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## **PATIENT INFORMATION LEAFLET**

**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 further questions, please ask your doctor or your pharmacist.
- This medicine 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.

**S4**

**INVERTRON TABLETS 300 mg** (Tablet)

**INVERTRON ORAL SOLUTION 20 mg/ml** (Solution)

Abacavir sulphate

### **HYPERSENSITIVITY REACTION (SERIOUS ALLERGIC REACTION)**

Since INVERTRON contains abacavir some patients taking INVERTRON may develop a hypersensitivity reaction (serious allergic reaction) which can be life-threatening if you continue to take INVERTRON. It is essential that you read the information on this reaction under “Take special care with INVERTRON” of this leaflet. There is also an Alert Card included in the INVERTRON 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 INVERTRON if:

- 1) you get a skin rash OR
  - 2) you get one or more symptoms from at least TWO of the following groups
- fever

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- 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 INVERTRON due to a hypersensitivity (allergic) reaction, YOU MUST NEVER TAKE INVERTRON, 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 INVERTRON 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 INVERTRON for disposal. Ask your doctor or pharmacist for advice.

## 1. WHAT INVERTRON CONTAINS

The active substance is abacavir.

### **INVERTRON TABLETS 300 mg:**

Each film-coated tablet contains abacavir sulphate equivalent to abacavir 300 mg.

The other ingredients are colloidal silicon dioxide, magnesium stearate, microcrystalline cellulose and sodium starch glycolate. The coating material contains hypromellose, iron oxide yellow (C.I. No: 77492), polysorbate 80, titanium dioxide (C.I. No: 77891) and triacetin.

Sugar free.

### **INVERTRON ORAL SOLUTION 20 mg/ml:**

Each 1 ml contains:

Abacavir sulphate equivalent to 20 mg of abacavir.

Preservatives: Methyl paraben.....0,15 % m/v

Propyl paraben.....0,018 % m/v

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The other ingredients are banana flavour, citric acid anhydrous, non crystallizing sorbitol solution, propylene glycol, purified water, saccharin sodium, sodium citrate dihydrate and strawberry flavour.

Sugar free.

## **2. WHAT INVERTRON IS USED FOR**

**INVERTRON** 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. **INVERTRON** reduces the growth of HIV, which helps your body maintain its supply of CD4 cells, which are important for fighting HIV and other infections. **INVERTRON** will not cure your HIV infection, and does not prevent a patient infected with HIV from passing the virus to other people.

## **3. BEFORE YOU TAKE INVERTRON**

### **Do not take INVERTRON:**

- If you are hypersensitive (allergic) to abacavir or any of the other ingredients of **INVERTRON**.
- If you have liver disease.
- If you are pregnant or breast-feeding.

**INVERTRON** must not be given to infants under 3 months of age.

### **Do not take INVERTRON ORAL SOLUTION 20 mg/ml:**

- If you have hereditary fructose intolerance – **INVERTRON ORAL SOLUTION 20 mg/ml** contains sorbitol which should not be taken if you have hereditary fructose intolerance.

### **Take special care with INVERTRON:**

<p><b>HYPERSENSITIVITY REACTION (SERIOUS ALLERGIC REACTION): About 4 % of patients, who are treated with abacavir, develop a hypersensitivity reaction.</b></p>
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**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 INVERTRON 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 INVERTRON due to a hypersensitivity (allergic) reaction, YOU MUST NEVER TAKE INVERTRON, 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 INVERTRON 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 INVERTRON or any other abacavir containing medicine again. It is important that you follow this advice.**

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**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 INVERTRON for disposal. Ask your doctor or pharmacist for advice.**

- **INVERTRON** 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.
- **INVERTRON** can cause severe effects on the liver. Call your doctor at once if you have any of these liver symptoms while taking **INVERTRON**: nausea, stomach pain, loss of appetite, low fever, dark urine, clay-coloured stools, jaundice (yellowing of the skin or eyes).
- Tell your doctor if you have a history of liver disease.
- Even while taking **INVERTRON**, 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.
- **INVERTRON** 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.
- **INVERTRON ORAL SOLUTION 20 mg/ml** contains sorbitol which may cause abdominal/stomach pains and diarrhoea.

