

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S4**

BAVIR TABLETS 300 mg (tablet)

Sugar free.

BAVIR ORAL SOLUTION 20 mg/ml (solution)

Contains sugar: sorbitol 344.4 mg/mL.

Abacavir sulphate

Read all of this leaflet carefully before you start taking BAVIR.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **BAVIR** 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 **BAVIR** is and what it is used for
2. What you need to know before you take **BAVIR**
3. How to take **BAVIR**
4. Possible side effects
5. How to store **BAVIR**
6. Contents of the pack and other information

HYPERSENSITIVITY REACTION (SERIOUS ALLERGIC REACTION)

Since BAVIR contains abacavir some patients taking BAVIR may develop a hypersensitivity reaction (serious allergic reaction) which can be life-threatening if you continue to take BAVIR.

It is essential that you read the information on this reaction under "Take special care with BAVIR" of this leaflet. There is also an Alert Card included in the BAVIR pack, to remind you and medical staff about abacavir hypersensitivity. This card should be removed and kept with you at all times.

CONTACT YOUR DOCTOR IMMEDIATELY for advice on whether you should stop taking BAVIR if:

1) you get a skin rash OR

2) you get one or more symptoms from at least TWO of the following groups

- fever
- shortness of breath, sore throat or cough
- nausea or vomiting or diarrhoea or abdominal pain
- severe tiredness or achiness or generally feeling ill

If you have discontinued BAVIR due to a hypersensitivity (allergic) reaction, **YOU MUST NEVER TAKE BAVIR**, or any other medicine containing abacavir again as you may experience a life-threatening lowering of your blood pressure or death. If you stop taking BAVIR for any other reason, do not start taking it again without first talking to your doctor.

If you are hypersensitive (allergic) to abacavir you should return all your unused BAVIR for disposal. Ask your doctor or pharmacist for advice.

1 What BAVIR is and what it is used for

BAVIR is an antiretroviral medicine. It belongs to a group called nucleoside reverse transcriptase inhibitors (NRTIs).

BAVIR is a prescription medicine used in combination with other medicines to treat adults and children who are infected with HIV (the human immunodeficiency virus), the virus that causes AIDS. **BAVIR** reduces the growth of HIV, which helps your body maintain its supply of CD4 cells, which are important for fighting HIV and other infections. **BAVIR** will not cure your HIV infection, and does not prevent a patient infected with HIV from passing the virus to other people.

2 What you need to know before you take BAVIR

Do not take BAVIR TABLETS:

- If you are hypersensitive (allergic) to abacavir or any of the other ingredients of **BAVIR**.
- If you have liver disease.
- If you are pregnant or breast-feeding.
- **BAVIR** must not be given to infants under 3 months of age.

Warnings and precautions

Take special care with BAVIR:

HYPERSENSITIVITY REACTION (SERIOUS ALLERGIC REACTION): About 4 % of patients, who are treated with abacavir, develop a hypersensitivity reaction.

The most common symptoms of this reaction are high temperature (fever) and a skin rash. Other frequently observed signs are nausea, vomiting, diarrhoea, abdominal pain and severe tiredness.

Other symptoms may include joint or muscle pain, swelling of the neck, shortness of breath, sore throat, cough and headache. Inflammation of the eye (conjunctivitis), mouth ulcers or low blood pressure may occur.

The symptoms of this allergic reaction can occur at any time during treatment with

abacavir. However they usually occur in the first six weeks of treatment. The symptoms worsen with continued treatment and may be life-threatening if treatment is continued.

CONTACT YOUR DOCTOR IMMEDIATELY for advice on whether you should stop taking BAVIR if:

1) you get a skin rash OR

2) you get one or more symptoms from at least TWO of the following groups

- fever

- shortness of breath, sore throat or cough

- nausea or vomiting or diarrhoea or abdominal pain

- severe tiredness or achiness or generally feeling ill

If you have discontinued BAVIR due to a hypersensitivity (allergic) reaction, **YOU MUST NEVER TAKE BAVIR**, or any other medicine containing abacavir again as you may experience a life-threatening lowering of your blood pressure or death.

If you have stopped taking BAVIR for any reason, particularly because you think you are having side-effects or for other illness, it is important to contact your doctor before re-starting. Your doctor will check whether any symptoms you had may be related to this hypersensitivity reaction. If your doctor thinks there is a possibility that they were related, you will be instructed never to take BAVIR or any other abacavir containing medicine again. It is important that you follow this advice.

