

Arrow - Simva

Simvastatin 10 mg, 20 mg, 40 mg and 80 mg tablets

What is in this leaflet

This leaflet answers some common questions about ARROW - SIMVA.

It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking ARROW - SIMVA against the benefits he/she expects it will have for you.

If you have any concerns about taking this medicine, talk to your doctor or pharmacist.

Keep this leaflet with your medicine. You may need to read it again.

What ARROW - SIMVA is used for

ARROW - SIMVA helps lower high cholesterol and triglyceride levels.

Your doctor has prescribed ARROW - SIMVA to reduce the health risks associated with coronary heart disease (CHD). If you have CHD, diabetes, history of stroke or other vessel disease (regardless of the amount of cholesterol in your blood), ARROW - SIMVA:

- can prolong your life by reducing the risk of heart attack or stroke
- reduces the need for surgery to increase blood flow to the legs and major organs such as the heart
- reduces the need for hospitalisation for chest pain (also known as angina).

Cholesterol

Everyone has cholesterol and triglycerides in their blood. They are the types of blood fat needed by the body for building cell walls, making bile acids (which help to digest food) and certain hormones, and other functions.

There are different types of cholesterol, for example, low-density lipoprotein (LDL) and high-density lipoprotein (HDL) cholesterol. LDL cholesterol is the 'bad' cholesterol that can block your blood vessels. HDL cholesterol is the 'good' cholesterol that is thought to remove the bad cholesterol from the blood vessels.

Your body makes cholesterol, but it also comes from food. Normally, the body balances the cholesterol it makes with the cholesterol it gets from food. This means if more cholesterol comes from food, less is made by the body. However, if you eat a diet high in fat, your body may not keep this balance and your cholesterol levels rise, especially the LDL.

High cholesterol is more likely to occur with certain diseases or if you have a family history of high cholesterol.

When you have high levels of cholesterol, it may 'stick' to the inside of your blood vessels instead of being carried to the parts of the body where it is needed. In most people, there are no symptoms of high cholesterol at early stage and it would only be shown in blood test. After a certain period of time, the built-up of cholesterol can form hard areas, called plaque, on the walls of blood vessels, making it more difficult for the blood to flow. This blocking of your blood vessels can lead to coronary heart disease (such as heart attack and angina), and stroke.

In patients with CHD accompanied by high cholesterol levels, simvastatin may slow down the hardening of blood vessels and may reduce the development of new plaques.

Triglycerides

Triglycerides are an energy source for the body. However, as with cholesterol, too much triglycerides can be a problem.

How ARROW - SIMVA works

ARROW - SIMVA contains the active ingredient simvastatin, which belongs to a group of medicines known as HMG-CoA reductase inhibitors. It works by reducing the amount of cholesterol made by the liver. In most patients, simvastatin reduces the bad cholesterol and can actually raise the good cholesterol.

Simvastatin does not reduce the cholesterol that comes from fat in food. Therefore, when you are taking ARROW - SIMVA, you also need to follow a low fat diet and other measures, such as exercise and weight control.

Use in Children

Safety and effectiveness of simvastatin have been evaluated in adolescent boys aged 10 to 17 years old and in girls of the same age group who had started their menstrual period at least one year before.

Simvastatin has not been studied in children under the age of 10 years and, thus, is not recommended for use in this population.

Your doctor may have prescribed ARROW - SIMVA for another reason. Ask your doctor if you have any questions about why ARROW - SIMVA has been prescribed for you.

There is no evidence that ARROW - SIMVA tablets are addictive.

ARROW - SIMVA is available only with a doctor's prescription.

Before you take ARROW - SIMVA

When you must not take it

Do not take ARROW - SIMVA if you are allergic to medicines containing simvastatin or any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- lumpy skin rash ("hives"), hayfever or fainting.

Do not take ARROW - SIMVA if you are pregnant or intend to become pregnant.

Simvastatin can cause harm to the unborn baby.

Do not take ARROW - SIMVA if you are breastfeeding or intend to breastfeed.

Simvastatin may cause harm to the breastfed baby.

Do not take ARROW - SIMVA if you have or have had the following medical conditions:

- active liver disease
- muscle pain, tenderness or weakness from other medicines used to treat high cholesterol or triglycerides.

Do not take ARROW - SIMVA if the expiry date (Exp.) printed on the pack has passed.
It may not work well if you do.

Do not take ARROW - SIMVA if the packaging is torn or shows signs of tampering.

Before you start to take it

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

Tell your doctor if you intend to become pregnant or to breastfeed.
ARROW - SIMVA should not be used during pregnancy or while breast-feeding.

Tell your doctor if you:

- have liver disease (your doctor will need to do a blood test to check your liver function)
- have kidney disease or any other medical conditions
- have severe breathing problems
- drink alcohol regularly.

