Package leaflet: Information for the user

Sebivo® 600 mg film-coated tablets
Telbivudine

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 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.

What is in this leaflet

1. What Sebivo is and what it is used for

Sebivo contains the active substance telbivudine. Sebivo belongs to a group of medicines called antiviral medicines, which are used to treat infections caused by viruses.

Sebivo is used to treat adults with chronic hepatitis B. Starting treatment with Sebivo should only be considered when it is not possible or appropriate to use an alternative medicine to which the hepatitis B virus is less likely to develop resistance. Your doctor will decide which treatment is most appropriate for you.

Hepatitis B is caused by infection with the hepatitis B virus, which multiplies in the liver and causes liver damage. Treatment with Sebivo reduces the amount of hepatitis B virus in the body by blocking its growth, resulting in less liver damage and improved liver function.

2. What you need to know before you take Sebivo

Do not take Sebivo
- if you are allergic to telbivudine or any of the other ingredients of this medicine (listed in section 6).
- if you are being treated with pegylated or standard interferon alfa (see “Taking other medicines”).

If this applies to you, **do not take Sebivo. Talk to your doctor**.

Warnings and precautions
Talk to your doctor before taking Sebivo:
- if you have or have had any kidney problems. Your doctor may order laboratory tests to check your kidneys are working properly before and during treatment. Depending on the results of these tests your doctor may advise you to change how often you take Sebivo.
- if you suffer from cirrhosis of the liver (a serious condition which causes liver “scarring”). In this case your doctor will want to monitor you more closely.

- if you have had a liver transplant.
- if you are taking any medicines that may cause muscle problems (talk to your doctor or pharmacist if you are unsure).
- if you are infected with HIV, hepatitis C or D, or are being treated with any antiviral medicines.

If any of these applies to you, **tell your doctor before you take Sebivo**.

During the treatment with Sebivo:
- Sebivo can cause persistent unexplained muscle weakness or muscle pain (myopathy). Muscle symptoms may progress and become serious, sometimes leading to muscle breakdown (rhabdomyolysis) which can cause kidney damage.
- Uncommonly Sebivo can induce numbness, tingling, pain and/or burning sensations in the arms and/or legs (peripheral neuropathy).

If you experience any of these symptoms during your treatment with Sebivo, **call your doctor immediately**.

Other side effects of this type of medicine
Sebivo can cause an excess of lactic acid in the blood (lactic acidosis) which is usually associated with an enlargement of the liver (hepatomegaly). Lactic acidosis is a rare but serious side effect which can occasionally be fatal. Your doctor will monitor you regularly while you are receiving Sebivo. If you experience muscle pain, severe and persistent stomach pain with nausea and vomiting, severe and persistent trouble breathing, tiredness or abdominal discomfort while taking Sebivo, **call your doctor immediately**.

Some people may get very serious hepatitis symptoms when they stop taking medicines like Sebivo. Your doctor will monitor your health and do regular blood tests to check your liver after you stop treatment with Sebivo. Tell your doctor immediately about any new or unusual symptoms that you notice after stopping treatment (see "If you stop taking Sebivo" in section 3 of this leaflet).

Take care not to infect other people
Even if you take Sebivo, you may still infect others with hepatitis B virus (HBV) through sexual contact or exposure to contaminated blood or other body fluids. If you have sexual intercourse with a partner who is not immune against hepatitis B, always use condoms and avoid any other exchange of body fluids. Never share needles. Do not share personal items that could have blood or body fluids on them, such as toothbrushes or razor blades. A vaccine is available to prevent infection with HBV.

Children and adolescents
Sebivo is not recommended for use in children and adolescents.

Other medicines and Sebivo
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Your doctor or pharmacist needs to know about other medicines because some medicines could affect your kidneys and because Sebivo mainly leaves the body via the kidneys in the urine.

Do not take Sebivo if you are using pegylated or standard interferon alfa (see "Do not take Sebivo"), because the combination of these medicines may increase your risk of developing peripheral neuropathy (numbness, tingling, and/or burning sensations in the arms and/or legs). Tell your doctor or pharmacist if you are being treated with interferon.

Pregnancy and breast-feeding
- Do not use Sebivo during pregnancy unless your doctor recommends it. If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. Your doctor will discuss with you the potential risks of taking Sebivo during pregnancy.

- If you have hepatitis B and become pregnant, talk to your doctor about how you can best protect your baby. Sebivo may reduce the risk of passing your hepatitis B virus on to your unborn baby if taken in combination with Hepatitis B immune globulin and Hepatitis B vaccine.

- Do not breast-feed during treatment with Sebivo. Tell your doctor if you are breast-feeding.

Driving and using machines
Sebivo has minor influence on the ability to drive and use machines. If you feel dizzy while taking this medicine, do not drive a vehicle or use any tools or machines.

