NOVARTIS

SYBRAVA®

284 mg/1,5 mL solution for injection in pre-filled syringe

PATIENT INFORMATION LEAFLET

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NOVARTIS

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Sybrava® 284 mg/1,5 ml solution for injection in pre-filled syringe

Inclisiran

Sugar-free

Read all of this leaflet carefully before you are given Sybrava

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

What is in this leaflet

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

1. What Sybrava is and what it is used for

What Sybrava is

Sybrava contains the active substance inclisiran, which is a cholesterol-lowering double-stranded small interfering ribonucleic acid (siRNA).

What Sybrava is used for

Sybrava is used to lower cholesterol in addition to a cholesterol-lowering diet if you are an adult with a high cholesterol level in your blood (primary hypercholesterolaemia [including heterozygous familial hypercholesterolaemia]).

It is given in addition to other cholesterol lowering medicines, for example a statin (a commonly used medicine that treats high cholesterol).

How Sybrava works

Inclisiran uses one of the body's own natural processes to lower "bad" cholesterol (also called LDL cholesterol). It works by limiting the production of a protein called PCSK9 (proprotein convertase subtilisin/kexin type 9) that can increase "bad" cholesterol levels. By preventing its production, Sybrava can lower your levels of "bad" cholesterol. If you have any questions about how Sybrava works or why this medicine has been prescribed for you, ask your doctor or healthcare provider.

2. What you need to know before you are given Sybrava

You must not be given Sybrava

- If you are allergic to inclisiran or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor, pharmacist or nurse before you are given Sybrava:

- If you have kidney disease and you are receiving dialysis
- If you have severe liver disease

Children and adolescents

Sybrava is not recommended in children and adolescents under 18 years of age.

Other medicines and Sybrava

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Pregnancy and breast-feeding

Sybrava is not recommended during pregnancy or breast-feeding. If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Driving and using machines

Sybrava is not expected to affect your ability to drive or use machines.

3. How Sybrava is given

Sybrava is given as an injection under the skin (subcutaneous injection) in your abdomen. You will not be expected to give yourself Sybrava. It will be given to you by a person who is qualified to do so.

The recommended dosage of Sybrava is 284 mg administered as a single subcutaneous injection: initially, again at 3 months and then every 6 months.
Before starting Sybrava you should be on a diet to lower your cholesterol and it is likely that you will be taking a statin. You should stay on this cholesterol lowering diet and keep taking the statin all the time you receive Sybrava.

If you receive more Sybrava than you should

Since a health care provider will administer Sybrava, he / she will control the dosage.
However, in the event of overdosage your doctor will manage the overdosage.

If you miss your dose of Sybrava

If you miss an appointment to have Sybrava administered, at your earliest convenience ask your doctor, pharmacist or nurse when to book your next treatment.

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

4. Possible side effects

Sybrava can have side effects.

Not all side effects reported for Sybrava are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Sybrava, please consult your health care provider for advice.

Common: may affect up to 1 in 10 people

- Injection site reactions, such as pain, redness or rash.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of Sybrava.

5. How to store Sybrava

Store at or below 25 °C.

Store all medicines out of reach of children.

Do not use this medicine after the expiry date which is stated on the label and carton.
The expiry date refers to the last day of that month.

Do not freeze.

The doctor, pharmacist or nurse will check this medicine and will discard it if it contains particles or is discoloured.

Return all unused medicine to your pharmacist.

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

6. Contents of the pack and other information

What Sybrava contains

- The active substance is inclisiran. Each pre-filled syringe contains 284 mg of inclisiran in 1,5 ml of solution.
- The other ingredients are sodium hydroxide, phosphoric acid and water for injections.

What Sybrava looks like and contents of the pack

Sybrava is a clear, colourless to pale yellow solution, essentially free of particulates.

Each pack contains one single use pre-filled syringe.

Holder of certificate of registration

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Access to the corresponding Professional Information

Available on the SAHPRA website