

# A patient's guide to

# LEQVIO<sup>®</sup>▼ (inclisiran)

This leaflet is intended for patients who have been prescribed inclisiran for the treatment of high cholesterol.

This leaflet is not intended to replace the patient information leaflet that comes with your medicine, which contains important information. Please read the patient information leaflet carefully before you are given this medicine as it contains important information for you. If you have any further questions, ask your doctor, pharmacist or nurse. You should take your medication as instructed by your healthcare professional.

▼This medicine is subject to additional monitoring.

This will allow quick identification of new safety information. You can help by reporting any side effects you may get.

See [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) for how to report side effects.

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# INTRODUCTION

As you have been prescribed inclisiran by your healthcare professional, this leaflet aims to give you some useful information about your medicine. It will explain how inclisiran works and what you need to know when you are given it.

Throughout this leaflet, you will find some words in **bold**. These words are described in more detail on pages 12 and 13.

## **IN THIS LEAFLET, YOU WILL FIND THE FOLLOWING INFORMATION:**

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# WHY HAVE I BEEN PRESCRIBED INCLISIRAN?

Your healthcare professional has prescribed inclisiran for you because your cholesterol levels are too high. This can increase the risk of developing **cardiovascular disease** (or **CVD**), which includes conditions such as **angina, heart attack, stroke** and **peripheral arterial disease** (or **PAD**).

Because of this, it is important to lower your cholesterol levels with lifestyle changes and, if needed, medication as well.

Inclisiran is a medicine used to lower the levels of a type of cholesterol, called **LDL (low-density lipoprotein)-cholesterol**, in the blood. However inclisiran's effect on **CVD** has not been determined yet. It is given to people with high levels of cholesterol due to any of the following causes:

- **Primary hypercholesterolaemia**: this may be non-familial (not inherited) or familial (inherited, **heterozygous** type only)
- **Mixed dyslipidaemia**: high levels of cholesterol and other fats, for example **triglycerides**, in the blood

Your healthcare professional may give you inclisiran alongside another type of cholesterol-lowering medication called a **statin**, if your cholesterol levels are not low enough with a **statin** alone. If you are unable to take a **statin**, you may be given inclisiran instead. If **statins** do not work well or cannot be used, inclisiran may also be given alongside other cholesterol-lowering therapies, such as **ezetimibe**. You should ensure you continue to eat a healthy diet, low in saturated fat, along with your medication.

Inclisiran is only approved for use in adults. It is a prescription-only medicine, which means that it cannot be purchased over the counter.



# WHY IS HIGH CHOLESTEROL A PROBLEM?

## WHAT IS CHOLESTEROL?

Cholesterol is a type of fat that is made in the liver and also comes from some of the foods we eat. Healthy levels are regulated by the liver, which makes most of our cholesterol and also breaks it down. Cholesterol plays a key role in how your body works. It is needed to help cells to work, make bile to help you digest food, and make vitamin D and hormones.

Too much cholesterol in the blood, however, can be harmful. It can increase the risk of **CVD**, which affects the heart and blood vessels.

There are two main types of cholesterol carried in the bloodstream:

**LDL-cholesterol** and **HDL-cholesterol**.

- **LDL (low-density lipoprotein)** contains lots of cholesterol. Its job is to carry cholesterol from the liver to the cells that need it. **LDL-cholesterol** is sometimes known as the 'bad' cholesterol, because high levels can increase the risk of **CVD**. You may also hear **LDL-C** or 'bad' cholesterol being called '**non-HDL-C**'. This is because we now know that there are other forms of cholesterol, aside from LDL, which also increase your risk of **CVD**
- **HDL (high-density lipoprotein)** contains very little cholesterol. Its job is to carry cholesterol from the cells back to the liver where it is broken down and removed from the body. It is sometimes known as the 'good' cholesterol, because it can protect against **CVD**

A blood test is the only way to find out whether your cholesterol levels are higher than they should be. In this leaflet, we will look at high levels of **LDL-cholesterol** and the risks associated with it.