**Driving and using machinery:**

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No currently available information shows that **INVERTRON** 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 **INVERTRON** before considering driving or using machines.

**Taking INVERTRON with food and drink:**

- **INVERTRON** can be taken with or without food.
- Alcohol does increase the amount of abacavir in your blood.

**Pregnancy and Breast-feeding:**

- **INVERTRON** should not be used during pregnancy and if you are breast-feeding.
- Tell your doctor if you are pregnant, planning to become pregnant or breast-feeding.

If you are pregnant or breast-feeding your baby while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

**Taking other medicines with INVERTRON:**

- 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 **INVERTRON**, or you may need dosage adjustments or your doctor may need to monitor you carefully for side-effects.

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of **INVERTRON** with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional, for advice.

**4. HOW TO TAKE INVERTRON**

Always take **INVERTRON** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. If you have the impression that the effect of **INVERTRON** is too strong or too weak, talk to your doctor or pharmacist.

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- The usual daily dose of **INVERTRON** 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.
  - Depending on your weight, your doctor may adjust your dose to half a tablet (150 mg) in the morning and half a tablet (150 mg) at night.
  - Use the oral dosing syringe supplied with the oral solution pack to measure the dose accurately.

**If you take more INVERTRON than you should:**

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

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.

**If you forget to take INVERTRON:**

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.

**5. POSSIBLE SIDE-EFFECTS**

**INVERTRON** can have side-effects.

The following side-effects may occur:

- A hypersensitivity reaction (serious allergic reaction) has been reported in about 4 % of patients, who are treated with **INVERTRON**. This is described under “**Take special care with INVERTRON**” in this leaflet. It is important that you read and understand the information about this serious reaction.

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- Lactic acidosis (severe increase of lactic acid in the blood) - Inform your doctor immediately if you experience any of the following symptoms of lactic acidosis: nausea, vomiting, abdominal pain, shortness of breath, feeling very weak and tired, or weight loss.
  - Severe liver enlargement.

Other side-effects include: 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 and inflammation of the pancreas

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 **INVERTRON**.

Not all side-effects reported for this medicine are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

## **6. STORING AND DISPOSING OF INVERTRON**

### **INVERTRON TABLETS 300 mg:**

Store below 30 °C (room temperature).

### **INVERTRON ORAL SOLUTION 20 mg/ml:**

Store below 30 °C (room temperature). Keep the bottle well closed.

Discard oral solution two months after first opening.

**Keep all medicines out of the reach and sight of children.**

Return all unused medicine to your pharmacist.

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

## **7. PRESENTATION OF INVERTRON**

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### **INVERTRON TABLETS 300 mg:**

Tablets are packed in a white, round HDPE container with polypropylene closure with induction sealing wad. Each container contains 60 tablets.

### **INVERTRON ORAL SOLUTION 20 mg/ml:**

The oral solution is supplied in cartons containing a white, round HDPE bottle, with a polypropylene closure with screw cap with expanded polyethylene wad and pilfer proof skirt.

The bottle contains 240 ml (20 mg abacavir/ml) of solution. A oral dosing syringe is included in the pack.

## **8. IDENTIFICATION OF INVERTRON**

### **INVERTRON 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.

### **INVERTRON ORAL SOLUTION 20 mg/ml:**

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

## **9. REGISTRATION NUMBERS/REFERENCE NUMBERS**

**INVERTRON TABLETS 300 mg:** 41/20.2.8/0248

**INVERTRON ORAL SOLUTION 20 mg/ml:** 41/20.2.8/0386

## **10. NAME AND ADDRESS OF REGISTRATION HOLDER**

Novagen Pharma (Pty) Ltd.

Office 2, 100 Sovereign Drive, Route 21 Corporate Park

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**11. DATE OF PUBLICATION**

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