
APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S3

REPRES 2 mg (Tablet)

REPRES 4 mg (Tablet)

REPRES 8 mg (Tablet)

Perindopril tert-butylamine

Read all of this leaflet carefully before you start taking REPRES.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **REPRES** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

1. WHAT REPRES CONTAINS

The active substance is perindopril.

REPRES 2 mg: Each uncoated tablet contains perindopril tert-butylamine 2 mg.

The other ingredients are cellulose microcrystalline, lactose, magnesium stearate and silica hydrophobic colloidal anhydrous.

REPRES 4 mg: Each uncoated tablet contains perindopril tert-butylamine 4 mg.

The other ingredients are cellulose microcrystalline, lactose, magnesium stearate and silica hydrophobic colloidal anhydrous.

REPRES 8 mg: Each uncoated tablet contains perindopril tert-butylamine 8 mg.

The other ingredients are cellulose microcrystalline, lactose, magnesium stearate and silica hydrophobic colloidal anhydrous.

2. WHAT REPRES IS USED FOR

REPRES belongs to a class of medications called angiotensin-converting enzyme (ACE) inhibitors. It works by decreasing certain chemicals that tighten the blood vessels, so blood flows more smoothly and the heart can pump blood more efficiently.

REPRES is used to treat high blood pressure and is also used to treat congestive heart failure (a condition where the heart is unable to pump enough blood to meet the body's needs).

3. BEFORE YOU TAKE REPRES

Do not take REPRES:

- If you have ever had an allergic reaction to perindopril or any ingredient of the product.
- If you have ever had angioedema (a condition that causes difficulty swallowing or breathing and painful swelling of the face, throat, tongue, lips, eyes, hands, feet, ankles, or lower legs) related to previous treatment with an ACE-inhibitor or angiotensin receptor blocker.
- If you have hereditary (inherited) / idiopathic (unknown cause) angioedema.
- If you have hypertrophic obstructive cardiomyopathy (heart muscle disease).
- If you have severe kidney disease.
- If you have renal artery stenosis (narrowing of the artery supplying the kidney with blood).
- If you have aortic stenosis (a narrowing of the aortic valve in the heart, slowing blood flow from the heart into the main artery leaving the heart).
- If you are taking diuretics (water tablets used to reduce the amount of water in the body), such as spironolactone, triamterene, amiloride. These medicines do not cause your body to lose potassium.
- If you are taking a thiazide diuretic and have Addison's disease, or if you are taking a thiazide diuretic and have severe kidney problems, anuria (failure of kidneys to produce urine) or if you are allergic to other "sulpha" medicines.
- If you have porphyria (an inherited disorder of blood pigment metabolism).
- If you are taking lithium.
- If you are pregnant or breast-feeding. See "**Take special care with REPRES**" and "**Pregnancy and Breast-feeding**".
- **REPRES** must not be given to children.

REPRES can harm an unborn baby. If you get pregnant, immediately stop taking

REPRES. Call your doctor right away. Talk to your doctor about other medicines to take to lower your blood pressure.

**Take
special
care**

with REPRES:

- You should know that loss of water from your body due to vomiting or diarrhoea; being on dialysis; taking diuretics (medicine to increase excretion of urine); and too little salt in your diet can cause a drop in blood pressure, which may cause lightheadedness and fainting. Low blood pressure is also most likely to happen if you have heart problems. If you are at risk of low blood pressure, your doctor may need to monitor your therapy closely. Lie down if you feel faint or dizzy.
- If you develop swelling of the face around your lips, tongue, or throat or difficulty swallowing, you should immediately contact your doctor and stop taking **REPRES**.
- If you are elderly or have severe kidney disease, your doctor may need to adjust your dose.
- **REPRES** has been associated with a decrease in the number of a certain type of white blood cells. Low white blood cells happen more in people who have kidney problems and collagen vascular diseases (diseases of the connective tissue). Low white blood cells can give you a higher chance for getting infections. Call your doctor if you get a fever, sore throat, or other signs of infection that do not go away.
- Do not use salt substitutes which contain potassium, potassium supplements or other medicines which may increase potassium blood levels while taking **REPRES**, unless your doctor has told you to.
- Your doctor may monitor your kidney function or check your blood potassium level. Do not miss any scheduled visits to your doctor.
- A persistent, dry cough may occur while taking **REPRES**.
- To be sure this medication is helping your condition, your blood pressure will need to be checked on a regular basis. Do not miss any scheduled visits to your doctor.

