Applicant/PHCR*:* Ranbaxy Pharmaceuticals (Pty) Ltd **Product proprietary name***:* Zibovo 200/ 400 **Dosage form and strength***:* Pazopanib Tablets 200 mg and 400 mg	SUN PHARMA

Patient Information Leaflet

SCHEDULING STATUS:

S4

ZIBOVO 200 Film coated tablets

ZIBOVO 400 Film coated tablets

(Pazopanib Hydrochloride)

Sugar Free

Read all of this leaflet carefully before you start taking ZIBOVO

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- ZIBOVO 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 ZIBOVO is and what it is used for
2. What you need to know before you take ZIBOVO

3. How to take ZIBOVO

4. Possible side effects

5. How to store ZIBOVO

6. Contents of the pack and other information

1. What ZIBOVO is and what it is used for

Each ZIBOVO 200 tablet contains 200 mg of the active substance pazopanib hydrochloride equivalent to 200 mg pazopanib free base.

Each ZIBOVO 400 tablet contains 400 mg of the active substance pazopanib hydrochloride equivalent to 400 mg pazopanib free base.

ZIBOVO is used as a single medicine to treat renal cell carcinoma (a form of kidney cancer).

ZIBOVO is used as a single medicine to treat certain forms of advanced soft tissue sarcoma (STS), which is a type of cancer that affects the supportive tissues of the body. It can occur in muscles, blood vessels, fat tissue or in other tissues that support, surround, and protect the organs.

2. What you need to know before you take ZIBOVO

Do not take ZIBOVO :

If you are allergic, (hypersensitive) to pazopanib or to any of the ingredients contained in the product (listed in section 6). Check with your doctor if you think this may apply to you.

If you are pregnant or breastfeeding your baby.

Warnings and precautions

Before you take ZIBOVO your doctor needs to know:

- if you have heart disease

- if you have had heart failure or a heart attack, angina, ischemic stroke and transient ischemic attack

- if you have had prior blood clots in a vein or in a lung

- if you have had prior collapse of a lung

- if you have high blood pressure

-if you have liver disease

-if you have problems with bleeding

-if you have gastrointestinal problems

-if you have thyroid problems

-if you have posterior reversible encephalopathy syndrome

(PRES)/ Reversible posterior leukoencephalopathy syndrome (RPLS)

- if you have Interstitial lung disease (ILD)/Pneumonitis

- if you have tumour lysis syndrome (TLS)

- if you have infections

- if you are going to have a surgical or dental procedure, or if you have had either recently.

Check with your doctor if you think any of these may apply to you. You may need extra tests to check that your heart, liver, and thyroid are working properly. Your doctor may decide to adjust your dose or stop treatment based on the results of these tests

Other medicines and ZIBOVO

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

Some medicines may affect how ZIBOVO works or make it more likely that you'll have side effects. ZIBOVO can also affect how some other medicines work. These include:

- clarithromycin, ketoconazole, itraconazole, rifamicin, telithromycin, voriconazole (used to treat infection).
- atazanavir, indinavir, nelfinavir, ritonavir, saquinavir (used to treat HIV).
- nefazodone (used to treat depression).
- simvastatin and possibly other statins (used to treat high cholesterol levels).
- medicines that reduce stomach acid.
- lapatinib, paclitaxel (medicines used to treat cancer).
- midazolam (a medicine for sedation before examinations, or operations or in intensive care units.
- dextromethorphan (used to treat cough).

ZIBOVO with food, drink and alcohol

Do not drink grapefruit juice while you are being treated with ZIBOVO as this may increase the chance of side effects.

While you are taking ZIBOVO:

While you are taking ZIBOVO, your doctor will take blood samples to check for any liver problems or thyroid problems. Your doctor will also take blood and urine samples to check for any kidney problems.

You will also have your blood pressure checked. Your doctor will periodically record your electrocardiogram (ECG) to check your heart's electrical conduction.

Your doctor will also check on any recent surgical or dental procedures to see if you are healing properly.

Pregnancy, breast-feeding and fertility

Use a reliable method of contraception to avoid becoming pregnant while you are taking ZIBOVO.

ZIBOVO should not be taken if you are pregnant. Mothers should not breastfeed their babies while taking ZIBOVO. 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 healthcare professional for advice before taking this medicine.

Females of child-bearing potential and male patients

Use a reliable method of contraception to avoid becoming pregnant while you are taking ZIBOVO and for at least 2 weeks after you stop treatment with ZIBOVO.

Male patients (including those who have had vasectomies) with sexual female partners who are pregnant, possibly pregnant, or who could become pregnant should use condoms during sexual intercourse while taking ZIBOVO and for at least 2 weeks after the last dose of drug.

If you become pregnant or think you are pregnant, tell your healthcare provider right away.

