

Innovace[®] 5mg Tablets

Renitec[®] 5mg Tablets

Innovace[®] 20mg Tablets

Renitec 20mg Tablets

1648/1650
27.07.15[13]

(enalapril maleate)

PATIENT INFORMATION LEAFLET

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 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.

The product is available using any of the above names but will be referred to as Innovace throughout this leaflet.

Innovace Tablets are also available in other strengths.

What is in this leaflet:

1. What Innovace is and what it is used for
2. What you need to know before you take Innovace
3. How to take Innovace
4. Possible side effects
5. How to store Innovace
6. Contents of the pack and other information

1. WHAT INNOVACE IS AND WHAT IT IS USED FOR

Innovace contains an active substance called enalapril maleate. This belongs to the group of medicines called ACE inhibitors (angiotensin converting enzyme inhibitors).

Innovace is used:

- to treat high blood pressure (hypertension).
- to treat heart failure (weakening of heart function). It can lower the need to go to hospital and can help some patients live longer.
- to prevent the signs of heart failure. The signs include: shortness of breath, tiredness after light physical activity such as walking, or swelling of the ankles and feet.

This medicine works by widening your blood vessels. This lowers your blood pressure. The medicine usually starts to work within an hour, and the effect lasts for at least 24 hours. Some people will require several weeks of treatment until the best effect on your blood pressure is seen.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE INNOVACE

Do not take Innovace

- if you are allergic to enalapril maleate or any of the other ingredients of this medicine (listed in section 6).
- if you have ever had an allergic reaction to a type of medicine similar to this medicine called an ACE inhibitor.
- if you have ever had swelling of your face, lips, mouth, tongue or throat which caused difficulty in swallowing or breathing (angioedema) when the reason why was not known or it was inherited.
- if you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.
- if you are more than 3 months pregnant. (It is also better to avoid Innovace in early pregnancy – see Pregnancy section).

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 this medicine.

Warnings and Precautions

Talk to your doctor or pharmacist before taking innovace

- if you have a heart problem.
- if you have a condition involving the blood vessels in the brain.
- if you have a blood problem such as low or lack of white blood cells (neutropenia/agranulocytosis), low blood platelet count (thrombocytopenia) or a decreased number of red blood cells (anaemia).
- if you have a liver problem.
- if you have a kidney problem (including kidney transplantation). These may lead to higher levels of potassium in your blood which can be serious. Your doctor may need to adjust your dose of Innovace or monitor your blood level of potassium.
- if you are having dialysis.
- if you have been very sick (excessive vomiting) or had bad diarrhoea recently.
- if you are on a salt-restricted diet, are taking potassium supplements, potassium-sparing agents, or potassium-containing salt substitutes.
- if you are over 70 years of age.
- if you have diabetes. You should monitor your blood for low blood glucose levels, especially during the first month of treatment. The level of potassium in your blood can also be higher.
- if you have ever had an allergic reaction with swelling of the face, lips, tongue or throat with difficulty in swallowing or breathing. You should be aware that black patients are at increased risk of these types of reactions to ACE inhibitors.
- if you have low blood pressure (you may notice this as faintness or dizziness, especially when standing).
- if you have collagen vascular disease (e.g. lupus erthematosus, rheumatoid arthritis or scleroderma), are on therapy that suppresses your immune system, are taking the drugs allopurinol or procainamide, or any combinations of these.
- if you are taking any of the following medicines used to treat high blood pressure:
 - an angiotensin II receptor blocker (ARB) (also known as sartans - for example valsartan, telmisartan, irbesartan, etc.), 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 Innovace.”

You must tell your doctor if you think you are (or might become) pregnant. This medicine is not recommended in early pregnancy, and must not be taken if you are more than 3 months pregnant, as it may cause serious harm to your baby if used at that stage (see Pregnancy section).

You should be aware that this medicine lowers the blood pressure in black patients less effectively than in non-black patients.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking this medicine.