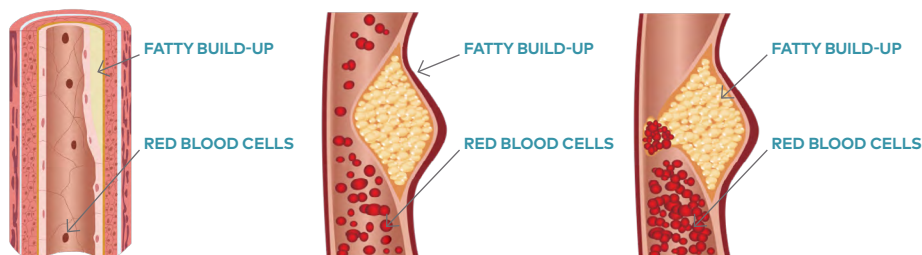
**Lowering LDL-cholesterol levels has been shown to reduce the risk of conditions that affect the heart and blood vessels**

## WHAT IS ATHEROSCLEROTIC CARDIOVASCULAR DISEASE?

When we talk about **CVD**, we refer to any of a number of conditions that affect the heart and blood vessels.

High levels of the 'bad' cholesterol (**LDL-cholesterol**) can lead to fatty build-up in the walls of arteries. This process is known as **atherosclerosis**. It narrows the arteries and prevents the blood flowing through them properly, which can cause a type of **CVD** called **atherosclerotic CVD** or **ASCVD** for short. **ASCVD** includes conditions such as **angina**, **heart attack**, **stroke**, **PAD** and **coronary heart disease** (or **CHD**).

## FATTY BUILD-UP CAN NARROW THE ARTERIES



High levels of **LDL-cholesterol** lead to fatty build-up in the walls of the arteries

The fatty build-up can grow over time, narrowing the artery

It can prevent blood from flowing through the artery properly

## WHAT IS FAMILIAL HYPERCHOLESTEROLAEMIA?

**Familial hypercholesterolaemia**, also known as **FH**, is a form of **primary hypercholesterolaemia** that runs in families. It is an inherited condition that is caused by your genes. It causes very high levels of **LDL-cholesterol** and, if left untreated, can cause **CVD** at an early age. There are two types of **FH**: **heterozygous** and **homozygous**. **Inclisiran** is only approved to treat one of these conditions, **heterozygous FH**.

# HOW IS HIGH CHOLESTEROL MANAGED?

If you have high cholesterol, you can help to reduce it with lifestyle changes, including eating a healthy diet, low in saturated fat, and undertaking physical activity. When these changes are not enough on their own, medicine is usually the next step to help you manage high cholesterol.

High cholesterol levels are in a sense ‘invisible’ – that is, you may not know you have them, unless you have a blood test or **CVD** develops. Because of this, it can be easy to forget how important it is to reduce them.

It is important to continue lifestyle changes, even once medication has been started.

These combined steps can make a huge difference to your cholesterol levels and cardiovascular health.

## HEALTHY EATING

Eating a healthy, balanced diet can make a difference to lowering cholesterol. There are other benefits too – protecting against high blood pressure and diabetes, and helping you maintain a healthy weight.

Dietary changes to help reduce your cholesterol include replacing **saturated fat** with **monounsaturated** and **polyunsaturated fats**, and cutting down on **trans fats**.



| Type of fat          | Should these be part of my diet?  | Where is it found?   |
|----------------------|---|--|
| Monounsaturated fats | Yes, have these in small amounts. You can use these to replace saturated fats                       | Olive oil, rapeseed oil, nuts and seeds  |
| Polyunsaturated fats | Yes, have these in small amounts. You can use these to replace saturated fats                       | Sunflower oil, nuts and seeds, and oily fish   |
| Saturated fats       | It is advisable to cut right down on saturated fats and replace with mono- and polyunsaturated fats | Butter, cheese, whole milk, fatty and processed meat, biscuits, cakes, pastries, pies, and coconut oil |
| Trans fats           | It is best to avoid trans fats wherever possible  | Sometimes present in pastries, fast foods and takeaways  |

For more information, speak with your healthcare professional or refer to the links for British Heart Foundation and HEART UK at the end of this leaflet.

