PART III: CONSUMER INFORMATION

Pr SEBIVO®
telbivudine

This leaflet is part III of a three-part "Product Monograph" published when SEBIVO® was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about SEBIVO. Contact your doctor or pharmacist if you have any questions about the drug.

Please read all of this leaflet carefully before you start taking this medicine. 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

ABOUT THIS MEDICATION

What the medication is used for:

- SEBIVO is a prescription medicine used for chronic infection with hepatitis B virus (HBV) in adults of 16 years and older, who also have active liver inflammation. SEBIVO has not been studied in children and is not recommended for anyone less than 16 years old.

What it does:
SEBIVO belongs to a group of medicines called antiviral medicines, which are used to treat infection with viruses.

Hepatitis B is caused by infection with the hepatitis B virus (HBV), which multiplies in the liver and causes liver damage.

SEBIVO may lower the amount of HBV in the body

SEBIVO may lower the ability of HBV to multiply and infect new liver cells

SEBIVO may reduce the damage to the liver by HBV

SEBIVO will not cure HBV infection

It is important to stay under your healthcare provider's care while taking SEBIVO. Your healthcare provider will test the level of the hepatitis B virus in your blood regularly.

When it should not be used:
Do not take SEBIVO if you are allergic (hypersensitive) to telbivudine or any of the other ingredients of SEBIVO (see "What the important nonmedicinal ingredients are" for a complete list of ingredients in SEBIVO).

Tell your healthcare provider if you think you have had an allergic reaction to any of these ingredients. If you think you may be allergic, ask your doctor for advice.

Do not take SEBIVO if you are being treated with pegylated interferon alfa-2a (see "BEFORE you use SEBIVO" and "INTERACTIONS WITH THIS MEDICATION")

What the medicinal ingredient is:
telbivudine

What the important nonmedicinal ingredients are:
SEBIVO contains the following nonmedicinal ingredients (in alphabetical order): colloidal silicon dioxide, magnesium stearate, microcrystalline cellulose, povidone, and sodium starch glycolate. The tablet coating contains hypromellose, polyethylene glycol, talc and titanium dioxide.

What dosage form it comes in:
SEBIVO is available in 600 mg film-coated tablets. These are white to slightly yellowish, ovaloid-shaped, film-coated tablets with "LDT" imprinted on one side.

Does SEBIVO lower the risk of passing HBV to others?
SEBIVO does not stop you from spreading HBV to others by sex, sharing needles, or being exposed to your blood. Talk to your healthcare provider about safe sexual practices that protect your partner. Never share needles. Do not share personal items that can have blood or body fluids on them, like toothbrushes or razor blades. A shot (vaccine) is available to protect people at risk from becoming infected with HBV.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

- Severe worsening of hepatitis (liver inflammation) has occurred in patients who have stopped taking anti-hepatitis B therapy. Your doctor will monitor your condition in this case and may resume therapy.
- Lactic acidosis (increase in lactic acid level in blood) which may or may not be associated with severe hepatomegaly with steatosis (enlarged fatty liver), including fatal cases have been reported in patients using SEBIVO, either alone or in combination. Lactic acidosis is a medical emergency and must be treated in the hospital. Call your healthcare provider right away if you get any of the signs of lactic acidosis (see below)

1. Some people who have taken medicines like SEBIVO (a nucleoside analogue) have developed a serious condition called lactic acidosis (build up of an acid in the blood). Lactic acidosis is a medical emergency and must be treated in the hospital. Call your healthcare provider right away if you get any of the following signs of lactic acidosis:

- you feel very weak or tired
- you have unusual muscle pain
- you have trouble breathing
- you have stomach pain with nausea and vomiting
- you feel cold, especially in your arms and legs
- you feel dizzy or light-headed
- you have a fast or irregular heartbeat
- you have abdominal swelling or discomfort

2. Some people who have taken medicines like SEBIVO have

developed serious liver problems called hepatotoxicity, with liver enlargement (hepatomegaly) and fat in the liver (steatosis). Call your healthcare provider right away if you get any of the following signs of liver problems:

- your skin or the white of your eyes turn yellow (jaundice)
- your urine turns dark
- your bowel movements (stools) turn light in colour
- you don't feel like eating food for several days or longer
- you feel sick to your stomach (nausea)
- you have lower stomach pain

3. Your hepatitis B infection may get worse or become very serious if you stop SEBIVO

- take SEBIVO exactly as prescribed
- do not run out of SEBIVO
- do not stop SEBIVO without talking to your healthcare provider

4. Like other medication in this drug class, SEBIVO may cause some people to experience generalized muscle pain, muscle weakness or muscle tenderness as a side effect. Rarely this may lead to a serious muscle problem including muscle breakdown (rhabdomyolysis) which can result in kidney damage. Tell your doctor right away if you get any of the following signs of muscle effects from SEBIVO:

- muscle pain
- muscle weakness
- muscle tenderness

Your healthcare provider will need to monitor your health and do regular blood tests to check your liver if you stop SEBIVO. Tell your healthcare provider right away about any new or unusual symptoms that you notice after you stop taking SEBIVO.

