

## **PACKAGE LEAFLET: INFORMATION FOR THE USER**

### **Unimax mite 2.5 mg / 2.5 mg and Unimax 5 mg / 5 mg prolonged release tablets ramipril/felodipine**

**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 Unimax mite and Unimax are and what they are used for
2. What you need to know before you take Unimax mite or Unimax
3. How to take Unimax mite or Unimax
4. Possible side effects
5. How to store Unimax mite and Unimax
6. Contents of the pack and other information

#### **1. What unimax mite and unimax are and what they are used for**

Unimax mite 2.5 mg / 2.5 mg and Unimax 5 mg / 5 mg prolonged release tablets (called also Unimax tablets in this leaflet) both contain two medicines called ramipril and felodipine.

- Ramipril belongs to a group of medicines called ‘angiotensin converting enzyme inhibitors’ (ACE inhibitors). It works by stopping the production of substances that raise blood pressure and makes your blood vessels relax and widen.
- Felodipine belongs to a group of medicines called ‘calcium antagonists’. It makes your blood vessels relax and widen. This helps to lower your blood pressure.

Unimax tablets is used to treat high blood pressure (hypertension). Unimax tablets should be used in patients whose blood pressure is not adequately controlled on felodipine or ramipril alone.

#### **2. What you need to know before you take unimax mite or unimax**

##### **Do not take Unimax tablets if:**

- You are allergic (hypersensitive) to:
  - o ramipril or any other ACE inhibitor
  - o felodipine or any other calcium antagonists
  - o any of the other ingredients of Unimax tablets (listed in section 6).
- You have ever had a serious allergic reaction called “angioedema”. The signs include itching, hives (urticaria), red marks on the hands, feet and throat, swelling of the throat and tongue, swelling around the eyes and lips, difficulty breathing and swallowing. Taking this medicine may increase the risk of having a more serious attack of this condition
- You have heart problems such as heart failure, cardiac valvular obstruction, dynamic cardiac outflow obstruction angina which is unstable, a heart condition known as atrioventricular block II or III, have ever had a heart attack (acute myocardial infarction), or a stroke (disturbance of the blood circulation in the brain)
- You have a severe kidney problem
- You are having dialysis
- You have a severe liver problem
- You are pregnant, trying to get pregnant or breast-feeding (see ‘Pregnancy and breast-feeding’ below)

- You have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Unimax tablets

### **Warnings and precautions:**

Talk to your doctor or pharmacist before taking Unimax mite or Unimax:

- You have kidney problems, diabetes mellitus or are taking medicines which increase potassium. Your doctor may carry out regular blood tests, particularly for checking the levels of potassium in your blood
- You are taking medicines or have conditions which may decrease sodium levels in your blood. Your doctor may carry out regular blood tests, particularly for checking the levels of sodium in your blood especially if you are elderly.
- You have kidney artery problems
- You have narrowing of the main blood vessel leading from the heart (aortic stenosis) or heart muscle disease (hypertrophic cardiomyopathy)
- You have any other heart problem
- You have systemic lupus erythematosus or scleroderma
- You suffer from liver problems
- You are going to have an anesthetic or surgery
- You are taking medicines which lower the number of certain blood cells
- You are black because the medicine may have less effect on your blood pressure and more side effects
- You are going to have treatment to lower the effect of an allergy to bee or wasp stings (desensitization)
- You are having treatment where your blood is treated outside the body, such as ‘low-density lipoprotein apheresis’.
- 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

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 Unimax tablets”.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Unimax tablets.

### **Other medicines and Unimax mite and Unimax**

Tell your doctor or pharmacist if you are using, have recently taken, or might take any other medicines. This includes medicines obtained without a prescription, including herbal medicines. This is because Unimax tablets can affect the way some other medicines work. Also some medicines can affect the way Unimax tablets work.

Your doctor may need to change your dose and/or take other precautions:

If you are taking an angiotensin II receptor blocker (ARB) or aliskiren (see also information under the heading “Do not take Unimax tablets” and “Warnings and precautions”).

In particular, tell your doctor if you are taking or being treated with any of the following:

- Medicines for lowering high blood pressure (antihypertensives), including those containing aliskiren, and other medicines that lower blood pressure (nitrates, antipsychotics, narcotics and anesthetics)
- Medicines to treat HIV infection
- Procainamide – used for treating heart rhythm disorders
- Water tablets (diuretics) which can cause high blood potassium such as amiloride, spironolactone, triamterene
- Heparin – used for thinning the blood
- Lithium preparations - used to treat mania, depression and manic-depressive illness
- Phenytoin, carbamazepine and barbiturates. These medicines are usually used to treat epilepsy, fits and convulsions. Barbiturates are also used for sleeping problems

- Theophylline – used for treating asthma
- Sympathomimetics such as adrenaline, noradrenaline or ephedrine (medicines which act on the heart and blood vessels)
- Erythromycin, itraconazole, ketoconazole – used for treating infections
- Rifampicin – used for treatment of tuberculosis
- Allopurinol – used for treating gout
- Non-steroidal anti-inflammatory drugs (NSAIDs) – used to relieve pain and inflammation
- Immunosuppressants – used in rheumatoid arthritis or after organ transplants
- Tacrolimus which is a medicine given to prevent the body from rejecting a transplanted organ, such as a kidney or liver
- Cytostatics – used to treat cancer
- Insulin, glibenclamide, metformin, vildagliptin and other medicines used for diabetes mellitus
- Glucocorticoids ('steroids')
- Potassium salts
- St John's Wort

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Unimax tablets.

