

Vatvio® FC (Each film-coated tablet contains 119,5 mg imatinib mesilate equivalent to 100 mg imatinib base)

Vatvio® 400 (Each film-coated tablet contains 478,00 mg imatinib mesilate equivalent to 400 mg imatinib base)

Patient Information Leaflet

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PATIENT INFORMATION LEAFLET

VATIVIO® FC (film-coated tablet)

VATIVIO® 400 (film-coated tablet)

Imatinib

Read all of this leaflet carefully before you start using VATIVIO

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

1. What VATIVIO is and what it is used for

VATIVIO is used to treat blood disorders in adults and children who have Philadelphia chromosome positive chronic myeloid leukaemia (CML) and adults who have acute lymphoblastic leukaemia (ALL).

It is also used to treat rare blood disorders in adults such as: myelodysplastic/ myeloproliferative disease, systemic mastocytosis, hypereosinophilic syndrome/ chronic eosinophilic leukaemia, gastrointestinal stromal tumours and dermatofibrosarcoma protuberans.

2. What you need to know before you take VATIVIO

Your VATIVIO treatment will be prescribed by a doctor with experience in the use of anticancer therapies.

Follow all the doctor's instructions carefully. They may differ from the general information contained in this leaflet.

Do not take VATIVIO:

- if you know that you are hypersensitive (allergic) to the active substance or any of the other ingredients of VATIVIO.
- if you are pregnant or intend to become pregnant
- do not breastfeed your baby if you are taking VATIVIO.

If this applies to you, **tell your doctor without taking VATIVIO**.

If you think you may be allergic, **ask your doctor** for advice.

Warnings and precautions:

Before taking VATIVIO, tell your doctor:

- if you have a liver, kidney or heart problem, or have had one of those problems.
- if you are receiving treatment with levothyroxine because your thyroid has been removed.
- if you are receiving treatment with other medicines, in particular medicines listed below in section "Other medicines and VATIVIO".
- if you have ever had or might now have a hepatitis B infection. This is because during treatment with VATIVIO, hepatitis B may become active again. Your doctor will check for signs of this infection before treatment with VATIVIO is started.

Check with your doctor if you think any of these may apply to you.

You may become more sensitive to the sun while taking VATIVIO. It is important to cover sun-exposed areas of skin and use sunscreen with high sun protection factor (SPF). These precautions are also applicable to children.

During treatment with VATIVIO, tell your doctor straight away if you put on weight very quickly.

VATIVIO may cause your body to retain water (severe fluid retention).

While you are taking VATIVIO, your doctor will regularly check whether the medicine is working. You will also have blood tests and be weighed regularly.

VATIVIO and older people:

VATIVIO can be used by patients over the age of 65.

Children and adolescents

VATIVIO is a treatment for children and adolescents with CML. There is no experience with the use of VATIVIO in children below 2 years of age for CML indication.

Some children and adolescents taking VATIVIO may have slower than normal growth. The doctor will monitor the growth at regular visits.

Other medicines and VATIVIO

Before taking VATIVIO, tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription (such as paracetamol) and including herbal medicines (such as St. John's wort).

These include in particular:

- medicines used to treat infections such as ketoconazole, itraconazole, erythromycin, or clarithromycin,
- some medicines used to treat epilepsy such as carbamazepine, oxcarbazepine, phenobarbitone, phenytoin, fosphenytoin, or primidone,
- some medicines used to treat high cholesterol such as statins,
- some medicines used to treat mental disorders such as benzodiazepines or pimozide,
- some medicines used to treat high blood pressure or heart disorders such as calcium channel blockers or metoprolol.

Some medicines can interfere with the effect of VATIVIO when taken together. They may increase or decrease the effect of VATIVIO, either leading to increased side effects or making VATIVIO less effective. VATIVIO may do the same to some other medicines.

Tell your doctor if you are using medicines that prevent the formation of blood clots.

Pregnancy, breast-feeding and fertility:

If you are pregnant or intend to become pregnant, or you are breast-feeding your baby, you should not use VATIVIO, as it may harm your baby. You should also not breast-feed you baby for 15 days after the last dose.

Safety in human pregnancy and lactation has not been established.

Females of child-bearing potential must use effective birth control while taking VATIVIO and for 15 days after ending treatment.

If you are a man using VATIVIO, you must use a condom when having sexual intercourse.

Birth defects have occurred in babies when pregnant women were treated with VATIVIO or whose father used VATIVIO.

Driving and using machines

Your doctor will tell you whether your illness allows you to drive vehicles and use machines safely. VATIVIO may cause dizziness or blurred vision. Therefore, you should wait to know what effects VATIVIO may cause before driving or using machines. If you feel dizzy or drowsy do not drive, use machines or perform any other tasks that require your attention.

3. How to take VATIVIO

Follow all instructions given to you by your doctor carefully.

Your doctor will advise you on the dose to be taken for your specific condition.

When and how to take VATIVIO

For patients unable to swallow the film-coated tablets, the tablets may be dispersed in a glass of water or apple juice. The required number of tablets should be placed in the appropriate volume of liquid and stirred with a spoon.

The suspension should be taken immediately after complete disintegration of the tablet(s).

During the course of the treatment your doctor may adjust the dose to suit your individual needs.

How long to take VATIVIO:

To benefit from VATIVIO you must take it every day.

If you take more VATIVIO than you should

If you accidentally take more VATIVIO than has been prescribed for you, please consult your doctor immediately. You may require medical attention. In the event of such overdose, your doctor will then observe and manage this situation and give appropriate supportive treatment.

