cause serious harm to your baby if used after the third month of pregnancy.

Breast-feeding

Tell your doctor if you are breast-feeding or about to start breast-feeding. Odrik is not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breast-feed, especially if your baby is newborn, or was born prematurely.

**Driving and using machines**

Odrik can make some people feel dizzy or faint, especially when they first start to take the capsules. This can be made worse by alcohol, even in small amounts. Do not drive, operate machinery or do anything that requires you to be alert for several hours after your first dose or any increase in the dose of Odrik. Wait and see how the capsules affect you.

**Odrik contains lactose**Odrik capsules contain lactose, a type of sugar. If you have been told that you have an intolerance to some sugars, contact your doctor before taking this medicine.

## 3. How to take Odrik

Always take Odrik exactly as you doctor has told you. You should check with your doctor or pharmacist if you are not sure.
Swallow your capsules whole without chewing them. If it helps, you can wash them down with a glass of water. The number of capsules that you will need to take will depend on what you are being treated for.
*Hypertension (high blood pressure)*
The usual starting dose is one 1 mg capsule once a day. Your doctor may increase this dose, depending on your blood pressure, up to a maximum of 4 mg once a day.
*Following a heart attack*
Treatment will normally be started quite soon after a heart attack, usually at a low dose of 0.5 mg each day. Your doctor will probably increase this dose gradually to a maximum of 4 mg each day.
*Patients with liver or kidney problems*
If you have liver or kidney problems, your doctor may start you off on a low dose of Odrik such as 0.5 mg once a day. Your doctor will monitor you closely and may increase this dose if necessary.
It is important that you keep taking these capsules until your doctor tells you to stop. Don't stop just because you feel better. If you stop taking the capsules, your condition may get worse.

**If you forget to take Odrik**
If you forget to take a dose, take it as soon as you remember unless it is almost time for your next dose. If it is, do not take the missed dose at all. Do not take a double dose to make up for the one you have missed.
**If you take more Odrik than you should**
If you or someone you know accidentally takes a lot more than the stated dose (an overdose), you should contact a doctor immediately or go to the nearest hospital emergency department. Show them your capsules.

## 4. Possible Side Effects

Like all medicines, Odrik can cause side effects in some patients. Do not be alarmed by the list below, as you may not experience any of them.

**If you notice:**
- Swelling of the face, lips or throat
- Difficulty breathing or wheeziness
- Skin rash and itching

**Tell you doctor immediately as these may be signs of an allergic reaction.**

**If you notice:**
- Yellowing of the eyes and/or skin
- Severe sore throat with fever
- Severe abdominal pain with bloating and sickness

**Tell your doctor immediately**

**In clinical trials with trandolapril, the side-effects that were observed, include:**
<u>Common (affecting less than 1 in 10 patients but more than 1 in 100 patients)</u>
- Headache
- Dizziness
- Cough
- Weakness

Uncommon (affecting less than 1 in 100 patients but more than 1 in 1,000 patients)
- Sensation of pounding or fluttering in the chest (palpitations)
- Feeling sick (nausea)
- Low blood pressure (hypotension)
- Rash, itching
- Malaise (a feeling of bodily discomfort)
- Nasal congestion (upper respiratory tract infection, inflammation and congestion)
- Disturbed sleep patterns (insomnia), Drowsiness
- Reduced sex drive or erectile dysfunction
- Balance disorder which makes you feel unsteady, giddy, woozy, or have a sensation of movement, spinning, or floating (vertigo)
- Hot flushes
- Diarrhoea, constipation, stomach pain or stomach problems
- Back pain, muscle spasms, pain in hands and feet
- Chest pain
- Swelling
- Feeling abnormal