#### **Unimax mite and Unimax with food and drink**

- Taking your tablet with alcohol may increase the effect of your medicine
- Taking this medicine with grapefruit juice is not recommended
- Increasing the amount of salt in your diet may lower the effect of this medicine
- Take the tablets on an empty stomach or after eating a light meal

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

Do not take Unimax tablets if:

- You are pregnant, might become pregnant or think you may be pregnant. This is because the medicine could harm your baby
- You are breast-feeding or planning to breast-feed. This is because small amounts may pass into the mothers' milk

If you suspect you have become pregnant while taking Unimax tablets, you should talk to your doctor immediately.

Ask your doctor or pharmacist for advice before taking any medicine.

#### **Driving and using machines**

You may feel dizzy or light-headed after taking this medicine and it may lower your ability to concentrate and react. If this happens, do not drive or use any tools or machines.

**Unimax tablets contain lactose, a type of sugar, and hydrogenated castor oil.** If you have been told by your doctor that you cannot tolerate some sugars, talk to your doctor before taking this medicine. Hydrogenated castor oil may cause stomach upset or diarrhea.

### **3. How to take Unimax mite or Unimax**

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

Unimax mite and Unimax are for adults only. Do not give to children.

#### **Taking this medicine**

- Take the tablets on an empty stomach or after eating a light meal
- Swallow the tablets whole with half a glass of water or other drink. Do not break, crush or chew the tablets
- Do not take your tablets with grapefruit juice or alcohol

**How much to take**

- The usual dose is 1 Unimax mite tablet or 1 Unimax tablet taken once a day
- Your doctor may start you on Unimax mite tablets and then change you to Unimax tablets to increase your dose
- The maximum dose is either two Unimax mite tablets once a day or one Unimax tablet once a day
- If you are already taking diuretics (water tablets), your doctor may stop or reduce the amount of the diuretic you take before beginning treatment with Unimax mite or Unimax

**If you take more Unimax mite or Unimax than you should**

If you take more Unimax mite or Unimax than you should, tell a doctor or go to the nearest hospital casualty department straight away. Take the medicine pack with you. This is so the doctor knows what you have taken. You may feel dizzy and light-headed because your blood pressure is too low.

**If you forget to take Unimax mite or Unimax**

If you forget to take a dose and remember on the same day:

- Take it as soon as you remember
- On the next day, take your usual dose of Unimax mite or Unimax

If you forget to take a dose and remember this the next day:

- Take only your usual dose of Unimax mite or Unimax
- Do not take a double dose to make up for a forgotten dose

**If you stop taking Unimax mite or Unimax**

Keep taking treatment until your doctor tells you to stop. Do not stop taking this medicine just because you feel better. If you stop, your blood pressure may rise again.

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. Some of these effects may be serious and may require medical attention.

**Tell your doctor immediately and stop taking Unimax tablets if you notice any of the following – you may need urgent medical treatment:**

- Swelling of the face, lips or throat, difficulty swallowing or breathing, itching and rashes, fainting. These could be signs of a severe allergic or anaphylactic/anaphylactoid reaction
- A skin rash with ulcers in your mouth, blisters or flaking skin. These could be signs of a severe skin problem such as toxic epidermal necrolysis, Stevens-Johnson syndrome or erythema multiforme

**Tell your doctor immediately if you notice any of the following:**

- Feeling dizzy, faint or light headed. This may be a sign of a large drop in your blood pressure
- Bruising more easily, bleeding for longer than normal, any sign of bleeding (e.g. bleeding from the gums), purple spots, blotching on the skin or getting infections more easily than usual, sore throat and fever, feeling tired, faint, dizzy or having pale skin. These could be signs of a blood or bone marrow problem
- Severe stomach pain which may reach through to your back. This could be a sign of pancreatitis
- A high temperature (fever), feeling tired, loss of appetite, stomach pain, feeling sick (nausea), yellowing of your skin or eyes (jaundice). These could be signs of liver problems such as hepatitis
- Fast heart beat, uneven or forceful heartbeat (palpitations), chest pain. These could be signs of a heart attack
- Feeling suddenly weak, numb, confused, having trouble walking, speaking or understanding what others are saying. These could be signs of a stroke