Occasionally life-threatening hypersensitivity reactions have occurred when abacavir was restarted in patients who reported only one of the symptoms on the Alert Card before stopping.

On very rare occasions hypersensitivity has been reported when abacavir was restarted in patients who had no symptoms of hypersensitivity before stopping.

If you are hypersensitive (allergic) to abacavir you should return all your unused BAVIR for disposal. Ask your doctor or pharmacist for advice.

- **BAVIR** can cause a condition called lactic acidosis (excess of lactic acid in your blood), together with an enlarged liver. Lactic acidosis can be fatal. Call your doctor at once if you have any of the following symptoms: nausea, vomiting, abdominal pain, shortness of breath, feeling very weak and tired, or weight loss.
- **BAVIR** can cause severe effects on the liver. Call your doctor at once if you have any of these liver symptoms while taking **BAVIR**: nausea, stomach pain, loss of appetite, low fever, dark urine, clay-coloured stools, and jaundice (yellowing of the skin or eyes).
- Tell your doctor if you have a history of liver disease.
- Even while taking **BAVIR**, you may continue to have HIV-related illnesses, including infections caused by other disease-producing organisms. Continue to see your doctor regularly and report any medical problems that occur.
- **BAVIR** does not prevent a patient infected with HIV from passing the virus to other people. To protect others, you must continue to practice safe sex, safe injection and take precautions to prevent others from coming into contact with your blood and other contaminated body fluids.
- Tell your doctor if you experience joint aches and pain, joint stiffness or difficulty in movement.
- It cannot be excluded that abacavir may increase the risk of having cardiovascular events. Tell your doctor if you have heart problems, if you smoke, or have other illnesses that may increase your risk of heart diseases such as high blood pressure, or diabetes. Do not stop taking **BAVIR** unless your doctor advises you to do so.

BAVIR ORAL SOLUTION 20 mg/ ml contains sorbitol

BAVIR ORAL SOLUTION 20 mg/ml contains sorbitol which may cause abdominal/stomach pains and diarrhoea. **BAVIR ORAL SOLUTION 20 mg/ml** contains sorbitol which should not be taken if you have hereditary fructose intolerance.

Taking BAVIR with food, drink and alcohol:

BAVIR can be taken with or without food. Avoid consumption of alcohol and alcohol-containing medicines while on treatment with **BAVIR**. Alcohol does increase the amount of abacavir in your blood.

BAVIR contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet/ml, that is to say essentially 'sodium free'.

Pregnancy and Breastfeeding:

You should not take **BAVIR** if you are pregnant or breastfeeding your baby (see “**Do not take BAVIR**”).

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 machinery:

No currently available information shows that **BAVIR** affects the ability to drive and use machines. However, you should take into account the state of your health and the possible side-effects of **BAVIR** before considering driving or using machines.

It is not always possible to predict to what extent **BAVIR** may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which **BAVIR** affects them.

Taking other medicines with BAVIR:

- Tell your doctor if you are using any of the following medicines: methadone or oral vitamin A related medicines e.g. isotretinoin. If you are using any of these medicines, you may not be able to take **BAVIR**, or you may need dosage adjustments or your doctor may need to monitor you carefully for side-effects.

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

3 How to take BAVIR

Do not share medicines prescribed for you with any other person. Always take **BAVIR** exactly as your doctor has instructed you. Your doctor will tell you how long your treatment with **BAVIR** will last. You should check with your doctor or pharmacist if you are unsure. If you have the impression that the effect of **BAVIR** is too strong or too weak, talk to your doctor or pharmacist.

- The usual daily dose of **BAVIR** in adults and adolescents over 12 years of age is one tablet of 300 mg or 15 mL of oral solution twice a day.
- In children three months to 12 years of age the dose given depends on the body weight of your child. The recommended dose is 8 mg/kg twice a day up to a maximum of 600 mg daily.
- Use the oral dosing syringe supplied with the oral solution pack to measure the dose accurately.

If you take more BAVIR than you should:

Seek emergency medical attention if you think you have used too much of this medicine.

In the event of overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take BAVIR:

If you forget to take a dose, take it as soon as you remember, and then continue as before. Do not take a double dose to make up for forgotten individual doses.

4 Possible Side Effects

BAVIR can have side effects.