Tell your doctor:

- if you have narrowing of the heart valves (aortic stenosis) or heart muscle disease (hypertrophic cardiomyopathy). See “**Do not take REPRES**”.
- if you have any other heart problems, such as heart failure, congestive heart failure, heart attack or ischaemic heart disease.
- if you suffer from a collagen vascular disease (disease of the connective tissue) such as systemic lupus erythematosus or scleroderma.
- if you have blood vessel problems in the brain (including stroke).
- if you have kidney problems, or if you are receiving dialysis.
- if you have liver problems or develop jaundice (yellow skin and eyes).
- if you have diabetes.
- if you have recently had a kidney transplant.
- if you are to undergo anaesthesia and / or surgery.
- if you are on a salt restricted diet or use salt substitutes which contain potassium.
- if you are going to have cholesterol removed from your blood by a machine (LDL apheresis).
- if you are going to have desensitisation treatment to reduce the effects of an allergy e.g. allergy to bee or wasp stings.
- if your blood pressure is not sufficiently lowered due to ethnic affiliation (particularly in patients with black skin colour).
- if you are taking lithium for mania or depression. See “**Do not take REPRES**” and “**Taking other medicines with REPRES**”.

Taking REPRES with food and drink:

REPRES should be taken before a meal.

Pregnancy and Breast-feeding:

Do not use this medication if you are pregnant or planning a pregnancy or if you are breast-feeding.

REPRES can cause birth defects in the baby if you take the medication during pregnancy. Use an effective form of birth control. Stop using this medication and tell your doctor right away if you become pregnant during treatment.

If you are pregnant or breast-feeding your baby do not take this medicine, please consult your doctor, pharmacist or other health care professional for advice before taking this medicine.

Driving and using machinery:

Do not drive or use machines if you feel dizzy or tired when taking **REPRES**.

Taking other medicines with REPRES:

Before taking **REPRES**, tell your doctor if you are using any of the following medicines:

- Other medicines for high blood pressure, including diuretics (medicines which increase the amount of urine produced by the kidneys).
- Potassium-sparing diuretics (water tablets which affect potassium, such as spironolactone, triamterene or amiloride), potassium supplements, potassium containing-salt substitutes, or medicines which may increase potassium levels in your blood (e.g. ciclosporin). **REPRES** must not be taken with potassium-sparing diuretics. See “**Do not take REPRES**”. Do not use salt substitutes which contain potassium, potassium supplements or other medicines which may increase potassium levels in your blood while taking **REPRES**, unless your doctor has told you to.
- Heparin (for thinning the blood) can also affect potassium levels in your blood.
- Lithium for mania or depression. See “**Do not take REPRES**”.
- Non-steroidal anti-inflammatory medications (e.g. ibuprofen, indomethacin) for treating pain and inflammation or high dose aspirin.
- Allopurinol (for gout).
- Medicines for diabetes (insulin or tablets).
- Procainamide (for irregular heartbeat).
- Medicines that make the blood vessels wider (vasodilators, such as nitrates).
- Medicines to treat mental disorders such as depression, anxiety, schizophrenia or other psychosis (e.g. tricyclic antidepressants, antipsychotics).
- Anaesthetics (medicines causing loss of sensation or pain/consciousness).
- Medicines used for the treatment of low blood pressure, shock or asthma (e.g. ephedrine, noradrenaline or adrenaline).

- Immunosuppressants (medicines which reduce the defence mechanism of the body) used for the treatment of auto-immune disorders or following transplant surgery (e.g. ciclosporin).

If you are using any of these medicines, you may not be able to take **REPRES**, or you may need dosage adjustments or your doctor may need to monitor you carefully for side-effects.

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of **REPRES** with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional, for advice.

4. HOW TO TAKE REPRES

- Take this medicine only as directed by your doctor.
- Do not take more or less of it or take it more often than prescribed by your doctor.
- REPRES** should be taken before a meal.

The usual dosages are as follows:

- High blood pressure:

The usual dosage is 4 mg taken in the morning before breakfast. After one month your doctor may decide this dosage can be increased to 8 mg once a day, if required.

