Additional possible side effects reported with some statins:
- sleep disturbances, including trouble sleeping and nightmares
- memory loss
- sexual difficulties. This is more likely if you have high levels of sugars and fats in your blood, are overweight and have high blood pressure. Your doctor will monitor you while you are taking this medicine.
- Laboratory Values
  - Liver function tests may be abnormal (increased transaminases and a muscle enzyme).
  - These tests have been observed.
  - If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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. By reporting side effects you can help provide more information on the safety of this medication.

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

Ireland
HPRA Pharmacovigilance
Earlsfort Terrace, IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6764977
Website: www.hpra.ie
email: mediation@hpра.ie

5. How to store Simvastatin 20mg/5ml Oral Suspension
- Keep out of the sight and reach of children.
- Do not store above 25°C.
- Do not store below 5°C.
- Do not use after the expiry date (month, year) stated on the label and carton after EXP.
- If it is out of date or you no longer want it, take it back to the pharmacy.
- Do not flush unneeded medicines down the drain. Ask your pharmacist how to properly dispose of medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Simvastatin 20mg/5ml Oral Suspension contains
- The active ingredient is simvastatin. Each 5ml contains 20mg simvastatin.
- The other ingredients are methylparaben (E218), propylparaben (E213), citric acid (E330), disodium hydrogen phosphate (E339), sodium laurilsulfate (E470a), acesulfame potassium (E950), strawberry flavour and purified water.
- This medicine works by lowering the amount of cholesterol and fatty substances called triglycerides in your blood.
- This medicine has been prescribed only for you. Do not pass it on.

What to do if you think you have taken too much Simvastatin 20mg/5ml Oral Suspension
- If you think you have taken too much Simvastatin 20mg/5ml Oral Suspension, please see your doctor or pharmacist immediately.

Contact your doctor immediately if you experience unexplained muscle pain, tenderness or weakness. This is because on rare occasions, muscle problems can be serious, including muscle breakdown resulting in kidney damage and very rare deaths have occurred.

Simvastatin can be used for:
- lowering high cholesterol levels or fat levels in the blood when diet, exercise and weight loss are not enough.
- lowering high cholesterol levels that are hereditary (close members of your family also have high cholesterol levels).
- Simvastatin may be given at the same time as other medicines that lower your cholesterol:
  - lowering risk of coronary heart disease (CHD) if you have diabetes, have had a stroke or you have other blood vessel diseases.

2. What you need to know before you take Simvastatin 20mg/5ml Oral Suspension
- Do not take simvastatin and tell your doctor if:
  - you are allergic (hypersensitive) to simvastatin or any other ingredients in this liquid (see section 6). An allergic reaction can include a rash, itching or shortness of breath.
  - you have liver problems.
  - you are pregnant or breast-feeding (see section 4). This belongs to a group of medicines called HMG-CoA reductase inhibitors (also known as statins).
  - you are taking, or have taken in the last 7 days, a medicine called fusidic acid, used to treat bacterial infections.
  - you are taking ciclosporin, used in organ transplant patients.
  - you are taking gemfibrozil, used to lower cholesterol.
  - you are taking antifungal drugs such as itraconazole, ketoconazole, posaconazole or voriconazole.
  - you are taking penicillin, used to lower cholesterol.
  - you are taking oral anticoagulants.
  - you have severe lung disease (respiratory failure).
  - you are taking danazol, a man-made hormone used to treat endometriosis.
  - you have kidney problems.
  - you have liver problems.
  - you have thyroid problems.
  - you have diabetes. This is more likely if you have high levels of sugars and fats in your blood, are overweight and have high blood pressure.
  - you have high cholesterol levels.
  - you have high blood pressure.
  - you are taking, or have taken in the last 7 days, a medicine called fusidic acid, used to treat bacterial infections.
  - you are taking ciclosporin, used in organ transplant patients.
  - you are taking penicillin, used to lower cholesterol.
  - you are taking oral anticoagulants.
  - you have severe lung disease (respiratory failure).
  - you are taking danazol, a man-made hormone used to treat endometriosis.
  - you have kidney problems.
  - you have liver problems.
  - you have thyroid problems.
  - you have diabetes. This is more likely if you have high levels of sugars and fats in your blood, are overweight and have high blood pressure.
  - you have high cholesterol levels.
  - you have high blood pressure.
  - you are taking, or have taken in the last 7 days, a medicine called fusidic acid, used to treat bacterial infections.
  - you are taking ciclosporin, used in organ transplant patients.
  - you are taking penicillin, used to lower cholesterol.
  - you are taking oral anticoagulants.