Other aspects of healthy eating include:

- Eating plenty of fruit and vegetables – at least 5 a day
- Choosing wholegrain and high fibre starchy foods such as wholemeal bread, oats, brown rice, wholegrain breakfast cereal
- Eating a variety of healthy sources of protein. For example, legumes (peas, beans and lentils), fish, nuts, seeds, and poultry. If red meat is eaten, choose lean meat, and be mindful of the quantity
- Eating foods with added plant stanols and sterols (including some types of spreads and dairy foods)
- Choosing reduced fat dairy foods or fortified plant based dairy alternatives, such as soya
- Aiming for two portions of fish a week, one of which should be oily, for example, salmon, mackerel, sardines and pilchards



Cutting back on salt and sugar, as well as sugary foods, is also recommended.

## EXERCISE

**Doing regular exercise** can lower **LDL-cholesterol** levels; experts recommend about **2 and a half hours every week**, over periods of 10–30 minutes. This should be moderate intensity exercise, which is enough to make you feel warm and slightly puffed out.

You can start to fit this into your daily routine, for example by opting for the stairs instead of the lift or walking instead of taking the car.



## MEDICINES

The most commonly used cholesterol-lowering medicines are **statins**. **Statins** can be very effective and can reduce your **LDL-cholesterol**. The amount your cholesterol can reduce by with **statin** treatment depends on the type of **statin** and the dose.

**Ezetimibe** is another medicine which can be used to lower **LDL-cholesterol**. It is often prescribed alongside a **statin** because they work in different ways to reduce cholesterol levels. Using both may help to lower cholesterol.



# HOW DOES INCLISIRAN WORK?

Inclisiran is a type of medicine called an **siRNA inhibitor**. It triggers a series of events that increases the amount of **LDL-cholesterol** taken up into the liver to be broken down, resulting in lower amounts of **LDL-cholesterol** in the bloodstream.

1

Inside the liver cell, inclisiran lowers the levels of a substance called **PCSK9**, which is a type of protein.



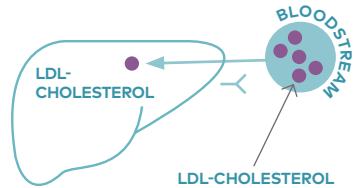
2

This increases the number of LDL receptors that sit on the surface of liver cells. LDL receptors may be thought of as 'doorways' to the cell.



3

The LDL receptors (the 'doorways' to the cell) allow **LDL-cholesterol** to move from the bloodstream to the inside of the liver cell to be broken down.



4

More LDL receptors on the surface of the liver cells means more **LDL-cholesterol** can be let inside the liver cells, where it is broken down and removed from the body.

This means there is less **LDL-cholesterol** in the bloodstream and the risk of fatty build-up in the arteries is reduced.



Because of the way inclisiran works in the body, its effects last in between doses.



# HOW, AND HOW OFTEN, WILL I BE GIVEN INCLISIRAN?

## HOW WILL I BE GIVEN INCLISIRAN?

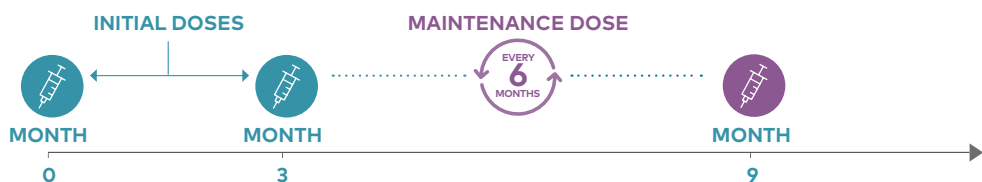
Inclisiran is given as an injection under the skin, by your healthcare professional.

It is usually given in the **abdomen** (the tummy area), but can also be given in the **upper arm or the thigh** (top of the leg). If you have any sunburn, skin rashes or infections, this area should be avoided.



## HOW OFTEN WILL I BE GIVEN INCLISIRAN?

Inclisiran is given as a single injection when you start treatment, then another 3 months later. After these initial injections, inclisiran is given **every 6 months**.



In the highly unlikely event that you are given too much (an overdose) the doctor or other healthcare professional will check you for side effects.