If any of the following happens, stop taking **BAVIR** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- You develop a skin rash OR
- You get one or more symptoms from at least TWO of the following groups:
 - Fever (high temperature),
 - Shortness of breath, sore throat or cough,
 - Nausea, vomiting, diarrhoea or abdominal pain,
 - Severe tiredness, achiness or generally feeling ill.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **BAVIR**. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Lactic acidosis (severe increase of lactic acid in the blood) - nausea, vomiting, abdominal pain, shortness of breath, feeling very weak and tired, or weight loss.
- Severe liver enlargement.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

- Loss of appetite,
- Raised sugar in the blood,
- Increased fats in the blood,
- Headache,
- Diarrhoea,
- Nausea,
- Vomiting,
- Skin rash (without any other illness),
- Serious skin reactions,

- Lethargy,
- Fatigue,
- Fever,
- Inflammation of the pancreas,
- Joint or muscle pain,
- Swelling of the neck,
- Inflammation of the eye (conjunctivitis),
- Mouth ulcers,
- Low blood pressure.

Tell your doctor if any of the above side effects are severe, bothersome, do not go away or about any concerns you have while taking **BAVIR**.

Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8> . By reporting side effects, you can help provide more information on the safety of **BAVIR**.

5 How to store BAVIR

BAVIR TABLETS 300 mg:

Store at or below 30 °C.

KEEP OUT OF REACH OF CHILDREN.

BAVIR ORAL SOLUTION 20 mg/ml:

Store at or below 30 °C. Keep well closed.

Discard oral solution two months after first opening.

KEEP OUT OF REACH OF CHILDREN.

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 BAVIR contains:

The active substance is abacavir.

BAVIR TABLETS 300 mg:

Colloidal silicon dioxide (Aerosil 200), Magnesium stearate, microcrystalline cellulose (Avicel PH 102), Opadry Yellow 13K52177 (comprised of Hypromellose 6 cp, Iron Oxide Yellow (C.I. No: 77492), Polysorbate 80, Titanium Dioxide (C.I. No: 77891) and Triacetin), Sodium starch glycolate (Primogel).

BAVIR ORAL SOLUTION 20 mg/ml:

Banana flavour 85509H \$, Citric acid anhydrous, Methyl paraben, Non crystallizing sorbitol solution (Neosorb 70/70B), Propylene glycol, Propyl paraben, Saccharin sodium, Sodium citrate dihydrate, Strawberry cream flavour (11407-33 \$).

What BAVIR looks like and contents of the pack

BAVIR TABLETS 300 mg:

1. Tablets are packed in a white round 110 mL HDPE container with 38 mm polypropylene closure with induction sealing wad.

Pack size: Each container contains 60 tablets.

2. Tablets are packed in 100 mL HDPE container with 38 mm closure with induction sealing wad.

Pack size: Each container contains 60 tablets.

BAVIR ORAL SOLUTION 20 mg/ml:

1. White, round 330 mL HDPE container with 28 mm polypropylene closure with screw cap with expanded polyethylene wad and pilfer proof skirt.

Pack size: 240 mL in a HDPE bottle.

2. White opaque 250 mL HDPE bottle with 28 mm closure.

Pack size: 240 mL in a HDPE bottle.

3. White opaque 250 mL HDPE bottle with 28 mm polypropylene child resistant closure with induction sealing wad

Pack size: 240 mL in a HDPE bottle.

An oral dosing syringe is included in the pack.

Identification of BAVIR

BAVIR TABLETS 300 mg:

Yellow coloured, biconvex, capsule shaped, coated tablets, debossed with "D" and "88" on either side of the score line on one side and plain with a score line on the other side.

BAVIR ORAL SOLUTION 20 mg/ml:

Clear to opalescent, yellowish, strawberry-banana flavoured liquid, in 300 ml white round HDPE bottle.

Registration numbers

BAVIR TABLETS 300 mg: 41/20.2.8/0917

BAVIR ORAL SOLUTION 20 mg/ml: 41/20.2.8/0387

Holder of Certificate of Registration

Aurobindo Pharma (Pty) Ltd.
Woodhill Office Park, Building 1,
53 Phillip Engelbrecht Avenue,
Meyersdal, Ext. 12,
1448, Johannesburg,
South Africa.

Date of registration:

BAVIR TABLETS 300 mg: 30 April 2010

BAVIR ORAL SOLUTION 20 mg/ml: 19 March 2010

This leaflet was last revised in

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