3. How to take Simvastatin 20mg/5ml Oral Suspension
- Take with meals if you find it easier.
- This medicine works by lowering the amount of cholesterol and fatty substances called triglycerides in your blood.

4. Possible side effects
- This medicine may be given at the same time as other medicines that lower your cholesterol.
- This medicine works by lowering the amount of cholesterol and fatty substances called triglycerides in your blood.

5. How to store Simvastatin 20mg/5ml Oral Suspension
- Keep out of the sight and reach of children.
- Do not store above 25°C.
- Do not store below 5°C.
- Do not use after the expiry date (month, year) stated on the label and carton after EXP.
- If it is out of date or you no longer want it, take it back to the pharmacy.
- Do not flush unneeded medicines down the drain. Ask your pharmacist how to properly dispose of medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Simvastatin 20mg/5ml Oral Suspension contains
- The active ingredient is simvastatin. Each 5ml contains 20mg simvastatin.
- The other ingredients are methylparaben (E218), propylparaben (E213), citric acid (E330), disodium hydrogen phosphate (E339), sodium laurilsulfate (E470a), acesulfame potassium (E950), strawberry flavour and purified water.
- This medicine works by lowering the amount of cholesterol and fatty substances called triglycerides in your blood.
- This medicine has been prescribed only for you. Do not pass it on.

What to do if you think you have taken too much Simvastatin 20mg/5ml Oral Suspension
- If you think you have taken too much Simvastatin 20mg/5ml Oral Suspension, please see your doctor or pharmacist immediately.

Contact your doctor immediately if you experience unexplained muscle pain, tenderness or weakness. This is because on rare occasions, muscle problems can be serious, including muscle breakdown resulting in kidney damage and very rare deaths have occurred.

The risk of muscle breakdown is greater at higher doses of simvastatin and is greater in certain patients. Talk with your doctor if any of the following applies:
- you drink large amounts of alcohol.
- you have liver problems.
- you have kidney problems.
- you have thyroid problems.
- you are 65 years or older.
- you are female.
- you or a close family member have a hereditary muscle problem.
- you have ever had muscle problems while taking other medicines used to lower cholesterol (see Section 2 ‘Other medicines and Simvastatin Oral Suspension’).
While you are on this medicine your doctor will monitor you closely if you have diabetes or are at risk of developing diabetes. You are likely to be at risk of developing diabetes if you have high levels of sugars and fats in your blood, are overweight and have high blood pressure.

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

Children
Safety and effectiveness have been studied in 10-17 year old boys and girls who had started their menarchal period at least one year before. Simvastatin has not been studied in children under the age of 10 years. For more information, talk to your doctor.

Other medicines and Simvastatin Oral Suspension
It is particularly important to talk to your doctor if you are taking any of the following medicines. Simvastatin can increase the risk of muscle problems (some of these have already been listed in the above section 'Do not take simvastatin'):

- antibiotics, used to treat infections and skin conditions
- diuretics, used to treat kidney problems and heart failure
- oral contraceptives, used to prevent pregnancy
- steroids, used to treat many conditions
- anti-inflammatory medicines, used to treat many conditions
- probiotics, used to help with diarrhoea
- cyclosporin, used to dampen the immune system

Simvastatin can increase the risk of muscle problems in people taking these medicines:

- medicines to treat conditions such as lupus and severe chronic pain
- medicines used to treat alpha thalassemia
- colchicines, used to treat gout

If you are taking any of these medicines, your doctor may need to stop your simvastatin. Or if you are on simvastatin, your doctor may need to adjust the dose of these medicines. This includes medicines bought without a prescription, including herbal medicines.

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

- medicines that stop blood clots from forming such as warfarin
- medicines to lower cholesterol such as fibrates
- medicines to lower cholesterol such as bile acid sequestrants such as cholestyramine
- medicines used to treat tuberculosis

Also tell your doctor if you are taking niacin (nicotinic acid or a niacin-containing product and are Chinese.

Having operations and tests
If you are going to have an operation, tell the doctor that you are taking simvastatin as it may affect the results of some tests.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Simvastatin Oral Suspension can cause side effects although not everybody gets them.

