

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Sebivo. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the final page. Some more recent information on the medicine may be available.

You should ensure that you speak to your pharmacist or doctor to obtain the most up to date information on the medicine. You can also download the most up to date leaflet from www.novartis.com.au.

Those updates may contain important information about the medicine and its use of which you should be aware.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking this medicine against the benefits they expect it will provide.

If you have any concerns about this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Sebivo is used for

Sebivo belongs to a group of medicines called antivirals.

Sebivo is used to treat chronic hepatitis B in patients. 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 multiplication, resulting in less liver damage and improvement in liver function.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another purpose.

This medicine is only available with a doctor's prescription. It is not addictive.

Sebivo does not reduce the risk of infecting others with hepatitis B virus (HBV) through sexual contact or exposure to contaminated blood or other body fluids. You should use appropriate precautions.

Before you take Sebivo

When you must not take it

Do not take Sebivo if:

- **you are allergic (hypersensitive) to telbivudine (active ingredient) or to any of the other ingredients listed at the end of this leaflet**
- **If you are being treated with pegylated interferon alfa-2a, 180 micrograms once weekly (see "Tell your doctor" and "Taking other medicines")**
- **the expiry date (EXP) printed on the pack has passed**

- **the packaging is torn or shows signs of tampering**

Tell your doctor:

- about any other medical conditions that you have and any other medicines that you are taking (see "Taking other medicines")
- if you are infected with HIV, hepatitis C or D, or have been treated with any antiviral medicines
- if you are being treated with other types of alpha interferon alfa-2a for chronic hepatitis B or C (see "When you must not take it" and "Taking other medicines")
- if you have or have had any kidney problems
- if you have had a liver transplant
- if you are taking any medicines that may affect your kidneys
- if you are allergic to any other medicines, foods, dyes or preservatives.
- if you are breastfeeding, pregnant or trying to become pregnant

If you are pregnant or think you may be, tell your doctor before taking Sebivo. If it is necessary for you to take Sebivo, your doctor will discuss the risks and benefits of taking it during the second and last three months of pregnancy.

It is not known whether Sebivo reduces the risk of passing your hepatitis B virus on to your unborn baby. You should talk to your doctor about how you can best protect your baby.

Medicines of the same class as Sebivo can cause excess of lactic acid in the blood (lactic acidosis) and enlargement of the liver (hepatomegaly) with fatty liver (steatosis). Lactic acidosis is a rare but serious side effect which can occasionally be fatal. If you experience muscle pain, stomach pain with nausea and vomiting, trouble breathing, or feel very weak or tired while taking Sebivo, call your doctor immediately.

Taking other medicines

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

Sebivo leaves the body primarily via the kidneys in the urine. It is therefore particularly important to tell your doctor or pharmacist if you are taking or have recently taken other medicines, as some of those may affect your kidneys.

Do not take Sebivo if you are being treated with pegylated interferon alfa-2a, 180 micrograms once weekly (see "Before you take Sebivo"). This combination 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 other types of alfa interferon for chronic hepatitis B or C.

You may need to take different amounts of your medicines or you may need to take different medicines. Your doctor and pharmacist have more information.

If you have not told your doctor about any of these things, tell him/her before you start taking this medicine.

How to take Sebivo

Follow all directions given to you by your doctor and pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

How much to take

The usual dose of Sebivo is one 600mg tablet once a day.

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

When to take it

Unless your doctor tells you otherwise, take Sebivo according to the following schedule:

How to take it

Take one 600mg tablet once a day, at about the same time each day.

The tablet should be swallowed whole with some water, and can be taken with or without food. Do not chew, split or crush the tablet.

How long to take it

It is important to take Sebivo every day and to continue the treatment exactly as prescribed.

If you forget to take it

If you miss a dose, take the missed dose as soon as you remember and then take your next dose at its regular time.

However, if it is almost time for 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 dose. This may increase the chance of you getting an unwanted side effect. Ask your

doctor or pharmacist if you are not sure what to do.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at your nearest hospital if you think that you or anyone else may have taken too much Sebivo. Do this even if there are no signs of discomfort or poisoning. Keep the telephone numbers for these places handy.

While you are taking Sebivo

Things you must do

Tell your doctor immediately if you find out that you are pregnant while taking Sebivo.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Sebivo.

Things you must not do

Your doctor has prescribed medicine to prevent hepatitis B virus from further damaging your liver. You may have been prescribed one tablet by itself or two tablets in combination. This medicine may include Sebivo. These medications are very important treatments that can improve the inflammation and scar tissue caused by hepatitis B virus in your liver and can reduce the chance of developing cirrhosis, liver failure and liver cancer.

It is extremely important that you do not stop taking these tablets without discussing it with your doctor. If the medicine is suddenly stopped, the hepatitis virus can become very active again and lead to sudden development of severe liver failure. There is a high risk of dying if liver failure develops and

liver transplantation may be necessary to save your life.

It is important to take your medicine every day or as directed by your doctor, to not miss medicine doses, and to make sure you have enough supply until you next see your doctor.

Do not stop taking Sebivo unless you are asked to do so by your doctor as it can be very dangerous. Your hepatitis B infection may get worse or become very serious. 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.

Do not give this medicine to anyone else, even if their condition seems similar to yours.

Do not use it to treat any other complaints unless your doctor tells you to.

Side effects

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

All medicines can have 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.

The most commonly reported side-effects are:

- headache
- dizziness
- diarrhoea
- nausea (feeling sick) or vomiting
- increased level of blood amylase and lipase
- skin rash
- fatigue
- increased level of liver enzymes

- increased level of blood creatine kinase

Uncommon side-effects are:

- muscle or joint pain
- inflammation of the muscles
- malaise (feeling unwell)
- peripheral neuropathy (numbness, tingling and/or burning sensations in the arms and/or legs)

Tell your doctor immediately if any of the following happen:

- sudden signs of allergy such as rash, itching or hives on the skin; swelling of the face, lips, tongue or other parts of the body; wheezing or troubled breathing
- unexplained muscle pain, tenderness, temporary paralysis or weakness of muscles. In very rare cases, muscle problems can be serious, including muscle breakdown (rhabdomyolysis) which can result in kidney damage.

Tell your doctor if you notice anything else that is making you feel unwell.

Some people may have other side effects not yet known or mentioned in this leaflet.

After taking Sebivo

Storage

- Keep your medicine in the original container until it is time to take a dose.
- Store it in a cool dry place.
- Do not store Sebivo or any other medicine in the bathroom or near a sink.
- Do not leave it in the car or on window sills.

Keep this medicine 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.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine you have left over.

Product description

What it looks like

Sebivo tablets are white to slightly yellow, ovaloid, film-coated tablets, "LDT" imprinted on one side; packs of 28 tablets.

Ingredients

Each tablet contains telbivudine 600 mg as the active ingredient. The tablets also contain the following inactive ingredients:

- microcrystalline cellulose
- povidone
- sodium starch glycolate
- colloidal anhydrous silica
- magnesium stearate
- hypromellose
- titanium dioxide (E171)
- talc
- macrogol

Sebivo tablets do not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Sponsor

Sebivo tablets are supplied in New Zealand by:

Novartis New Zealand Limited
Private Bag 65904 Mairangi Bay
Auckland Building G, 5 Orbit Drive
Rosedale Auckland 0632
Telephone: 0800 652 422
® = Registered Trademark

This leaflet was prepared in March 2011.