Driving and using machines

Do not drive or operate machinery unless you are feeling well.

ZIBOVO may cause side effects such as fatigue or blurred vision, that may impar your ability to handle machines

Patients should ensure that they do not engage in the above activities until they are aware of the measure to which ZIBOVO affects them.

ZIBOVO contains sodium

Sodium Content

This medicine contains less than 1 mmol sodium (23 mg) per dose, i.e. essentially 'sodium-free'.

3. How to take ZIBOVO

Always take ZIBOVO exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

How much to take

The usual dose is 800 mg ZIBOVO, taken once a day. Your doctor may decide to give you two 400 mg tablets or four 200 mg tablets to make up the 800 mg dose.

Swallow the tablets whole with water, one after the other, at about the same time each day.

Do not break or crush the tablets as this affects the way the medicine is absorbed and may increase the chance of side effects.

It is important that you take ZIBOVO either at least one hour before or at least two hours after food.

Depending on your response to treatment, your doctor may recommend adjusting your dose or temporarily stopping your treatment.

If you take more ZIBOVO than you should

If you take too much ZIBOVO you may be more likely to get side effects. Contact your doctor or pharmacist for advice. If possible, show them the ZIBOVO pack.

If possible, show them the ZIBOVO pack.

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

If you forget to take ZIBOVO

Do not take a double dose to make up for a missed dose. Take the next dose at the scheduled time.

If you stop taking ZIBOVO

Take ZIBOVO for as long as your doctor recommends. Do not stop unless your doctor advises you to.

4. Possible side effects

ZIBOVO can have side effects.

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

Some side effects could be serious

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

- Signs of liver problems (abnormal liver function, liver failure) which may include: yellowing of your skin or the whites of your eyes (jaundice), dark urine, tiredness, nausea and/or vomiting, loss of appetite, pain on the right side of your stomach area (abdomen), bruising easily.
- Signs of sudden and severe rise in blood pressure (hypertensive crisis) which may include: severe chest pain, severe headache, blurred vision, confusion, nausea and/or vomiting, severe anxiety, shortness of breath, seizures, fainting.
- Signs of brain swelling (posterior reversible encephalopathy syndrome, reversible posterior leukoencephalopathy syndrome) which may include: loss of speech, blindness or changes in vision, seizures, confusion, headache, lack of energy, high blood pressure.
- Signs of lung inflammation (interstitial lung disease, pneumonitis) which may include: cough that will not go away, shortness of breath.
- Signs of heart problems such as abnormal heart rhythm (QT-prolongation, Torsade de Pointes), cardiac dysfunction/heart failure, heart attack which may include: irregular or fast heartbeat, rapid fluttering of your heart, fainting, chest pain or pressure, pain in your arms, back, neck or jaw, shortness of breath, leg swelling.
- Signs of stroke, which may include numbness or weakness on one side of your body, trouble talking, headache, dizziness.
- Signs of blood clots in your veins, especially in your legs (deep vein thrombosis), which may also travel to your lungs (pulmonary embolism) which may include: sharp chest pain, shortness of breath, rapid breathing, leg pain, swelling of your arms/hands or

legs/feet.

- Signs of blood clots in the small blood vessels in the kidneys and brain accompanied by a decrease in red blood cells and cells involved in clotting (thrombotic microangiopathy) which may include: bruising easily, high blood pressure, fever, confusion, drowsiness, seizures, decrease in urine output.
- Signs of bleeding problems (haemorrhage) which may include: blood in your stool, black stool, blood in your urine, stomach pain, coughing and/or vomiting up blood.
- Signs of a tear in your stomach or intestinal wall (perforation) or the development of an abnormal connection between two parts of your digestive tract (fistula) which may include: severe stomach pain, nausea and or vomiting, bloody or foul-smelling drainage (pus) from an opening in your stomach area (abdomen) or near your anus.
- Signs of tumour lysis syndrome resulting from a fast breakdown of cancer cells which may include: irregular heartbeat, seizures, confusion, muscle cramps or spasms, decrease in urine output.
- Signs of infections (which can become serious) may include: fever, flu-like symptoms such as cough, tiredness and body aches that do not go away, shortness of breath and/or wheezing, pain while urinating, cuts, scrapes or wounds that are red, warm, swollen, or painful.