If you are about to have a procedure

If you are about to have any of the following, tell your doctor that you are taking Innovace:

- any surgery or receive anaesthetics (even at the dentist).
- a treatment to remove cholesterol from your blood called ‘LDL apheresis’.
- a desensitisation treatment, to lower the effect of an allergy to bee or wasp stings.
- If any of the above applies to you, talk to your doctor or dentist before the procedure.

Other medicines and Innovace

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes herbal medicines. This is because Innovace can affect the way some medicines work. Also some other medicines can affect the way Innovace works. Your doctor may need to change your dose and/or to take other precautions.

In particular tell your doctor or pharmacist if you are taking any of the following medicines:

- an angiotensin II receptor blocker (ARB) or aliskiren (see also information under the headings “Do not take Innovace” and “Warnings and precautions”)
- other medicines to lower blood pressure, such as beta-blockers or water tablets (diuretics)
- medicines containing potassium (including dietary salt substitutes)
- medicines for diabetes (including oral antidiabetic medicines and insulin)
- lithium (a medicine used to treat a certain kind of depression)
- medicines for depression called ‘tricyclic antidepressants’
- medicines for mental problems called ‘antipsychotics’
- certain cough and cold medicines and weight reducing medicines which contain something called a ‘sympathomimetic agent’
- certain pain or arthritis medicines including gold therapy
- non-steroidal anti-inflammatory drugs, including COX-2-inhibitors (medicines that reduce inflammation, and can be used to help relieve pain)
- aspirin (acetylsalicylic acid)
- medicines used to dissolve blood clots (thrombolytics)
- alcohol

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

Innovace with food and drink

Innovace can be taken with or without food. Most people take Innovace with a drink of water.

Pregnancy and breast-feeding

Pregnancy

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. Your doctor will normally advise you to stop taking Innovace before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Innovace. This medicine 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. Breast-feeding newborn babies (first few weeks after birth), and especially premature babies, is not recommended whilst taking this medicine. In the case of an older baby your doctor should advise you on the benefits and risks of taking this medicine whilst breast-feeding, compared to other treatments.

Driving and using machines

You may feel dizzy or sleepy while taking this medicine. If this happens, do not drive or use any tools or machines.

Innovace contains lactose

Innovace contains lactose, which is a type of sugar. If you have been told by your doctor that you have intolerance to some sugars, talk to your doctor before taking this medicine.

3. HOW TO TAKE INNOVACE

Always take this medicine exactly as your doctor or pharmacist has told you.

Check with your doctor or pharmacist if you are not sure.

- It is very important to continue taking this medicine for as long as your doctor prescribes it.
- Do not take more tablets than prescribed.

High Blood Pressure

- The usual starting dose ranges from 5 to 20 mg taken once a day.
- Some patients may need a lower starting dose.
- The usual long term dose is 20 mg taken once a day.
- The maximal long term dose is 40 mg taken once a day.

Heart Failure

- The usual starting dose is 2.5 mg taken once a day.
- Your doctor will raise this amount step by step until the dose that is right for you has been achieved.
- The usual long term dose is 20 mg each day, taken in one or two doses.
- The maximal long term dose is 40 mg each day, divided in two doses.

Patients with kidney problems

Your dose of medicine will be changed depending on how well your kidneys are working:

- moderate kidney problems - 5 mg to 10 mg each day.
- severe kidney problems - 2.5 mg each day.
- if you are having dialysis - 2.5 mg each day. On days you are not having dialysis, your dose may be changed depending on how low your blood pressure is.

Elderly patients

Your dose will be decided by your doctor and will be based on how well your kidneys are working.

Use in children

Experience in the use of Innovace in children with high blood pressure is limited. If the child can swallow tablets, the dose will be worked out using the child’s weight and blood pressure. The usual starting doses are:

- between 20 kg and 50 kg – 2.5 mg each day.
- more than 50 kg – 5 mg each day.

The dose can be changed according to the needs of the child:

- a maximum of 20 mg daily can be used in children who are between 20 kg and 50 kg.
- a maximum of 40 mg daily can be used in children who are more than 50 kg.

This medicine is not recommended in newborn babies (first few weeks after birth) and in children with kidney problems.