3. How to take Sebivo

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

How much Sebivo to take
The recommended dose of Sebivo is one 600 mg tablet once a day. Take the tablet at about the same time each day.

The tablet can be taken with or without food. Swallow it whole with some water. Do not chew, split or crush it.

You may need to take Sebivo less frequently if you have kidney problems. Tell your doctor if you have, or have ever had, any kidney problems.

How long to take Sebivo
Continue taking Sebivo every day for as long as your doctor tells you. Do not change your dose or stop taking Sebivo without talking to your doctor. This medicine is intended for long-term treatment, possibly lasting for months or years. Your doctor will regularly monitor your condition to check that the treatment is having the desired effect.

If you take more Sebivo than you should
If you have taken too much Sebivo, or if someone else accidentally takes your tablets, go to your doctor or hospital for advice straight away. Take the pack of tablets with you and show it to your doctor.

If you forget to take Sebivo
- If you forget to take Sebivo, take it as soon as you remember and then take your next dose at its regular time.
- However, if it is within 4 hours before your next dose, skip the dose you missed and take the next one at the usual time.

Do not take a double dose to make up for a forgotten tablet. This may increase the chance of you getting unwanted side effects. Ask your doctor or pharmacist if you are not sure what to do.

If you stop taking Sebivo
Stopping treatment with Sebivo may result in a worsening of your hepatitis B infection i.e. progression of the disease and abnormal test results (increase of viral load, ALT increase). Do not stop Sebivo unless your doctor tells you to. While you are taking Sebivo, make sure you do not run out of Sebivo.

Your doctor will monitor your health and do regular blood tests to check your liver after you stop treatment with Sebivo since your hepatitis B infection may get worse or become very serious after stopping treatment. Tell your doctor immediately about any new or unusual symptoms that you notice after stopping treatment.

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.

Some side effects could be serious:
- Persistent muscle weakness or muscle pain
- Numbness, tingling, pain and/or burning sensation in the arms and/or legs

If you experience any of these, **call your doctor immediately**.

Sebivo may also cause other side effects:
Common (may affect up to 1 in 10 people)
- Dizziness, headache
- Cough
- Diarrhoea, feeling sick (nausea), stomach (abdominal) pain
- Skin rash
- Tiredness (fatigue)
- Blood test results show higher levels of some liver enzymes (e.g. ALT, AST), amylase, lipase or creatine kinase

Uncommon (may affect up to 1 in 100 people)
- Joint pain
- Persistent muscle weakness or muscle pain (myopathy/myositis), muscle cramp
- Back, neck and flank pain
- Numbness, tingling, pain and/or burning sensation in the arms and/or legs or around the mouth
- Pain in lower back or hip that may radiate into the leg (sciatica)
- Taste disturbance
- Feeling unwell (malaise)

Rare (may affect up to 1 in 1,000 people)
- Excess of lactic acid in the blood (lactic acidosis)
- Muscle breakdown (rhabdomyolysis)

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.

Ireland	HPRA Pharmacovigilance Earlsfort Terrace IRL - Dublin 2 Tel: +353 1 6764971 Fax: +353 1 6762517 Website: www.hpra.ie e-mail: medsafety@hpra.ie
Malta	ADR Reporting Website: www.medicinesauthority.gov.mt/adrportal
United Kingdom	Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

5. How to store Sebivo

Keep this medicine out of the sight and reach of children.

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

This medicinal product does not require any special storage conditions.

Do not use this medicine if the pack is damaged or shows signs of tampering.

Do not throw away any 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 Sebivo contains
- The active substance is telbivudine. Each tablet contains 600 mg telbivudine.
- The other ingredients are: cellulose, microcrystalline; povidone; sodium starch glycolate; silica, colloidal anhydrous; magnesium stearate; hypromellose; titanium dioxide (E171); talc; macrogol.

What Sebivo looks like and contents of the pack
Sebivo film-coated tablets are white to slightly yellowish, oval, film-coated tablets with “LDT” imprinted on one side.

Sebivo film-coated tablets are supplied in packs of 28 or 98 tablets. Not all pack sizes may be marketed in your country.

Marketing Authorisation Holder
Novartis Europharm Limited
Vista Building
Elm Park, Merrion Road
Dublin 4
Ireland

Manufacturer
Novartis Pharma GmbH
Roonstrasse 25
90429 Nuremberg
Germany

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

Ireland
Novartis Ireland Limited
Tel: +353 1 260 12 55

Malta
Novartis Pharma Services Inc.
Tel: +356 2122 2872

United Kingdom
Novartis Pharmaceuticals UK Ltd.
Tel: +44 1276 698370

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Other sources of information
Detailed information on this medicine is available on the European Medicines Agency website: http://www.ema.europa.eu