The following terms are used to describe how often side effects have been reported:

- Rare (occurring in 1 or more of 10,000 and less than 1 of 1000 patients treated)
- Very rare (occurring in less than 1 of 10,000 patients treated)
- Frequency not known

The following rare serious side effects were reported. If any of these serious side effects happen, stop taking simvastatin and tell your doctor immediately or go to the emergency room at your nearest hospital:

- muscle pain, tenderness, weakness or cramps. On rare occasions, muscle problems can be serious, including muscle breakdown resulting in kidney damage; and very rare, deaths have occurred.
- an allergic reaction including:
  - rash, hives, hives with swelling of the lips, tongue and throat which may cause difficulty in breathing
  - severe muscle pain usually in the shoulders and hips
  - rash with weakness of limbs and such muscle
  - pain or inflammation of the joints
  - inflammation of the blood vessels
  - unusual bruising, skin eruptions and swelling, hives, skin sensitivity to the sun, fever, itching
  - shortness of breath and feeling unwell
  - lupus-like disease picture (including rash, joint disorders and effects on blood cells)
  - inflammation of the pericardium with severe abdominal pain
  - inflammation of the pancreas with severe abdominal pain
  - inflammation of the liver with yellowing of the skin and eyes, itching, darkened urine or pale-coloured stool, liver enlargement
  - lupus-like disease picture (including rash, joint disorders and effects on blood cells)

- fever
- trouble swallowing (very rare)
- poor memory (very rare).

Side effects where the frequency is not known (cannot be estimated from the available data):

- peripheral neuropathy
- depression
- other

- the lungs causing breathing problems including persistent cough and/or shortness of breath
- low blood pressure
- problems with the skin
- serious skin disorders
- problems with blood
- problems with the joints
- anaemia
- tuberculosis

T tendon problems, sometimes complicated by rupture of the tendon.

Continued overleaf
While you are on this medicine your doctor will monitor you closely if you have diabetes or are at risk of developing diabetes. You are likely to be at risk of developing diabetes if you have high levels of sugars and fats in your blood, are overweight and have high blood pressure.

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

**Children**

Safety and effectiveness have been studied in 10-17 year old boys and girls who had started their menstrual period at least one year before. The dose is not recommended for children under the age of 10 years. For more information, talk to your doctor.

**Other medicines and Simvastatin Oral Suspension**

It is particularly important to tell your doctor if you are taking any of the following medicines. These medicines may increase the risk of muscle problems (some of these have already been listed in the above section ‘Do not take simvastatin’):

- statins, used to treat the high cholesterol levels in people with heart disease
- clopidogrel, used to prevent blood clots in people with heart disease
- proton pump inhibitors, used to treat heartburn
- proton pump inhibitors, used to treat heartburn
- psoriasis, used to treat psoriasis
- cephalosporins, used to treat infections
- beta blockers, used to treat high blood pressure

The following side effects have also been reported rarely:

- severe muscle pain
- shortness of breath and feeling unwell
- inflammation of the lungs causing breathing problems including persistent cough and/or
- muscle pain, tenderness, weakness or cramps. On rare occasions, muscle problems can
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- muscle pain, tenderness, weakness or cramps. On rare occasions, muscle problems can

**Side effects where the effects have also been reported rarely**:

- fever
- shortness of breath and feeling unwell
- inflammation of the lungs causing breathing problems including persistent cough and/or
- muscle pain, tenderness, weakness or cramps. On rare occasions, muscle problems can
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- muscle pain, tenderness, weakness or cramps. On rare occasions, muscle problems can

**4. Possible side effects**

Like all medicines, Simvastatin Oral Suspension can cause side effects although not everybody gets them.

The following terms are used to describe how often side effects have been reported:

- Rare (occurring in 1 in more of 10,000 patients treated)
- Very rare (occurring in less than 1 of 1000 patients treated)
- Very rare (occurring in less than 1 of 1000 patients treated)
- Very rare (occurring in less than 1 of 1000 patients treated)
- Very rare (occurring in less than 1 of 1000 patients treated)

The following rare serious side effects were reported.

If any of these serious side effects happen, stop taking simvastatin and tell your doctor immediately or go to the emergency room at your nearest hospital:

- muscle pain, tenderness, weakness or cramps. On rare occasions, muscle problems can be serious, including muscle breakdown resulting in kidney damage; and very rare, deaths have occurred.
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- muscle pain, tenderness, weakness or cramps. On rare occasions, muscle problems can be serious, including muscle breakdown resulting in kidney damage; and very rare, deaths have occurred.