If you miss your appointment for your LEQVIO injection, contact your doctor, pharmacist or nurse as soon as you can to arrange your next injection.

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

If your healthcare professional has advised you to take other medications with inclisiran, you should continue to take these, including cholesterol-lowering medications.

Generally, there is not a set treatment duration with inclisiran. You should continue to receive it unless your healthcare professional says otherwise. If you have any concerns about your treatment, please talk to your healthcare professional.

# WHAT SHOULD I KNOW BEFORE I AM GIVEN INCLISIRAN?

## **SIDE EFFECTS OF INCLISIRAN**

Like all medicines, some side effects may be experienced with inclisiran. The most common side effects are pain, redness and a rash on the area where the injection was given. In studies, the side effects were mild or moderate and passed after a short time. If you have any side effects, speak to your healthcare professional.

## **PREGNANCY AND BREASTFEEDING**

As there is limited information about using inclisiran during pregnancy, you should tell your healthcare professional if you are pregnant or are planning to become pregnant. Using inclisiran should be avoided during pregnancy.

If you are breastfeeding or are planning to breastfeed, speak with your healthcare professional. It is not yet known whether inclisiran passes into breast milk, so your doctor will help you to decide whether to continue breastfeeding or to start treatment with inclisiran.

## **OTHER CONSIDERATIONS**

Tell your doctor, pharmacist or nurse if you are using, have recently used or might use any other medicines.

Inclisiran should not affect your ability to drive or use machinery.

## **TALK TO YOUR DOCTOR, PHARMACIST OR NURSE BEFORE YOU ARE GIVEN LEQVIO:**

- if you are receiving dialysis
- if you have severe liver disease
- if you have severe kidney disease



# SOME OF THE TERMS YOU MAY HEAR OR READ ABOUT

**Angina:** Pain or discomfort felt in your chest caused by partial narrowing of the arteries supplying the heart with blood. This narrowing is caused by fatty build-up in the walls of the arteries, and means that the heart does not get enough blood.

**Atherosclerotic cardiovascular disease, or ASCVD:** A type of **cardiovascular disease (CVD)** that is caused by fatty build-up in the walls of the arteries (**atherosclerosis**). ASCVD includes conditions such as **angina, heart attack, stroke, PAD** and **CHD**.

**Atherosclerosis:** Fatty build-up in the walls of arteries, leading to narrowing of the arteries. This is associated with high levels of 'bad' cholesterol, LDL-cholesterol, in the blood.

**Cardiovascular disease, or CVD:** A term used to refer to conditions that affect the heart or blood vessels. CVD can have many different causes.

**Coronary heart disease, or CHD:** Disease caused by fatty build-up in the walls of the arteries that supply the heart. This leads to reduced blood supply to the heart and symptoms such as chest pain (**angina**).

**Ezetimibe:** A type of medicine used to lower cholesterol in the blood.

**Familial hypercholesterolaemia, or FH:** A condition that runs in families and can cause very high levels of **LDL-cholesterol** and, if left untreated, can cause **CVD** at an early age. There are two types of FH: heterozygous and homozygous. Inclisiran is only approved for treating **heterozygous FH**.

**Heart attack:** A complete blockage in the arteries supplying the heart with blood, caused by fatty build-up in their walls. This leads to damage to the area of heart supplied by these arteries. A heart attack is

a medical emergency and should be treated immediately.

**Heterozygous:** A term that describes inheriting two different versions of the same gene, one from your mother and one from your father. One gene may be normal and the other faulty.

**Heterozygous familial hypercholesterolaemia, or heterozygous FH:** People with this type of FH only inherit one faulty gene. Inclisiran is only approved for treating this type of FH.

**HDL-cholesterol (high-density lipoprotein cholesterol):** Sometimes known as the 'good' cholesterol. HDL picks up cholesterol from cells where it is not needed, and transports it as HDL-cholesterol back to the liver, to be broken down.

**LDL-cholesterol (low-density lipoprotein cholesterol):** Sometimes known as the 'bad' cholesterol, LDL-cholesterol is carried from the liver to the cells that need it. If there is too much of this cholesterol, it can build-up in the walls of the arteries, narrowing them and preventing the blood flowing through them properly. This increases the risk of **ASCVD**.