If you take more Innovace than you should

If you take more Innovace than you should, talk to your doctor or go to a hospital straight away. Take the medicine pack with you. The following effects may happen: feeling of light-headedness or dizziness. This is due to a sudden or excessive drop in blood pressure.

If you forget to take Innovace

- If you forget to take a tablet, skip the missed dose.
- Take the next dose as usual.
- Do not take a double dose to make up for a forgotten dose.

If you stop taking Innovace

Do not stop taking your medicine unless your doctor tells you to. 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. The following side effects may happen with this medicine:

Stop taking Innovace and talk to a doctor straight away, if you notice any of the following:

- swelling of your face, lips, tongue or throat which may cause difficulty in breathing or swallowing.
- swelling of your hands, feet or ankles.
- if you develop a raised red skin rash (hives).

You should be aware that black patients are at increased risk of these types of reactions. If any of the above happen, stop taking Innovace and talk to a doctor straight away.

When you start taking this medicine you may feel faint or dizzy. If this happens, it will help to lie down. This is caused by your blood pressure lowering. It should improve as you continue to take the medicine. If you are worried, please talk to your doctor.

Other side effects include:

Very Common (may affect more than 1 in 10 people)

- feeling dizzy, weak or sick.
- blurred vision.
- cough.

Common (may affect up to 1 in 10 people)

- light-headedness due to low blood pressure, changes in heart rhythm, fast heartbeat, angina or chest pain.
- headache, depression, fainting (syncope), change in sense of taste
- shortness of breath
- diarrhoea, abdominal pain
- tiredness (fatigue)
- rash, allergic reactions with swelling of the face, lips, tongue or throat with difficulty in swallowing or breathing
- high levels of potassium in the blood, increased levels of creatinine in your blood (both are usually detected by a test)

Uncommon (may affect up to 1 in 100 people)

- flushing
- sudden fall in blood pressure
- fast or uneven heart beats (palpitations)
- heart attack (possibly due to very low blood pressure in certain high-risk patients, including those with blood flow problems of the heart or brain)
- stroke (possibly due to very low blood pressure in high-risk patients)
- anaemia (including aplastic and haemolytic)
- confusion, sleeplessness or sleepiness, nervousness
- feeling your skin prickling or being numb
- vertigo (spinning sensation)
- ringing in your ears (tinnitus)
- runny nose, sore throat or hoarseness
- asthma-associated tightness in chest
- slow movement of food through your intestine (ileus), inflammation of your pancreas
- being sick (vomiting), indigestion, constipation, anorexia
- irritated stomach (gastric irritations), dry mouth, ulcer.
- muscle cramps
- impaired kidney function, kidney failure
- increased sweating
- itching or nettle rash
- hair loss
- generally feeling unwell (malaise), high temperature (fever)
- impotence
- high level of proteins in your urine (measured in a test)
- low level of blood sugar or sodium, high level of blood urea (all measured in a blood test).

Rare (may affect up to 1 in 1,000 people)

- Raynaud's phenomenon' where your hands and feet may become very cold and white due to low blood flow
- changes in blood values such as a lower number of white and red blood cells, lower haemoglobin, lower number of blood platelets
- bone marrow depression
- swollen glands in neck, armpit or groin
- autoimmune diseases
- strange dreams or sleep problems
- accumulation of fluid or other substances in the lungs (as seen on X-rays)
- inflammation of your nose
- inflammation of the lungs causing difficulty breathing (pneumonia)
- inflammation of the cheeks, gums, tongue, lips, throat
- reduced amount of urine
- rash that looks like targets (erythema multiforme)
- 'Stevens-Johnson syndrome' and 'toxic epidermal necrolysis' (serious skin conditions where you have reddening and scaling of your skin, blistering or raw sores), exfoliative dermatitis/erythroderma (severe skin rash with flaking or peeling of the skin), pemphigus (small fluid-filled bumps on the skin)
- liver or gallbladder problems such as lower liver function, inflammation of your liver, jaundice (yellowing of the skin or eyes), high levels of liver enzymes or bilirubin (measured in a blood test)
- enlargement of breasts in males (gynaecomastia).

Very Rare (may affect up to 1 in 10,000 people)

- swelling in your intestine (intestinal angioedema).