**5. Treatment of high cholesterol levels**

- The usual starting dose is 10mg (2.5ml) to 20mg (5ml) each day. This may be increased gradually by your doctor up to 40mg (10ml) each day
- The usual dose is 20mg (5ml) in the evening.
- The usual dose is 20mg (5ml) in the evening.
- The usual dose is 20mg (5ml) in the evening.
- The usual dose is 20mg (5ml) in the evening.
- The usual dose is 20mg (5ml) in the evening.

**Precautions of coronary heart disease (CHD):**

- The usual dose is 20mg (5ml) in the evening.
- The usual dose is 20mg (5ml) in the evening.
- The usual dose is 20mg (5ml) in the evening.
- The usual dose is 20mg (5ml) in the evening.
- The usual dose is 20mg (5ml) in the evening.

**Take into the evening.**

**People with kidney problems**

**Take this dose in the evening.**

**Take this dose in the evening.**

**Take this dose in the evening.**

**Take this dose in the evening.**

- The doctor will start you on a lower dose and gradually increase it.
- The doctor will start you on a lower dose and gradually increase it.
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- The doctor will start you on a lower dose and gradually increase it.

**Children (10 – 17 years old)**

- The recommended usual starting dose is 10mg (2.5ml) a day in the evening.
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**Take these in the evening.**

**Take these in the evening.**

**Take these in the evening.**

**Take these in the evening.**

**Take these in the evening.**

- Do not take a double dose (two doses at the same time) to make up for a forgotten dose.
- Do not take a double dose (two doses at the same time) to make up for a forgotten dose.
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- Do not take a double dose (two doses at the same time) to make up for a forgotten dose.
- Do not take a double dose (two doses at the same time) to make up for a forgotten dose.

**6. Possible side effects**

If you feel that the effect of your medicine is too strong or too weak, do not change the dose. Talk to your doctor or pharmacist.

**Hiring operations and tests**

If you are going to have an operation, tell the doctor that you are taking simvastatin as it may cause dizziness. If you feel this, take extra care when driving or using tools or machines.

**Taking Simvastatin Oral Suspension**

You must not drink grapefruit juice while taking this medicine as it could increase your risk of shortness of breath or fever

**If you forget to take Simvastatin Oral Suspension**

Do not use Simvastatin Oral Suspension unless your doctor tells you to. It may make your cholesterol levels rise again.

**If you have any further questions on the use of this medicine, ask your doctor or pharmacist.**
1. What Simvastatin 20mg/5ml Oral Suspension is and what it is used for

Simvastatin 20mg/5ml Oral Suspension contains the active substance simvastatin, which is used to lower your cholesterol levels and triglycerides in your blood. This medicine belongs to a group of medicines called HMG-CoA reductase inhibitors (also known as statins). It is used to treat high levels of cholesterol in your blood. Simvastatin is in a brown glass bottle holding 150ml of suspension.

2. What you need to know before you take Simvastatin 20mg/5ml Oral Suspension

Simvastatin can be used for:
- Lowering high cholesterol levels or fat levels in the blood when diet, exercise and weight loss are not enough
- Lowering high cholesterol levels that are hereditary (close members of your family also have high cholesterol levels). Simvastatin may be given at the same time as other medicines that lower your cholesterol
- Lowering the risk of coronary heart disease (CHD) if you have diabetes, have had a stroke or you have other blood vessel diseases.

3. How to take Simvastatin 20mg/5ml Oral Suspension

This leaflet belongs to a group of medicines called HMG-CoA reductase inhibitors (also known as statins). This belongs to a group of medicines called HMG-CoA reductase inhibitors (also known as statins). This is a guide to taking this medicine. This leaflet contains important information for you.

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 other questions, ask your doctor or pharmacist.
This medicine has been prescribed only for you. Do not pass it on to others. It may harm them, even if their signs and symptoms are the same as yours.
If you get any side effects that you think may be due to this medicine, talk to your doctor or pharmacist. Reports of side effects can help other people receive the benefit of a medicine, while avoiding its risks.
If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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

United Kingdom

Yellow Card Scheme
Website: www.mhra.gov.uk/yelllowcard

Ireland

HPRA Pharmacovigilance
Earlsfort Terrace, IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpра.ie
E-mail: medsafety@hpра.ie