**Mixed dyslipidaemia:** High levels of cholesterol and other fats, for example **triglycerides**, in the blood.

**Monounsaturated fats:** A type of fat found in olive oil, nuts and seeds. Monounsaturated fats and polyunsaturated fats can replace saturated fats as part of a healthy diet.

**Non-familial hypercholesterolaemia:** A form of primary hypercholesterolaemia. Non-familial hypercholesterolaemia is caused by genes interacting with other risk factors, like diet, physical inactivity and smoking.

**Non-HDL cholesterol:** All of your 'bad' cholesterol (including **LDL cholesterol**), which can increase your risk of ASCVD. We now know that **LDL-cholesterol** is not the only form of cholesterol that increases this risk.

**PCSK9 (proprotein convertase subtilisin kexin 9):** A protein found in the liver. High levels of PCSK9 can cause high levels of **LDL-cholesterol** in the blood.

**PCSK9 inhibitor:** A type of medicine that stops PCSK9 from working, which leads to lower **LDL-cholesterol** levels in the blood.

**Peripheral arterial disease, or PAD:** Restriction of blood supply in the outer arteries of the body, which is due to fatty build up causing the arteries to narrow. PAD usually affects the leg muscles. It is often associated with an ache in the legs when walking.

**Polyunsaturated fats:** A type of fat found in sunflower oil, nuts and seeds, and oily fish.

**Polyunsaturated fats** and **monounsaturated fats** can replace saturated fats as part of a healthy diet.

**Primary hypercholesterolaemia:** High levels of cholesterol in the blood, which are caused by your genes. There are two types: **familial hypercholesterolaemia** and **non-familial hypercholesterolaemia**. **Heterozygous familial hypercholesterolaemia** is caused by a single gene and runs in families, while **non-familial hypercholesterolaemia** is caused by genes interacting with other factors, like diet and smoking.

**Saturated fats:** A type of fat found in butter, cheese, whole milk, fatty and processed meat, biscuits, cakes, pastries, pies and coconut oil. Cutting down on saturated fats and replacing them with **monounsaturated** or **polyunsaturated** fats can help to lower cholesterol.

**siRNA inhibitor:** A type of drug that uses small interfering RNA (siRNA) to turn off production of specific genes that contribute to disease. siRNA occurs naturally in the body.

**Statin:** A class of medicine that is widely used to lower cholesterol. Examples include atorvastatin, fluvastatin, pravastatin, rosuvastatin and simvastatin.

**Stroke:** A stroke is caused by reduced blood flow to part of the brain, leading to damage to the brain cells there. A stroke is a medical emergency and should be treated immediately.

**Total cholesterol:** A measure of the overall amount of cholesterol in the blood, including the different types such as **LDL-cholesterol** and **HDL-cholesterol**.

**Trans fats:** A type of fat sometimes present in pastries, fast foods and takeaways. Trans fats should be avoided wherever possible to help lower cholesterol.

**Triglycerides:** Another type of fat found in the blood. Triglycerides are taken to the body's cells where they are used for energy or stored for later. They are found in certain foods such as dairy, meat and cooking oil.



# LDL-CHOLESTEROL TRACKER

On the date of dd/mm/yy my **LDL-cholesterol** level was: \_\_\_\_\_.

My healthcare professional advised that I should aim for a reduction of \_\_\_\_\_ %, or a level of \_\_\_\_\_.

Your healthcare professional may take various different measures of cholesterol, so ask them for your **LDL-cholesterol** reading specifically. You can use this chart to plot your **LDL-cholesterol** levels. Add the date of your **LDL-cholesterol** reading at the top of the column, and then mark your reading for that date with an 'X' along the line corresponding to your **LDL-cholesterol** level. This will help you see how your levels change over time.