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

- overproduction of antidiuretic hormone, which causes fluid retention, resulting in weakness, tiredness or confusion
- A symptom complex has been reported which may include some or all of the following: fever, inflammation of the blood vessels (serositis/vasculitis), muscle pain (myalgia/myositis), joint pain (arthralgia/arthritis). Rash, photosensitivity or other skin manifestations may occur.

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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom: Yellow Card Scheme

at: www.mhra.gov.uk/yellowcard

5. HOW TO STORE INNOVACE

Keep out of the sight and reach of children.

Do not use Innovace after the expiry date which is stated on the blister and the carton after 'EXP'. The expiry date refers to the last day of that month.

Do not store above 25°C. Store in the original package.

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 Innovace contains:

- The active substance is enalapril maleate.
Each tablet contains either 5 mg or 20 mg of enalapril maleate.
- The other ingredients are: lactose monohydrate, magnesium stearate E572, maize starch, pregelatinised maize starch, sodium bicarbonate E500. The 20mg tablets also contain red iron oxide E172, yellow iron oxide E172.

What Innovace looks like and the contents of the pack

- The 5 mg tablets are white rounded, rectangle-shaped tablets one side embossed 'RENITEC', the other side scored.
- The 20 mg tablets are peach-coloured, rounded, rectangle-shaped tablets one side embossed 'RENITEC', the other side scored and embossed 'MS"DE'.

The 5 mg tablets are available in blister packs of 30 and 60 tablets.

The 20 mg tablets are available in blister packs of 28 tablets.

Manufacturer and Product Licence Holder

Manufactured by Merck Sharp & Dohme, B.V., Waarderweg 39, 2031 BN Haarlem, The Netherlands. Procured from within the EU by Product Licence holder: Star Pharmaceuticals Ltd, 5 Sandridge Close, Harrow, Middlesex, HA1 1XD. Repackaged by Servipharm Ltd.

POM

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Innovace 20mg Tablets/Renitec 20mg Tablets - PL 20636/1650

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Enalapril Maleate 5mg Tablets

Enalapril Maleate 20mg Tablets

(enalapril maleate)

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- If you have 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.

The product is available using any of the above names but will be referred to as Enalapril throughout this leaflet. Enalapril Tablets are also available in other strengths.

What is in this leaflet:

1. What Enalapril is and what it is used for
2. What you need to know before you take Enalapril
3. How to take Enalapril
4. Possible side effects
5. How to store Enalapril
6. Contents of the pack and other information

1. WHAT ENALAPRIL IS AND WHAT IT IS USED FOR

Enalapril contains an active substance called enalapril maleate. This belongs to the group of medicines called ACE inhibitors (angiotensin converting enzyme inhibitors).

Enalapril is used:

- to treat high blood pressure (hypertension).
- to treat heart failure (weakening of heart function). It can lower the need to go to hospital and can help some patients live longer.
- to prevent the signs of heart failure. The signs include: shortness of breath, tiredness after light physical activity such as walking, or swelling of the ankles and feet.

This medicine works by widening your blood vessels. This lowers your blood pressure. The medicine usually starts to work within an hour, and the effect lasts for at least 24 hours. Some people will require several weeks of treatment until the best effect on your blood pressure is seen.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ENALAPRIL

Do not take Enalapril

- if you are allergic to enalapril maleate or any of the other ingredients of this medicine (listed in section 6).
- if you have ever had an allergic reaction to a type of medicine similar to this medicine called an ACE inhibitor.
- if you have ever had swelling of your face, lips, mouth, tongue or throat which caused difficulty in swallowing or breathing (angioedema) when the reason why was not known or it was inherited.
- if you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.
- if you are more than 3 months pregnant. (It is also better to avoid Enalapril in early pregnancy – see Pregnancy section).

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 this medicine.