Rare (affecting less than 1 in 1,000 patients but more than 1 in 10,000 patients)
- Urinary tract infection
- Inflammation of the upper airways(bronchitis)
- Inflammation of the back of the throat (pharyngitis)
- Blood disorders including a reduction in the levels of white and red blood cells.
- Hypersensitivity
- Increased levels of glucose, lipids, cholesterol and uric acid in your blood.
- Reduced amount of sodium in the blood
- Gout
- Anorexia or an increase in appetite
- Enzyme abnormality
- Seeing and hearing things which are not there (hallucinations), depression, anxiety, agitation, sleep disorders, apathy.
- Migraine with or without aura
- Stroke
- Fainting, muscle twitching, tingling of the hands and feet
- A change in the way things taste
- Swelling of the eyelids and eyes, blurred vision
- Ringing in the ears
- Heart problems including heart attack, heart disease, angina, heart failure, irregular heartbeat, increased heart beat and slow heartbeat
- High blood pressure, low blood pressure on standing
- Disease of the blood vessels, narrowing of the blood vessels, varicose veins
- Shortness of breath, productive cough
- Pain in the mouth or throat (Oropharyngeal pain)
- Nose bleed
- Being sick (vomiting), which can sometimes include blood
- Indigestion, dry mouth, wind, inflammation of the lining of the stomach (gastritis)
- Hepatitis, increased level of a substance called bilirubin in your blood
- Generalised swelling, psoriasis, eczema, acne, dry skin, increased sweating
- Pain in the bones and joints (including osteoarthritis)
- Kidney failure
- Increased levels of urea and other nitrogen containing substances in the blood (azotemia)
- Increase in the frequency of passing water, increase in the amount of urine passed
- Birth defects including skin disorders and abnormal blood vessel formation
- Swelling (edema)
- Tiredness

- Injury

Very Rare (affecting less than 1 in 10,000 patients)
- Reduction or stoppage of bile flow (cholestasis)
- Psoriasis
- Increased levels of potassium in the blood

The following side effects are of unknown frequency:
- Inflammation of the lining of the sinuses (sinusitis)
- Hayfever (rhinitis)
- Inflammation and/or pain in the tongue (glossitis)
- Reduction in the levels of some white and red blood cells in the blood.
- High potassium levels in the blood (hyperkalaemia)
- Mini stroke (transient ischemic attack)
- Confusion
- Rupturing of a blood vessel in the brain (cerebral hemorrhage)
- Balance disorder
- Blurred vision
- Abnormal heart rhythm, loss of heart function (cardiac arrest), disruption in the electrical signals of the heart
- Contraction of the bands of muscles around your airways (bronchospasm)
- Blockage of the small or large intestine (ileus)
- Inflammation of the pancreas (Pancreatitis)
- Swelling of the intestines (Intestinal angioedema)
- Yellowing of the eyes and/or skin (jaundice)
- Hair loss
- Hives (urticaria)
- Muscle pain
- Severe allergic reactions including Stevens-Johnson syndrome and toxic epidermal necrolysis
- Skin conditions (erythema multiforme, dermatitis psoriasiform)
- Fever
- Abnormal results of blood tests or other medical examinations

If any of the side effects become severe, or if you notice any side effect not listed in the leaflet, please tell your doctor or pharmacist.

**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, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; e-mail: medsafety@hpra.ie
By reporting side effects, you can help provide more information on the safety of this medicine.

## 5. How to store Odrik

Do not take your capsules after the expiry date, which is printed on the blister as well as the carton after Exp. Do not store above 25°C. Store in the original package. Keep out of the reach and sight of children. Your medicine could harm them.
If your doctor decides to stop the treatment, return any left over to your pharmacist. Only keep the capsules if your doctor tells you to.

## 6. Contents of the pack and other information

The active ingredient in Odrik is trandolapril. The capsules are available in three different strengths containing either 0.5 mg, 1 mg or 2 mg of trandolapril.
Odrik 0.5 mg capsules are opaque red/yellow and contain 0.5mg of trandolapril.

Odrik 1 mg capsules are opaque red/orange and contain 1 mg of trandolapril.
Odrik 2 mg capsules are opaque red/red and contain 2 mg of trandolapril.
The capsules also contain lactose monohydrate, maize starch, povidone and sodium stearyl fumarate.
The capsule shells contain gelatin, titanium dioxide (E171), erythrosine (E127), yellow iron oxide (E172) and sodium laurilsulfate.
Each calendar pack of Odrik 0.5 mg, Odrik 1 mg and Odrik 2 mg contains 7, 28 or 56 hard capsules. Not all pack sizes are marketed

**Marketing Authorisation Holder and Manufacturer**
*Marketing Authorisation Holder:*
Mylan IRE Healthcare Limited
Unit 35/36
Grange Parade
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Dublin 13

*Manufactured by:*
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Date of revision of leaflet: July 2020