## LDL-cholesterol chart

|      | Date     |          |          |          |          |          |          |          |          |          |
|------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|
|      | dd/mm/yy | dd/mm/yy | dd/mm/yy | dd/mm/yy | dd/mm/yy | dd/mm/yy | dd/mm/yy | dd/mm/yy | dd/mm/yy | dd/mm/yy |
| 10.0 |          |          |          |          |          |          |          |          |          |          |
| 9.8  |          |          |          |          |          |          |          |          |          |          |
| 9.6  |          |          |          |          |          |          |          |          |          |          |
| 9.4  |          |          |          |          |          |          |          |          |          |          |
| 9.2  |          |          |          |          |          |          |          |          |          |          |
| 9.0  |          |          |          |          |          |          |          |          |          |          |
| 8.8  |          |          |          |          |          |          |          |          |          |          |
| 8.6  |          |          |          |          |          |          |          |          |          |          |
| 8.4  |          |          |          |          |          |          |          |          |          |          |
| 8.2  |          |          |          |          |          |          |          |          |          |          |
| 8.0  |          |          |          |          |          |          |          |          |          |          |
| 7.8  |          |          |          |          |          |          |          |          |          |          |
| 7.6  |          |          |          |          |          |          |          |          |          |          |
| 7.4  |          |          |          |          |          |          |          |          |          |          |
| 7.2  |          |          |          |          |          |          |          |          |          |          |
| 7.0  |          |          |          |          |          |          |          |          |          |          |
| 6.8  |          |          |          |          |          |          |          |          |          |          |
| 6.6  |          |          |          |          |          |          |          |          |          |          |
| 6.4  |          |          |          |          |          |          |          |          |          |          |
| 6.2  |          |          |          |          |          |          |          |          |          |          |
| 6.0  |          |          |          |          |          |          |          |          |          |          |
| 5.8  |          |          |          |          |          |          |          |          |          |          |
| 5.6  |          |          |          |          |          |          |          |          |          |          |
| 5.4  |          |          |          |          |          |          |          |          |          |          |
| 5.2  |          |          |          |          |          |          |          |          |          |          |
| 5.0  |          |          |          |          |          |          |          |          |          |          |
| 4.8  |          |          |          |          |          |          |          |          |          |          |
| 4.6  |          |          |          |          |          |          |          |          |          |          |
| 4.4  |          |          |          |          |          |          |          |          |          |          |
| 4.2  |          |          |          |          |          |          |          |          |          |          |
| 4.0  |          |          |          |          |          |          |          |          |          |          |
| 3.8  |          |          |          |          |          |          |          |          |          |          |
| 3.6  |          |          |          |          |          |          |          |          |          |          |
| 3.4  |          |          |          |          |          |          |          |          |          |          |
| 3.2  |          |          |          |          |          |          |          |          |          |          |
| 3.0  |          |          |          |          |          |          |          |          |          |          |
| 2.8  |          |          |          |          |          |          |          |          |          |          |
| 2.6  |          |          |          |          |          |          |          |          |          |          |
| 2.4  |          |          |          |          |          |          |          |          |          |          |
| 2.2  |          |          |          |          |          |          |          |          |          |          |
| 2.0  |          |          |          |          |          |          |          |          |          |          |
| 1.8  |          |          |          |          |          |          |          |          |          |          |
| 1.6  |          |          |          |          |          |          |          |          |          |          |
| 1.4  |          |          |          |          |          |          |          |          |          |          |
| 1.2  |          |          |          |          |          |          |          |          |          |          |
| 1.0  |          |          |          |          |          |          |          |          |          |          |

If you have any questions regarding your condition or your treatment, please speak with your healthcare professional.

For further information on **CVD** and support, please visit:

<https://www.heartuk.org.uk>

<https://www.bhf.org.uk>

**For further information on inclisiran, please ask your healthcare professional for a copy of the patient information leaflet which comes with the medicine.**

**This can also be accessed online:**

**<https://www.medicines.org.uk/emc/product/12039/pil>**

#### Reporting of side effects

If you get any side effects with any medication you are taking, talk to your doctor, pharmacist or nurse.

This includes any possible side effects not listed in the information leaflet that comes in the pack.

The medicine referred to in this material is subject to additional monitoring. This will allow quick identification of new safety information.

You can help by reporting any side effects you may get.

Please see [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) (UK) for instructions on how to report side effects.