Warnings and Precautions

Talk to your doctor or pharmacist before taking Enalapril

- if you have a heart problem.
- if you have a condition involving the blood vessels in the brain.
- if you have a blood problem such as low or lack of white blood cells (neutropenia/agranulocytosis), low blood platelet count (thrombocytopenia) or a decreased number of red blood cells (anaemia).
- if you have a liver problem.
- if you have a kidney problem (including kidney transplantation). These may lead to higher levels of potassium in your blood which can be serious. Your doctor may need to adjust your dose of Enalapril or monitor your blood level of potassium.
- if you are having dialysis.
- if you have been very sick (excessive vomiting) or had bad diarrhoea recently.
- if you are on a salt-restricted diet, are taking potassium supplements, potassium-sparing agents, or potassium-containing salt substitutes.
- if you are over 70 years of age.
- if you have diabetes. You should monitor your blood for low blood glucose levels, especially during the first month of treatment. The level of potassium in your blood can also be higher.
- if you have ever had an allergic reaction with swelling of the face, lips, tongue or throat with difficulty in swallowing or breathing. You should be aware that black patients are at increased risk of these types of reactions to ACE inhibitors.
- if you have low blood pressure (you may notice this as faintness or dizziness, especially when standing).
- if you have collagen vascular disease (e.g. lupus erthematosus, rheumatoid arthritis or scleroderma), are on therapy that suppresses your immune system, are taking the drugs allopurinol or procainamide, or any combinations of these.
- if you are taking any of the following medicines used to treat high blood pressure:
 - an angiotensin II receptor blocker (ARB) (also known as sartans - for example valsartan, telmisartan, irbesartan, etc.), 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 Enalapril.”

You must tell your doctor if you think you are (or might become) pregnant. This medicine is not recommended in early pregnancy, and must not be taken if you are more than 3 months pregnant, as it may cause serious harm to your baby if used at that stage (see Pregnancy section).

You should be aware that this medicine lowers the blood pressure in black patients less effectively than in non-black patients. If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking this medicine.

If you are about to have a procedure

If you are about to have any of the following, tell your doctor that you are taking Enalapril:

- any surgery or receive anaesthetics (even at the dentist).
- a treatment to remove cholesterol from your blood called ‘LDL apheresis’.
- a desensitisation treatment, to lower the effect of an allergy to bee or wasp stings.
- If any of the above applies to you, talk to your doctor or dentist before the procedure.

Other medicines and Enalapril

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes herbal medicines. This is because Enalapril can affect the way some medicines work. Also some other medicines can affect the way Enalapril works. Your doctor may need to change your dose and/or to take other precautions.

In particular tell your doctor or pharmacist if you are taking any of the following medicines:

- an angiotensin II receptor blocker (ARB) or aliskiren (see also information under the headings “Do not take Enalapril” and “Warnings and precautions”)
- other medicines to lower blood pressure, such as beta-blockers or water tablets (diuretics)
- medicines containing potassium (including dietary salt substitutes)
- medicines for diabetes (including oral antidiabetic medicines and insulin)
- lithium (a medicine used to treat a certain kind of depression)
- medicines for depression called ‘tricyclic antidepressants’
- medicines for mental problems called ‘antipsychotics’
- certain cough and cold medicines and weight reducing medicines which contain something called a ‘sympathomimetic agent’
- certain pain or arthritis medicines including gold therapy
- non-steroidal anti-inflammatory drugs, including COX-2-inhibitors (medicines that reduce inflammation, and can be used to help relieve pain)
- aspirin (acetylsalicylic acid)
- medicines used to dissolve blood clots (thrombolytics)
- alcohol

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

Enalapril with food and drink

Enalapril can be taken with or without food. Most people take Enalapril with a drink of water.

Pregnancy and breast-feeding

Pregnancy

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. Your doctor will normally advise you to stop taking Enalapril before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Enalapril. This medicine 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. Breast-feeding newborn babies (first few weeks after birth), and especially premature babies, is not recommended whilst taking this medicine. In the case of an older baby your doctor should advise you on the benefits and risks of taking this medicine whilst breast-feeding, compared to other treatments.

Driving and using machines

You may feel dizzy or sleepy while taking this medicine. If this happens, do not drive or use any tools or machines.

Enalapril contains lactose

Enalapril contains lactose, which is a type of sugar. If you have been told by your doctor that you have intolerance to some sugars, talk to your doctor before taking this medicine.