If you are elderly or have heart failure, your doctor will prescribe a lower dosage.

- Congestive heart failure:

The usual starting dose is 2 mg once daily in the morning. Your doctor can increase this dose to 4 mg once a day.

If you are taking water tablets (diuretics):

- Your doctor may decide to stop them before you start taking **REPRES**.

Always take **REPRES** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. If you have the impression that the effect of **REPRES** is too strong or too weak, talk to your doctor or pharmacist.

If you take more REPRES than you should:

The following effects may occur: low blood pressure, shock, kidney problems, fast breathing, fast heartbeat, uneven heartbeat (palpitations), slow heartbeat, feeling dizzy or anxious and cough.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control center.

If you forget to take REPRES:

It is important to take your medicine every day as regular treatment works better.

If you forget to take **REPRES**, take the missed dose as soon as you remember it. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

5. POSSIBLE SIDE-EFFECTS

REPRES can have side-effects.

Get emergency medical help if you have any of these signs of an allergic reaction:

- Difficulty breathing
- Swelling of your face, lips, tongue, or throat

Call your doctor at once if you have any of these serious side-effects:

- Fainting, feeling light-headed or feeling faint, particularly when standing. This may mean your blood pressure is too low.
- Jaundice (yellowing of the skin and eyes).
- Urinating less than usual, or not at all.
- Palpitations (rapid irregular action of heart) or arrhythmias (irregular heart beat).
- Angina (chest pain that happens in heart disease).
- Heart attack (chest pain, shortness of breath, excess sweating, weakness, light-headedness, nausea, vomiting, palpitations, fatigue).
- Stroke (sudden numbness or weakness of the face, arm or leg, especially on one side of the body; sudden severe headache; sudden confusion, trouble speaking or understanding; sudden trouble walking, dizziness, loss of co-ordination).
- Pale skin, easy bruising or bleeding.

- Fever, sore throat, chills, and other signs of infection.
- Severe abdominal and back pain accompanied with feeling very unwell (inflammation of the pancreas).

Other side-effects include: Sleep problems; mood swings; headache; dizziness; feeling of spinning or rotation of surroundings (vertigo); pins and needles; feeling confused; problems with vision; sensation of noises in the ears; cough; shortness of breath; tight feeling in the chest, wheezing and short of breath (bronchospasm); chest infection (eosinophilic pneumonia); blocked up or runny nose (rhinitis); diarrhoea; constipation; nausea (feeling sick); vomiting (being sick); abdominal pain; changes in your sense of taste; heartburn; dry mouth; inflamed liver (hepatitis); skin rash; hives; itching; skin reaction like an allergy (erythema multiforme); muscle cramps; kidney problems; impotence (unable to get an erection); disorders of the blood (your doctor may carry out blood tests to check for this); lack of energy; sweating; anaemia.

Tell your doctor if any of the above side-effects are severe, bothersome, do not go away or about any concerns you have while taking **REPRES**.

Not all side-effects reported for this medicine are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

6. STORING AND DISPOSING OF REPRES

Store at or below 25 °C in a dry place. Do not remove the blisters from the carton until required.

Store all medicines out of the reach and sight of children.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF REPRES

REPRES 2 mg, REPRES 4 mg, AND REPRES 8 mg:

Blister Packs:

Tablets are packed in blister packs (composed of clear PVC film and silver coloured aluminium lidding foil). Each blister contains 10 tablets. Three blisters are packed in a bag together with a silica gel sachet.

Pack size 30's: Each carton contains 3 blisters of 10 tablets each.

8. IDENTIFICATION OF REPRES

REPRES 2 mg

White to off-white coloured round biconvex uncoated tablets, with debossing "D" on one side "57" on other side.

REPRES 4 mg

White to off-white coloured capsule shaped uncoated tablets, with debossing "D" on one side and "5" & "8" on either side of the breakline on another side.

REPRES 8 mg

White to off-white coloured round biconvex uncoated tablets, with debossing "D" on one side and "5" & "9" on either side of breakline on another side.

9. REGISTRATION NUMBER/REFERENCE NUMBER

REPRES 2 mg: 43/7.1.3/1032

REPRES 4 mg: 43/7.1.3/1033

REPRES 8 mg: 43/7.1.3/1034

10. NAME AND ADDRESS OF REGISTRATION HOLDER

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