BEFORE you use SEBIVO talk to your healthcare provider if:

- you are treated with any type of alpha interferons **or** if you are treated with pegylated interferon alfa-2a (see also "When it should not be used" and "Interactions With This Medication").
- you have any kidney problems. Your doctor may change the way you take SEBIVO.
- You are taking any other medicines. Your doctor is concerned with those that affect the kidney.
- you have had a liver transplant.
- you are pregnant or planning to become pregnant. Your doctor will advise you whether you should take SEBIVO while you are pregnant. If you take SEBIVO while you are pregnant, talk to your doctor about how you can be included in the Antiretroviral Pregnancy Registry. Do not stop treatment with SEBIVO without your doctor's advice.
- You are breast-feeding or planning to breast-feed. It is not known if SEBIVO can pass into your breast milk or if it can harm your baby. You should not breast-feed during treatment with SEBIVO.

Be sure to also tell your doctor if you are infected with HIV, hepatitis C or D, or have been treated with any antiviral medicines.

Tell your healthcare provider about all the medicines you take including prescription and non-prescription medicines, herbal and vitamin supplements.

Know the medicines you take. Keep a list of your medicines with you to show your healthcare provider and pharmacist.

INTERACTIONS WITH THIS MEDICATION

SEBIVO is eliminated primarily by the kidney. Co-administration of SEBIVO with medicine that affects kidney function may affect blood levels of SEBIVO and/or the co-administered medicine.

Do not take SEBIVO if you are being treated with pegylated interferon alfa-2a. 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 (see also "ABOUT THIS MEDICATION" and "BEFORE you use SEBIVO").

PROPER USE OF THIS MEDICATION

SEBIVO should only be started in patients with certain hepatitis B virus levels because of the risk of developing resistance. Your healthcare professional will need to do blood tests to determine this.

Take SEBIVO exactly as prescribed. Your healthcare provider will tell you how frequent and how much SEBIVO to take. You should check with your healthcare provider if you are not sure. You can take SEBIVO with or without food.

Usual adult dose (16 years and over):

The usual dose is one 600 mg tablet once a day, at about the same time each day.

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

Your doctor may prescribe a different dosing schedule if you have kidney problems. Tell your doctor if you have, or ever have had, any kidney problems.

Do not change your dose or the way you take SEBIVO, or stop taking SEBIVO without talking to your healthcare provider. Your hepatitis B symptoms may get worse or become serious if you stop taking SEBIVO. Once it has been decided with your healthcare provider to stop taking SEBIVO, it is important to stay under your healthcare provider's care. Your healthcare provider will need to do regular blood tests to check your liver.

When your supply of SEBIVO starts to run low, get more from your healthcare provider or pharmacy. Do not run out of SEBIVO.

Overdose:

In case of drug overdose, contact a healthcare practitioner, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

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 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 tablet. 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.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

This is not a complete list of side effects. For any unexpected effects while taking SEBIVO, contact your doctor or pharmacist.

The most common side effects of SEBIVO are tiredness, headache, nausea, dizziness, diarrhea, and rash. A very common lab abnormality is the increase in a blood marker which may be produced by the muscle.

SEBIVO may cause the following serious side effects (see WARNINGS and PRECAUTIONS)

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Frequency/Symptom /Effect		Talk with your doctor or pharmacist immediately		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Rare	**Effect:** Lactic acidosis **Symptoms:** Difficulty breathing		✓	
	Tiredness		✓	
	Drowsiness		✓	
	Unusual muscle pain		✓	
	Headache/ Dizziness		✓	
	Stomach pain with nausea and vomiting		✓	
	Fast/irregular heartbeat		✓	

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Frequency/Symptom /Effect		Talk with your doctor or pharmacist immediately		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Very rare	**Effect:** Flare-ups of hepatitis B virus infection following treatment discontinuation **Symptoms:** Skin/white of eyes turn yellow		✓	
	Stool turn light in colour		✓	
	Dark urine		✓	
	Loss of appetite for several days or longer		✓	
	Nausea		✓	
	Lower stomach pain		✓	
Unknown (post-marketing experience)	**Effect:** Muscle breakdown (rhabdomyolysis) **Symptoms:** Muscle pain		✓	
	Muscle weakness		✓	
	Muscle tenderness		✓	

These are not all the side effects of SEBIVO. The list of side effects is not complete at this time because SEBIVO is still under study. Report any new or continuing symptoms to your healthcare provider. If you have any questions about side effects, ask your health care provider. Your healthcare provider may be able to help you manage these side effects.

HOW TO STORE IT

Store SEBIVO film-coated tablets at room temperature (15-30ºC).

As with all medicines, keep SEBIVO out of the reach and sight of children.

Do not use SEBIVO after the expiry date shown on the carton.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
  - Fax toll-free to 1-866-678-6789, or
  -Mail to: Canada Vigilance Program
  Health Canada
  Post Locator 1908C
  Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the product monograph, prepared for health professionals can be found at: www.novartis.ca
or by contacting the sponsor, Novartis Pharmaceuticals Canada Inc., at: 1-800-363-8883

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