3. HOW TO TAKE ENALAPRIL

Always take this medicine exactly as your doctor or pharmacist has told you.

Check with your doctor or pharmacist if you are not sure.

- It is very important to continue taking this medicine for as long as your doctor prescribes it.
- Do not take more tablets than prescribed.

High Blood Pressure

- The usual starting dose ranges from 5 to 20 mg taken once a day.
- Some patients may need a lower starting dose.
- The usual long term dose is 20 mg taken once a day.
- The maximal long term dose is 40 mg taken once a day.

Heart Failure

- The usual starting dose is 2.5 mg taken once a day.
- Your doctor will raise this amount step by step until the dose that is right for you has been achieved.
- The usual long term dose is 20 mg each day, taken in one or two doses.
- The maximal long term dose is 40 mg each day, divided in two doses.

Patients with kidney problems

Your dose of medicine will be changed depending on how well your kidneys are working:

- moderate kidney problems - 5 mg to 10 mg each day.
- severe kidney problems - 2.5 mg each day.
- if you are having dialysis - 2.5 mg each day. On days you are not having dialysis, your dose may be changed depending on how low your blood pressure is.

Elderly patients

Your dose will be decided by your doctor and will be based on how well your kidneys are working.

Use in children

Experience in the use of Enalapril in children with high blood pressure is limited. If the child can swallow tablets, the dose will be worked out using the child’s weight and blood pressure. The usual starting doses are:

- between 20 kg and 50 kg – 2.5 mg each day.
- more than 50 kg – 5 mg each day.

The dose can be changed according to the needs of the child:

- a maximum of 20 mg daily can be used in children who are between 20 kg and 50 kg.
- a maximum of 40 mg daily can be used in children who are more than 50 kg.

This medicine is not recommended in newborn babies (first few weeks after birth) and in children with kidney problems.

If you take more Enalapril than you should

If you take more Enalapril than you should, talk to your doctor or go to a hospital straight away. Take the medicine pack with you. The following effects may happen: feeling of light-headedness or dizziness. This is due to a sudden or excessive drop in blood pressure.

If you forget to take Enalapril

- If you forget to take a tablet, skip the missed dose.
- Take the next dose as usual.
- Do not take a double dose to make up for a forgotten dose.

If you stop taking Enalapril

Do not stop taking your medicine unless your doctor tells you to. 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. The following side effects may happen with this medicine:

Stop taking Enalapril and talk to a doctor straight away, if you notice any of the following:

- swelling of your face, lips, tongue or throat which may cause difficulty in breathing or swallowing.
- swelling of your hands, feet or ankles.
- if you develop a raised red skin rash (hives).

You should be aware that black patients are at increased risk of these types of reactions. If any of the above happen, stop taking Enalapril and talk to a doctor straight away.

When you start taking this medicine you may feel faint or dizzy. If this happens, it will help to lie down. This is caused by your blood pressure lowering. It should improve as you continue to take the medicine. If you are worried, please talk to your doctor.

Other side effects include:

Very Common (may affect more than 1 in 10 people)

- feeling dizzy, weak or sick.
- blurred vision.
- cough.

Common (may affect up to 1 in 10 people)

- light-headedness due to low blood pressure, changes in heart rhythm, fast heartbeat, angina or chest pain.
- headache, depression, fainting (syncope), change in sense of taste
- shortness of breath
- diarrhoea, abdominal pain
- tiredness (fatigue)
- rash, allergic reactions with swelling of the face, lips, tongue or throat with difficulty in swallowing or breathing
- high levels of potassium in the blood, increased levels of creatinine in your blood (both are usually detected by a test)

Uncommon (may affect up to 1 in 100 people)