**The following side effects have been reported:**

**Very common side effects (may occur in  $\geq 10$  patients in 100)**

- Swollen arms and legs

**Common side effects (may occur in 1 to 10 patients in 100)**

- Feeling dizzy. This is more likely to happen when you start taking Unimax mite/ Unimax or start taking a higher dose
- Hypotension (abnormally low blood pressure), especially when you stand or sit up quickly
- Feeling weak, tired or drowsy
- Fainting
- Flushing
- Headache
- Dry tickly cough
- Itchy, lumpy rash
- Inflammation of your sinuses (sinusitis), difficulty breathing, shortness of breath, wheezing, tightness in the chest with a persistent cough (bronchitis)
- Chest pain
- Muscle cramps, muscle pain
- Feeling bloated, stomach cramps or pain, being sick (vomiting), indigestion, heartburn, upset stomach, diarrhoea
- Blood tests may show more potassium than usual in your blood

**Uncommon side effects (may occur in 1 to 10 patients in 1,000)**

- Blurred vision
- Feeling depressed, or anxious, more nervous than usual, shaky or restless, sleep problems or feeling sleepy
- Loss of appetite
- Loss or change in the way things taste
- Unusual skin sensations such as numbness, tingling, pricking, burning or creeping on the skin (paraesthesia)
- Runny nose, itching, sneezing and stuffy nose
- Worsening of asthma
- Constipation, loss of appetite, dry mouth. These could be signs of a blocked bowel (ileus). Stomach pains with feeling sick (nausea) and being sick (vomiting) could also be a sign of a condition called “intestinal angioedema”
- Swollen mouth, face and lips (angioedema)
- Being less interested in sex than usual, impotence in men
- Joint pain
- Sweating more than usual
- Water (urine) tests showing that you are losing more protein in your water (urine) than usual or passing more water (urine) in general
- Fever
- Fast heartbeat, uneven or forceful heartbeat
- Heart attack
- Blood tests may show changes in the way your liver, pancreas or kidneys are working
- Blood tests showing more of a certain kind of white blood cells (eosinophilia) in your blood

**Rare side effects (may occur in 1 to 10 patients in 10,000)**

- Feeling confused
- Balance problems
- A change in your hearing or ringing in your ears
- Red and swollen tongue
- Red, itchy, swollen or watery eyes
- Nail problems
- Itching, flaking skin, blisters

- Yellowing of the skin or the whites of the eyes
- If your blood already has problems getting delivered to all of your body (blood perfusion disturbance), this could get worse
- Blood tests showing a decrease in the number of red blood cells, white blood cells or platelets or in the amount of haemoglobin

**Very rare side effects** (may occur in less than 1 in 10,000 patients)

- Being more sensitive to the sun than usual.
- Nose bleeds, as well as feeling tired, and having pale skin (often with a yellow tinge)
- Drugs like felodipine, one of the active ingredients in Unimax, Unimax mite, may cause your gums to become swollen and sore. Good dental hygiene will help control this problem.
- Skin rash or bruising. This could be a sign of swollen blood vessels
- Swelling of the face, lips or throat, difficulty swallowing or breathing, itching and rashes, fainting. These could be signs of a severe allergic reaction.
- Blood tests showing more sugar than usual in your blood

**Not known (frequency cannot be estimated from available data)**

- Fingers and toes changing colour when cold and tingling or painful on warming up. These could be signs of a problem called Raynaud's phenomenon,
- Hair loss
- If you already have a skin problem called psoriasis, this could get worse
- Slowed or impaired reactions
- A change in the way things smell
- Stroke
- Breast enlargement in men
- Blood tests showing more of substances called 'antinuclear antibodies' in your blood
- Blood tests showing less sodium than usual in your blood,
- Painful ulcers in your mouth or upper throat

### **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 **the national reporting system listed in Appendix V**. By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Unimax mite and Unimax**

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

Do not store above 30°C Medicines should not be disposed of 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 Unimax mite and Unimax contain**

- The active substances in Unimax mite and Unimax prolonged release tablets are: ramipril and felodipine.
  - o Unimax mite tablets contain 2.5 mg of ramipril and 2.5 mg of felodipine
  - o Unimax tablets contain 5 mg of ramipril and 5 mg of felodipine
- The other ingredients are: cellulose microcrystalline, hypromellose, iron oxides E172, lactose anhydrous, macrogol 6000, macrogolglycerol hydroxystearate, maize starch, paraffin, propyl gallate, sodium aluminium silicate, sodium stearyl fumarate, titanium dioxide E 171

**What Unimax mite and Unimax look like and contents of the pack**

- Unimax mite tablets are apricot coloured and have “H/OD” marked on one side and “2.5” marked on the other side
- Unimax tablets are reddish-brown and have “H/OE” marked on one side and “5” on the other side
- Unimax mite and Unimax come in blister packs containing 14, 15, 28, 30, 49, 50, 56, 98, 100 and 10x49 in bottles containing 15, 30, 100 and 250

Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer**

<[To be completed nationally]>

{Name and address}

<{tel}>

<{fax}>

<{e-mail}>

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

Germany UNIMAX

Greece UNITENS

Finland UNIMAXMITE, UNIMAX

Sweden UNIMAX MITE, UNIMAX

**This leaflet was last approved in 18 February 2015**

BLUE BOX FOR LOCAL REQUIREMENTS