

## **Package leaflet: information for the patient**

### **Viskaldix® 10 mg/5mg Tablets Pindolol & Clopamide**

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

Please 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 symptoms 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 Viskaldix Tablets are and what they are used for
2. What you need to know before you take Viskaldix Tablets
3. How to take Viskaldix Tablets
4. Possible side effects
5. How to store Viskaldix Tablets
6. Contents of the pack and other information

#### **1. What Viskaldix Tablets are and what they are used for**

The name of your medicine is Viskaldix 10 mg/5mg Tablets (called Viskaldix Tablets in this leaflet).

Viskaldix Tablets contain the active ingredients pindolol and clopamide.

Pindolol belongs to a group of medicines called beta blockers and clopamide belongs to a group of medicines called diuretics (water tablets).

Viskaldix Tablets are used in adults to treat moderately high blood pressure (hypertension).

#### **2. What you need to know before you take Viskaldix Tablets Do not take Viskaldix Tablets if you:**

- are allergic to pindolol or clopamide or any of the other ingredients of Viskaldix Tablets, listed in section 6 (allergic reactions include mild symptoms such as itching and/or rash. More severe symptoms include swelling of the face, lips, tongue and/or throat with difficulty in swallowing or breathing);
- have a history of asthma or wheezing attacks;
- have any heart problems (e.g. heart failure, heart disease);
- have an untreated tumour of the adrenal gland (phaeochromocytoma);
- have any heart rhythm disorders (sick-sinus syndrome);
- have a partial or complete block of impulses originating from sinus node in heart (sino-atrial block)
- have a very low pulse rate (less than 50 beats per minute);
- have low blood pressure (hypotension);

- have any problems with your chest or breathing, such as chronic obstructive pulmonary disease (COPD);
- need to undergo anaesthesia for surgery as some anaesthetics can interact with Viskaldix Tablets;
- have Prinzmetal's angina (a specific type of chest pain);
- have high levels of acid in your blood (metabolic acidosis);
- have not eaten for a long time;
- have problems with your circulation;
- have low levels of sodium or potassium in your blood;
- have high levels of calcium in your blood;
- have Addison's disease (a hormone deficiency which affects the adrenal glands);
- have severe kidney or liver problems;
- have difficulty passing urine;
- have symptomatic hyperuricaemia (a condition where there is an elevated level of uric acid in the blood stream);
- are taking lithium;
- are pregnant and have high blood pressure;
- are taking a medicine which belongs to a group of medicines called calcium channel blockers (e.g. verapamil).

### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Viskaldix Tablets if you:

- have heart disease or a weak heart;
- have low blood sugar levels;
- have a skin condition called psoriasis;
- have a problem with the electrical conduction of your heart, such as heart block;
- have thickening of the walls of your arteries (arteriosclerosis);
- have a condition called myasthenia gravis;
- have an untreated tumour of the adrenal gland (phaeochromocytoma);
- are taking medicines by mouth called calcium channel blockers (such as verapamil, diltiazem);
- have problems with your kidneys;
- develop a skin rash or dry eyes;
- have recently had a heart attack;
- are diabetic and taking insulin or any other anti-diabetic drugs;
- have ever had a serious allergic reaction (e.g. abnormal sensitivity to insect bites or stings, severe eczema, hay fever);
- have gout (a condition which causes pain, swelling and inflammation of one or more joints);
- are taking a group of medicines called ACE inhibitors (enalapril, ramipril);
- have a condition called lupus erythematosus;
- blood tests should be performed periodically to test levels of potassium, magnesium, sodium, calcium etc.

If you are going to have a general anaesthetic, you should tell the doctor or dentist in charge that you are taking Viskaldix Tablets, as your treatment might need to be stopped a few days before the surgery.

If any of the above applies to you, or if you are not sure, please tell your doctor before taking Viskaldix Tablets.

### **Other medicines and Viskaldix Tablets**

Please tell your doctor or pharmacist if you are taking or have recently taken, or might take any other medicines, including medicines obtained without a prescription.

This is especially important if you are taking:

- any calcium channel blockers (used to treat high blood pressure and angina) (e.g. verapamil, nifedipine);
- any barbiturates (e.g. phenobarbitone);
- an antibiotic called rifampicin;
- any other medicines for high blood pressure (hypertension);
- medicines that may lower your potassium levels (e.g. steroids, amphotericin B);
- medicines used to treat cancer (e.g. methotrexate, cyclophosphamide);
- medicines used to treat spasms and muscle twitching (e.g. biperiden);
- Vitamin D or calcium salts;
- medicine to suppress your immune system (e.g. cyclosporine);
- a medicine which belongs to a group of medicine called sympathomimetics (e.g. phenylephrine);

or if you are taking any medicines for:

- problems such as depression or mental illness (lithium, monoamine oxidase inhibitors (MAOIs), tri-cyclic antidepressants, reserpine, fluoxetine);
- heart failure (e.g. digoxin);
- an irregular heart beat (e.g. lidocaine, amiodarone, disopyramide);
- migraine (e.g. ergotamine);
- anaesthesia (e.g. halothane);
- malaria (e.g. mefloquine);
- gout (e.g. sulfinpyrazone, allopurinol);
- Parkinson's disease (e.g. amantadine);
- high cholesterol (e.g. cholestyramine);
- low blood sugar levels (e.g. diazoxide);
- diabetes (e.g. insulin or other sugar lowering anti-diabetic medicines);
- stomach ulcers (e.g. cimetidine);
- relief of pain (e.g. aspirin, ibuprofen, naproxen or other medicines known as non steroidal anti-inflammatory drugs).