- flushing
- sudden fall in blood pressure
- fast or uneven heart beats (palpitations)
- heart attack (possibly due to very low blood pressure in certain high-risk patients, including those with blood flow problems of the heart or brain)
- stroke (possibly due to very low blood pressure in high-risk patients)
- anaemia (including aplastic and haemolytic)
- confusion, sleeplessness or sleepiness, nervousness
- feeling your skin prickling or being numb
- vertigo (spinning sensation)
- ringing in your ears (tinnitus)
- runny nose, sore throat or hoarseness
- asthma-associated tightness in chest
- slow movement of food through your intestine (ileus), inflammation of your pancreas
- being sick (vomiting), indigestion, constipation, anorexia
- irritated stomach (gastric irritations), dry mouth, ulcer.
- muscle cramps
- impaired kidney function, kidney failure
- increased sweating
- itching or nettle rash
- hair loss
- generally feeling unwell (malaise), high temperature (fever)
- impotence
- high level of proteins in your urine (measured in a test)
- low level of blood sugar or sodium, high level of blood urea (all measured in a blood test).

Rare (may affect up to 1 in 1,000 people)

- Raynaud's phenomenon' where your hands and feet may become very cold and white due to low blood flow
- changes in blood values such as a lower number of white and red blood cells, lower haemoglobin, lower number of blood platelets
- bone marrow depression
- swollen glands in neck, armpit or groin
- autoimmune diseases
- strange dreams or sleep problems
- accumulation of fluid or other substances in the lungs (as seen on X-rays)
- inflammation of your nose
- inflammation of the lungs causing difficulty breathing (pneumonia)
- inflammation of the cheeks, gums, tongue, lips, throat
- reduced amount of urine
- rash that looks like targets (erythema multiforme)
- 'Stevens-Johnson syndrome' and 'toxic epidermal necrolysis' (serious skin conditions where you have reddening and scaling of your skin, blistering or raw sores), exfoliative dermatitis/erythroderma (severe skin rash with flaking or peeling of the skin), pemphigus (small fluid-filled bumps on the skin)
- liver or gallbladder problems such as lower liver function, inflammation of your liver, jaundice (yellowing of the skin or eyes), high levels of liver enzymes or bilirubin (measured in a blood test)
- enlargement of breasts in males (gynaecomastia).

Very Rare (may affect up to 1 in 10,000 people)

- swelling in your intestine (intestinal angioedema).

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

- overproduction of antidiuretic hormone, which causes fluid retention, resulting in weakness, tiredness or confusion
- A symptom complex has been reported which may include some or all of the following: fever, inflammation of the blood vessels (serositis/vasculitis), muscle pain (myalgia/myositis), joint pain (arthralgia/arthritis). Rash, photosensitivity or other skin manifestations may occur.

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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom: Yellow Card Scheme
at: www.mhra.gov.uk/yellowcard

5. HOW TO STORE ENALAPRIL

Keep out of the sight and reach of children.

Do not use Enalapril after the expiry date which is stated on the blister and the carton after 'EXP'. The expiry date refers to the last day of that month.

Do not store above 25°C. Store in the original package.

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 Enalapril contains:

- The active substance is enalapril maleate. Each tablet contains either 5 mg or 20 mg of enalapril maleate.
- The other ingredients are: lactose monohydrate, magnesium stearate E572, maize starch, pregelatinised maize starch, sodium bicarbonate E500. The 20mg tablets also contain red iron oxide E172, yellow iron oxide E172.

What Enalapril looks like and the contents of the pack

- The 5 mg tablets are white rounded, rectangle-shaped tablets one side embossed 'RENITEC', the other side scored.
- The 20 mg tablets are peach-coloured, rounded, rectangle-shaped tablets one side embossed 'RENITEC', the other side scored and embossed 'MS''DE'.

The 5 mg tablets are available in blister packs of 30 and 60 tablets.

The 20 mg tablets are available in blister packs of 28 tablets.

Manufacturer and Product Licence Holder

Manufactured by Merck Sharp & Dohme, B.V., Waarderweg 39, 2031 BN Haarlem, The Netherlands. Procured from within the EU by Product Licence holder: Star Pharmaceuticals Ltd, 5 Sandridge Close, Harrow, Middlesex, HA1 1XD. Repackaged by Servipharm Ltd.

POM

Enalapril Maleate 5mg Tablets - PL 20636/1648
Enalapril Maleate 20mg Tablets - PL 20636/1650

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