Possible side effects include the following listed below. If these side effects become severe, please tell your doctor, pharmacist, or healthcare provider

Frequent side effects

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

- diarrhoea
- feeling or being sick (nausea or vomiting)
- loss of appetite
- stomach pain or discomfort
- high blood pressure
- headache
- weakness
- loss of strength
- lack of energy
- changes in hair colour
- dizziness
- slow heart rate
- cough
- muscle pain
- pain in the bones, muscles, ligaments, joints, and tendons
- mouth sores
- unusual hair loss or thinning

− temporary reduction in blood supply to the brain (mini stroke/transient ischaemiac attack)

− reduction of blood supply to the heart (angina)

− changes in the heart's electrical conduction (QT-prolongation

- heart attack

-severe bleeding in the lung

- under-active thyroid gland

− increase in some substances (enzymes) produced by the liver

− indigestion

– nosebleed

– dry skin

– nail disorder

– skin rash

– hoarseness

– blurred vision

– chills

– blood in the urine

– weight loss

– problems with taste

- a skin reaction or pain on the palms of the hands or soles of the feet including tingling,numbness, pain, swelling or reddening

- loss of skin pigment
- sudden collapse of a lung(pneumothorax)
- heart becomes less effective at pumping blood (cardiac dysfunction)
- inflammation of the lining in the mouth
- decrease in albumin (a protein found in the blood)
- severe bleeding in digestive tract (stomach and intestine)
- protein in urine
- difficulty sleeping
- a decrease in the number of cells involved in blood clotting (thrombocytopenia)
- increase in bilirubin (a substance produced by the liver)
- chest pain, shortness of breath, leg pain, and swelling of the legs/feet (signs of thromboembolism, including deep vein thrombosis and pulmonary embolism
- increase in gamma-glutamyl transpeptidase (a liver enzyme)
- abnormal liver function
- low white blood cell count (neutropenia)
- increase in lipase (an enzyme from the pancreas)
- infections, with or without changes in white blood cells (cells that fight infection)

Tell your doctor or pharmacist if any of these side effects becomes troublesome.

Less Frequent side effects

Tell your doctor if you notice any of the following:

- severe bleeding (*haemorrhage*) in brain
- abnormal connection between parts of the digestive tract (*fistula*)
- stroke
- inflammation of the pancreas (*pancreatitis*)
- hole (*perforation*) in digestive tract
- a dangerous rapid fluttering of the heart (*Torsade de Pointes*)
- abnormal increase in concentration of haemoglobin in the blood
- separation or tear of the lining of the back part of the eye (*retinal detachment or tear*).
- This can result in blurry or impaired vision.
- blood clots accompanied by a decrease in red blood cells and cells involved in clotting. These clots may harm organs such as the brain and kidneys (*thrombotic microangiopathy)*.
- liver failure
- a sudden and severe rise in blood pressure which may be life-threatening (*hypertensive crisis*)
- inflammation of the lung (*pneumonitis*)
- swelling of the brain that may be associated with high blood pressure,

headache, loss of speech or vision, and/or seizure which may be life threatening

- tumour lysis syndrome resulting from a fast breakdown of cancer cells

Frequency unknown

- flatulence
- muscle spasms

Not all side effects reported for ZIBOVO 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.

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

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of ZIBOVO.Suspected adverse reactions can also be reported directly to the HCR via email:pharmacovigilance.africasme@sunpharma.com or tel: +27(0) 12 643 2000.

5.How to store ZIBOVO

Store at or below 30 ºC. Protect from moisture.

Store all medicines out of reach of children.

Do not use ZIBOVO after the expiry date.

If you have any unwanted tablets, do not put them in wastewater or household rubbish. Ask your pharmacist how to dispose of tablets you do not need. This will help to protect the environment.

6. Contents of the pack and other information

What ZIBOVO contains:

Film-Coated tablet

Each ZIBOVO 200 tablet contains 200 mg pazopanib.

Each ZIBOVO 400 tablet contains 400 mg pazopanib.

The other ingredients are:

Intragranular ingredients: Microcrystalline cellulose, sodium starch glycolate, povidone, purified water.

Extragranular ingredients: Microcrystalline cellulose,sodium starch glycolate , magnesium stearate.

Film Coating material:

Opadry Complete Film Coating Solution

YS-1-17506-A GRAY: Ferrosoferric oxide, hypromellose, magrogoll/PEG, polysorbate 80, titanium dioxide

Opadry Complete film coating system

White YS-1-7706-G: Hypromellose, magrogol/PEG, polysorbate 80,titanium dioxide

Purified Water

What ZIBOVO looks like and contents of the pack

ZIBOVO 200

Grey coloured, capsule shaped, film coated tablets debossed with 'S7' on one side and plain on other side

ZIBOVO 400

White coloured, capsule shaped, film coated tablets plain on both the sides.

Each bottle contains 30 tablets packed in white round HDPE screwed neck heavy weight bottles.

Holder of Certificate of Registration

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ZIBOVO 400: 61/26/1849

Access to the corresponding Professional Information and Afrikaans Patient Information Leaflet can be found on the Sun Pharma website: https://sunpharma.com/south-africa-products/