### **Viskaldix Tablets with food, drink and alcohol**

It is advisable not to drink alcohol whilst taking Viskaldix Tablets as it may increase the effect of your medicine.

Excessive amounts of caffeine or nicotine may decrease the effect of Viskaldix Tablets.

### **Pregnancy and breast-feeding**

Viskaldix Tablets should not be taken during pregnancy. Viskaldix Tablets should not be taken whilst breast-feeding as they may suppress your breast milk supply.

**Driving and using machines**

You can drive while being treated with Viskaldix Tablets but do not drive until you know how it affects you. It may make you feel dizzy. If it affects you in this way, do not drive or operate any machinery.

**Viskaldix Tablets contain 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 Viskaldix Tablets**

Always take Viskaldix Tablets exactly as your doctor instructed you. You should check with your pharmacist or doctor if you are unsure.

The recommended dose is:

One tablet daily taken in the morning.

No more than three tablets should be taken in one day.

Swallow the tablet whole with a glass of water. Do not chew the tablet.

**If you take more Viskaldix Tablets than you should**

If you take more Viskaldix Tablets than you should, contact your doctor or nearest hospital emergency department immediately. Take the container and any remaining tablets with you. Symptoms of overdose include slower or faster heart beat, feeling sick, being sick, feeling lightheaded or fainting on standing upright, and low blood levels of potassium which can cause muscle weakness, twitching or abnormal heart rhythm.

**If you forget to take Viskaldix Tablets**

If you forget to take a dose, just take the next dose at the usual time. DO NOT take a double dose.

**If you stop taking Viskaldix Tablets**

Ask your doctor before stopping treatment with Viskaldix Tablets, as treatment should be reduced gradually over several days and you must be monitored carefully by your doctor.

**4. POSSIBLE SIDE EFFECTS**

Like all medicines. Viskaldix Tablets can cause side effects, although not everybody gets them.

**If you notice:**

- Itching or skin rashes;

Difficulty in breathing or wheeziness;

**Stop taking the medicine and seek medical advice immediately. These may be signs of an allergic reaction.**

Other side effects may include:

- tiredness
- dizziness
- headache
- confusion
- mood changes
- depression
- heart failure
- low blood pressure
- diabetes mellitus, or worsening of underlying diabetes
- tremor, muscle spasms, muscle pain or joint pain
- an irregular heartbeat
- an abnormally high fever
- cold, blue hands and feet (Raynaud's phenomena)
- pins and needles, numbness or tingling of hands and feet
- worsening of existing pain in legs (intermittent claudication)
- upset stomach, feeling sick, being sick, diarrhoea, constipation
- heartburn, flatulence
- shortness of breath, or a worsening of any existing lung problems such as asthma
- erectile dysfunction or problems with your libido
- nightmares
- difficulty sleeping
- a very slow pulse (less than 50 beats per minute)
- blurred vision, vision changes or inflamed dry eyes
- seeing or hearing things that are not really there (hallucinations)
- skin rash, itchiness, excessive sweating
- dry mouth
- increased levels of proteins found in the blood vessels called anti-nuclear antibodies
- low blood pressure when you stand up (which causes dizziness and fainting)
- low levels of potassium in the blood (which can cause muscle weakness, muscle twitching or abnormal heartbeat)
- low levels of magnesium in the blood
- low levels of sodium in the blood
- low levels of chloride in the blood
- increased levels of calcium in the blood
- increased levels of uric acid in the blood
- gout (a condition which causes pain, swelling and inflammation of one or more joints)
- an increase or decrease in blood sugar levels, or the presence of glucose in your urine
- high cholesterol

Less common side effects include:

- skin rashes
- sensitivity to light
- low levels of neutrophils in the blood (neutropenia)
- reduction in blood platelets which increases the risk of bruising or bleeding
- severe reduction in the number of white blood cells which makes infections more likely

- inflammation of the blood vessel walls
- severe skin reaction which causes blistering of the skin
- a skin condition called cutaneous lupus erythematosus
- a blockage of the small bowel
- a disease called retroperitoneal fibrosis
- inflammation of the pancreas which causes severe stomach and back pain
- build up or accumulation of bile in the liver

Viskaldix Tablets may hide the symptoms of low blood sugar levels or an over active thyroid gland. Viskaldix Tablets may make underlying psoriasis worse, or may unmask a condition called 'myasthenia gravis'.

### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme, website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard). By reporting side effects you can help provide more information on the safety of this medicine.

### **5. How to store Viskaldix Tablets**

Do not take Viskaldix Tablets after the expiry date which is stated on the carton.

### **KEEP OUT OF THE SIGHT AND REACH OF CHILDREN**

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. Contents of the pack and other information**

#### **What Viskaldix Tablets contain**

Each Viskaldix Tablet contains the active ingredients 10 mg pindolol and 5 mg clopamide. The other ingredients are: magnesium stearate, maize starch and lactose.

#### **What Viskaldix Tablets look like and the contents of the pack**

White, uncoated, round, flat, bevelled tablets, marked VISKALDIX on one side and with a score line on the other.

The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

They are packed in foil blister packs and are available in cartons of 28 tablets.

### **Marketing Authorisation Holder and Manufacturer**

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