Taking other medicines

Tell your doctor if you are taking any other medicines, including those you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines may be affected by ARROW - SIMVA, or may affect how well it works.
These include:

- other medicines to lower cholesterol levels, eg fibric acid derivatives including gemfibrozil and bezafibrate, or large doses (≥ 1 g/day) of niacin or nicotinic acid
- erythromycin, clarithromycin, telithromycin or fusidic acid, antibiotics used to treat infections
- ketoconazole and itraconazole, medicines used to treat certain fungal infections
- cyclosporin, a medicine used to suppress the immune system
- danazol, a hormone used to treat gynaecological problems
- nefazodone, a medicine used to treat depression
- amiodarone, a medicine used to treat an irregular heartbeat
- verapamil, diltiazem or amlodipine (medicines used to treat high blood pressure, angina, or other heart conditions)
- indinavir, nelfinavir, ritonavir or saquinavir, protease inhibitors used to treat HIV infection
- warfarin, phenprocoumon or acenocoumarol, anticoagulants used to prevent blood clots.

Your doctor can tell you what to do if you are taking these medicines. If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking ARROW - SIMVA.

If you have not told your doctor about any of the above, tell him/her before you start taking ARROW - SIMVA.

How to take ARROW - SIMVA

Follow all directions given to you by your doctor or pharmacist carefully.
They may differ from the information contained in this leaflet.

How much to take ARROW - SIMVA

Take ARROW – SIMVA exactly as your doctor has prescribed.

Your doctor will tell you how many tablets you need to take each day. This depends on your cholesterol and triglyceride levels and other factors, such as kidney disease.

Adults: usual starting dose is 20 mg or 40 mg per day, which may need to be increased up to 80 mg daily.

Children (10 - 17 years old): usual starting dose is 10 mg per day; the maximum daily dose is 40 mg.

Your doctor may prescribe lower doses, particularly if you are taking some of the medications listed above (see *Taking other medicines*) or have certain kidney or liver problems.

How to take it

ARROW - SIMVA tablets may be swallowed with a glass of water.

When to take it

Take ARROW - SIMVA once a day in the evening.

The liver produces its greatest amount of cholesterol when the body is at rest and when there is no dietary intake. For most people, this is at night when asleep. Therefore, ARROW - SIMVA is more effective when taken in the evening. A good time would be after your evening meal. However, it does not matter whether you take it before or after food.

Take ARROW - SIMVA at about the same time of each evening.

Taking your tablet(s) at the same time of each evening will have the best effect. It will also help you remember when to take the tablets.

How long to take it

ARROW - SIMVA helps lower your cholesterol. It does not cure your condition. Therefore, you must continue to take it as directed by your doctor so to lower your cholesterol and keep it down. You may have to take cholesterol-lowering medicine for the rest of your life. If you stop taking ARROW - SIMVA, your cholesterol levels may rise again.

If you have any questions about taking ARROW - SIMVA, ask your doctor or pharmacist.

If you forget to take ARROW - SIMVA

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take the missed dose as soon as you remember, and then go back to taking your tablets as you would normally.

Do not take a double dose to make up for the dose you missed.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you take too much ARROW – SIMVA (overdose)

Immediately telephone your doctor, or the National Poisons Information Centre (0800 POISON or 0800 764 766), or go to the Accident and Emergency department at your nearest hospital, if you think that you or anyone else may have taken too many ARROW - SIMVA tablets.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Keep the telephone numbers for these places handy.

While you are taking ARROW - SIMVA

Things you must do

Before starting any new medicine, tell your doctor or pharmacist that you are taking ARROW - SIMVA.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking ARROW - SIMVA.

If you become pregnant while you are taking ARROW - SIMVA, stop taking it and contact your doctor immediately.

If you are about to have surgery, tell your doctor that you are taking ARROW - SIMVA. Your doctor may suggest stopping the tablets a few days before surgery.

To make sure ARROW - SIMVA is working, have your blood cholesterol levels checked when your doctor says so.

Tell your doctor if, for any reason, you have not taken your medicine exactly as directed.

Otherwise, your doctor may think that it is not working and change your treatment unnecessarily.

Things you must not do

Do not stop taking ARROW - SIMVA or change the dose without checking with your doctor.

Do not use ARROW - SIMVA to treat any other conditions unless your doctor tells you to.

Do not give ARROW - SIMVA to anyone else, even if their symptoms seem similar to yours.

Things to be careful of

Avoid drinking large quantities of alcohol.

Drinking large quantities of alcohol may increase your chance of simvastatin causing liver problems.

Avoid drinking large quantities of grapefruit juice.

Grapefruit juice contains one or more components that alter the metabolism of some medicines, including simvastatin. Therefore, drinking very large quantities (over 1 litre) of grapefruit juice each day increases your chance of simvastatin causing side effects. These include aching muscles, muscle tenderness or weakness, which is not caused by exercise.

Be careful driving, operating machinery or doing jobs that require you to be alert while you are taking ARROW - SIMVA until you know how it affects you.

ARROW - SIMVA generally does not cause any problems with your ability to drive a car or operate machinery. However, as with many other medicines, simvastatin may cause dizziness in some people. Make sure you know how you react to ARROW - SIMVA before you drive a car or operate machinery.