If you forget to take VATIVIO

If a dose is missed or vomiting occurs, do not make up the dose. Instead wait until it is time for your next dose.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

VATIVIO can have side effects.

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

You may tend to see side effects more frequently when you start your medication or increase to a higher dose. In most cases, side effects will gradually disappear as your body becomes used to VATIVIO.

The most frequently reported adverse events are mild nausea, vomiting, diarrhoea, myalgia, muscle cramps and rash, which are easily manageable.

Fluid retention may also occur and can be managed by supportive measures.

Some side effects may be serious. Tell your doctor straight away if you get any of the following:

Frequent side effects

- Rapid weight gain, swelling of extremities (calves, ankles), generalised swelling such as swelling of the face (signs of water retention).
- Weakness, spontaneous bleeding or bruising, frequent infections with signs such as fever, chills, sore throat or mouth ulcers (signs of low level of blood cells).
- Unexpected bleeding or bruising (when you have not hurt yourself).

Less frequent side effects

- Pale skin, tiredness, breathlessness, dark urine (signs of breakdown of red blood cells).
- Vision impairment, blurred vision, blood in eye.
- Crushing chest pain, fever, tiredness, irregular heartbeat (signs of heart disorders such as heart attack, angina).
- Nausea, diarrhoea, vomiting, abdominal pain, fever (signs of inflammatory bowel disease).
- Severe rash, red skin, blistering of the lips, eyes, skin or mouth, skin peeling, fever, red raised or purple skin patches, itching, burning, pustular eruption (signs of skin disorder).
- Pain and having difficulty walking.
- Inflammation of the skin caused by an infection (sign of cellulitis).
- Painful red lumps on the skin, skin pain, skin reddening (inflammation of fatty tissue under the skin; signs of panniculitis).
- Severe headache, weakness or paralysis of limbs or face, difficulty speaking, sudden loss of consciousness (signs of nervous system disorder such as bleeding or swelling in skull / brain).
- Seizure.
- Light-headedness, dizziness or fainting (which may be signs of low blood pressure).
- Severe abdominal pain, vomiting blood, black or bloody stools, or having black stools, swelling of the abdomen/fluid within the abdomen, constipation, stomach pain (signs of gastrointestinal disorders).
- Nausea, loss of appetite, dark-coloured urine or yellowing of your skin or eyes go yellow (sign of liver disorders).
- Thirst, weight loss and severely decreased urine output (signs of low intake of drinks/fluids).
- Blood in urine.
- Swelling and pain in one part of the body (signs of clots in blood vessels).
- Cough, difficult or painful breathing, wheezing, pain in chest when breathing (signs of lung infections/disorders).

- Muscle weakness, muscle spasms, abnormal heart rhythm (signs of changes in level of potassium in the blood).
- Muscle spasms, fever, red-brown urine, kidney disorders, pain or weakness in muscles, (signs of muscle disorders).
- Pelvic pain sometimes accompanied by nausea and vomiting, unexpected vaginal bleeding, (signs of gynaecological disorder).
- Severe allergic reaction that can result in difficulty breathing, dizziness.
- Nausea, shortness of breath, irregular heartbeat, clouding of urine, tiredness and/or joint discomfort associated with abnormal laboratory values (such as high potassium, uric acid, and calcium levels and low phosphorous levels in the blood).
- Severe headache, dizziness, blurred vision (signs of increased pressure inside the skull).

Not known (frequency cannot be estimated from the available data):

- Combination of a widespread severe rash, feeling sick, fever, high level of certain white blood cells or yellow skin or eyes (signs of jaundice) with breathlessness, chest pain/discomfort, severely decreased urine output and feeling thirsty (signs of a treatment-related allergic reaction).
- Reactivation of hepatitis B infection when you have had hepatitis B (an infection of the liver) in the past.

If any of these affects you severely, **tell your doctor**.

If you notice any other side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly to

<https://www.sahpra.org.za/Publications/Index/8> . By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store VATIVIO

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

VATIVIO® FC: Store in a cool dry place at or below 30 °C in the original pack.

VATIVIO® 400: Store in a cool dry place at or below 25 °C in the original pack.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems.

Do not use after the expiry date stated on the box.

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

Protect from moisture.

The blisters should not be removed from the carton until required for use.

6. Contents of the pack and other information

What VATIVIO contains

VATIVIO 100 mg and 400 mg film-coated tablets (divisible or non-divisible)

- The active substance of VATIVIO is imatinib mesilate.
- The other ingredients are microcrystalline cellulose, crospovidone, hypromellose, magnesium stearate and silica colloidal anhydrous. The coating is composed of hypromellose, macrogol, talc, iron oxide red (E 172) and iron oxide yellow (E 172).

What VATIVIO looks like and contents of the pack

VATIVIO® FC: Very dark yellow to brownish orange, round, biconvex, film-coated tablets with bevelled edges. Debossed with "NVR" on one side and "SA" and a score on the other side.

VATIVIO® 400: Very dark yellow to brownish orange, ovaloid, biconvex, film-coated tablets with bevelled edges. Debossed with "400 on one side and score on the other side and "SL' on each side of the score.

VATIVIO Tablets are supplied in either 20, 30 or 60 film-coated tablets in colourless, transparent blisters with an aluminium foil backing.

The outer carton is a printed cardboard box.

Holder of Certificate of Registration

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