What is in this leaflet

1. What Simvastatin 20mg/5ml Oral Suspension is and what it is used for
2. What you need to know before you take Simvastatin 20mg/5ml Oral Suspension
3. How to take Simvastatin 20mg/5ml Oral Suspension
4. Possible side effects
5. How to store Simvastatin 20mg/5ml Oral Suspension
6. Contents of the pack and other information

5. How to store Simvastatin 20mg/5ml Oral Suspension

- Keep out of the sight and reach of children
- Do not store above 25°C
- Do not use 1 month after you first open it. Take it back to the pharmacy
- Do not use after the expiry date (month, year) stated on the label and carton after EXP.
- The expiry date refers to the last day of that month
- If it is out of date or you no longer want it, take it back to the pharmacy
- Do not use Simvastatin Oral Suspension if you notice anything wrong with the medicine.
- Talk to your pharmacist
- Do not throw away medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Simvastatin 20mg/5ml Oral Suspension contains

The active ingredient is simvastatin. Each 5ml contains 20mg simvastatin. The other ingredients are methyl parahydroxybenzoate (E218), acesulfame potassium (E950), strawberry flavour and purified water.

What Simvastatin 20mg/5ml Oral Suspension looks like and contents of the pack

This leaflet contains the following information:
- The active ingredient is simvastatin. Each 5ml contains 20mg simvastatin.
- The other ingredients are methyl parahydroxybenzoate (E218), acesulfame potassium (E950), strawberry flavour and purified water.
- It comes in a brown glass bottle holding 150ml of suspension.

What to do if you forget to take a dose

If you forget to take a dose of Simvastatin, take it as soon as you remember it. Do not take a double dose to make up for a missed one.

What to do if you take too much Simvastatin

In an emergency, telephone your doctor, local hospital, your doctor’s surgery or the nearest poisons centre immediately.

Additional possible side effects reported with some statins:
- memory loss
- sleep disturbances, including trouble sleeping and nightmares
- weakness. This is because on rare occasions, muscle problems can be serious, including muscle breakdown.
- muscle breakdown is greater at higher doses of simvastatin and is greater in certain patients. Talk with your doctor if any of the following applies:
  - you drink large amounts of alcohol
  - you have kidney problems
  - you have thyroid problems
  - you are 65 years or older
  - you are female
  - you or a close family member have a hereditary muscle problem

Do not take simvastatin and tell your doctor if:
- you are allergic (hypersensitive) to simvastatin or any other ingredients in this liquid (see Section 6). An allergic reaction can include a rash, itching or shortness of breath
- you have liver problems
- you are pregnant or breast-feeding (see section below 'Pregnancy and breast-feeding')
- you are taking clopidogrel (see Section 2 'Other medicines and Simvastatin Oral Suspension')
- you are taking ergotamine (see Section 2 'Other medicines and Simvastatin Oral Suspension')
- you are taking olmesartan medoxomil (see Section 2 'Other medicines and Simvastatin Oral Suspension')
- you are taking tadalafil (see Section 2 'Other medicines and Simvastatin Oral Suspension')
- you are taking etrogolol (see Section 2 'Other medicines and Simvastatin Oral Suspension')
- you are taking amiodarone (see Section 2 'Other medicines and Simvastatin Oral Suspension')
- you are taking danazol, a man-made hormone used to treat endometriosis (see Section 2 'Other medicines and Simvastatin Oral Suspension')
- you are taking a medicine to treat depression called nefazodone
- you are taking boceprevir or telaprevir, used to treat hepatitis C virus
- you have liver problems
- you drink large amounts of alcohol
- you have kidney problems
- you have thyroid problems
- you are 65 years or older
- you are female
- you or a close family member have a hereditary muscle problem
- you have ever had muscle problems whilst taking other medicines used to lower cholesterol (see Section 2 'Other medicines and Simvastatin Oral Suspension').

Contact your doctor immediately if you experience unexplained muscle pain, tenderness or weakness. This is because on rare occasions, muscle problems can be serious, including muscle breakdown resulting in kidney damage and very rare deaths have occurred. The risk of muscle breakdown is greater at higher doses of simvastatin and is greater in certain patients. Talk with your doctor if any of the following applies:
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- you have kidney problems
- you have thyroid problems
- you are 65 years or older
- you are female
- you or a close family member have a hereditary muscle problem
- you have ever had muscle problems whilst taking other medicines used to lower cholesterol (see Section 2 'Other medicines and Simvastatin Oral Suspension').

What if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.