Things that would be helpful for lowering your cholesterol

Lowering high cholesterol can help reduce your chances of having CHD. However, your chances of having CHD may be increased by several other factors including high blood pressure, cigarette smoking, diabetes, excess weight, family history of CHD, being a male, and being a woman who has reached menopause.

Some self-help measures suggested below may help your condition and help reduce your chances of having CHD. Talk to your doctor, pharmacist or dietician about these measures and for more information.

- Diet - eat a healthy low-fat diet, which includes plenty of fresh fruit, vegetables, bread, cereals and fish. Also, eat less sugar. Check with your doctor, dietician or pharmacist for a suitable diet program.
- Weight - your doctor may advise you to lose weight if you are overweight.
- Exercise - regular exercise helps reduce cholesterol levels and helps the heart get fitter, but it is important not to overdo it. Walking is a good exercise. Try to find a route that is fairly flat. Before starting, ask your doctor for the most suitable exercise program for you.
- Smoking - your doctor may advise you to stop smoking or at least cut down.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking ARROW - SIMVA.

Like other medicines, ARROW - SIMVA can cause some side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

The most commonly reported side effects are:

- constipation, diarrhoea, wind
- stomach upset or pain, feeling sick (nausea)
- headache
- dizziness.

These are the more common side effects. They are usually mild and short-lived.

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

- aching muscles, muscle tenderness or weakness, which is not caused by exercise
- tingling in the hands or feet
- yellowing of the skin and/or eyes, also called jaundice
- signs of anaemia, such as tiredness, being short of breath and looking pale
- fever, generally feeling unwell
- skin rash, itchiness
- pinkish, itchy swellings on the skin, also called "hives" or nettlerash
- painful, swollen joints
- bruising more easily than normal
- larger breasts than normal in men.

These are rare but serious side effects. You may need urgent medical attention.

On rare occasions, muscle problems can be serious, including muscle breakdown resulting in kidney damage. The risk of muscle breakdown is greater for patients taking higher doses of simvastatin, older patients (65 years of age and older), female patients, patients with abnormal kidney function and patients with thyroid problems.

If you think you are having an allergic reaction to ARROW - SIMVA tablets, tell your doctor immediately or go to Accident and Emergency at the nearest hospital. Symptoms of an allergic reaction may include some of all of the following:

- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- lumpy skin rash ("hives"), hayfever or fainting.

Also, tell your doctor if you notice:

- hair loss
- muscle cramps
- memory loss
- trouble sleeping
- "low moods" that becomes more often and severe than usual episodes (also known as depression)
- sexual difficulties
- breathing problems including persistent cough and/or shortness of breath or fever.

These are other side effects that have been reported with simvastatin or with some statins.

Liver problems can also occur and may be serious. Your doctor will do blood tests to check your liver.

This is not a complete list of all possible side effects. Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything that is making you feel unwell.

After taking ARROW - SIMVA

Storage

Keep ARROW - SIMVA where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Keep ARROW - SIMVA in a cool, dry place where the temperature stays below 25°C.

Keep your tablets in the packs until it is time to take them.

If you take the tablets out of the pack, they may not keep well.

Do not store ARROW - SIMVA or other medicines in the bathroom or near a sink.

Do not leave the tablets in the car or on window sills.

Heat, light and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking ARROW - SIMVA, or your tablets have passed their expiry date, ask your pharmacist what to do with any tablets that are left over.

Product Description

What ARROW - SIMVA looks like

ARROW - SIMVA is available in 4 different strengths of tablets:

- ARROW - SIMVA 10 – White oblong biconvex film coated tablet with score line and “10” on one side and “SVT” on reverse side.
- ARROW - SIMVA 20 – White oblong biconvex film coated tablet with score line and “20” on one side and “SVT” on reverse side.
- ARROW - SIMVA 40 – White oblong biconvex film coated tablet with score line and “40” on one side and “SVT” on reverse side.
- ARROW - SIMVA 80 – White oblong biconvex film coated tablet with score line and “80” on one side and “SVT” on reverse side.

Ingredients

The active ingredient in ARROW - SIMVA tablets is simvastatin:

- each ARROW - SIMVA 10 tablet contains 10 mg of simvastatin
- each ARROW - SIMVA 20 tablet contains 20 mg of simvastatin
- each ARROW - SIMVA 40 tablet contains 40 mg of simvastatin
- each ARROW - SIMVA 80 tablet contains 80 mg of simvastatin.

The tablets also contain:

- anhydrous lactose
- microcrystalline cellulose
- pregelatinised maize starch
- butylated hydroxyanisole
- purified talc
- magnesium stearate
- hydroxypropylcellulose
- hypromellose
- titanium dioxide

The tablets do not contain gluten, sucrose, tartrazine or any azo dyes.

Supplier

ARROW - SIMVA is distributed in New Zealand by:

Arrow Pharmaceuticals (NZ) Limited
Mount Eden Central Business Park
33a Normanby Road, Mt Eden
Auckland, New Zealand.

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