PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

ZYQUIS 2,5 mg film-coated tablets

ZYQUIS 5 mg film-coated tablets

Apixaban

Contains sugar.

ZYQUIS 2,5: Each film-coated tablet contains 58,128 mg lactose.

ZYQUIS 5: Each film-coated tablet contains 113,064 mg lactose.

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

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

1. What ZYQUIS is and what it is used for

ZYQUIS contains the active substance apixaban and belongs to a group of medicines called

anticoagulants. It helps to prevent blood clots from forming by blocking Factor Xa, which is an important component of blood clotting.

ZYQUIS is used in adults:

- To prevent blood clots from forming in the veins of your legs (deep vein thrombosis) and in the blood vessels of your lungs (pulmonary embolism) when you have undergone hip or knee replacement surgery.
- To prevent a blood clot from forming in the heart in patients with an irregular heartbeat (atrial fibrillation) and at least one additional risk factor. Blood clots may break off and travel to the brain and lead to a stroke or to other organs and prevent normal blood flow to that organ (also known as a systemic embolism). A stroke can be life-threatening and requires immediate medical attention.
- To treat blood clots in the veins of your legs (deep vein thrombosis) and in the blood vessels of your lungs (pulmonary embolism), and to prevent blood clots from re-occurring in the blood vessels of your legs and/or lungs.

2. What you need to know before you take ZYQUIS

Do not take ZYQUIS:

- if you are hypersensitive (allergic) to apixaban or to any of the other ingredients of ZYQUIS listed in section 6 of this leaflet;
- if bleeding excessively;
- if you have a liver disease which leads to increased risk of bleeding (hepatic coagulopathy);
- if you have a disease in an organ of your body that increases the risk of serious bleeding (such as an active or a recent ulcer of your stomach or bowel, malignant tumour in your brain, recent brain or spinal injury, recent brain, spinal or eye surgery, recent bleeding in your brain, enlarged veins in your oesophagus [the tube connecting your throat and stomach with each other], malformations of the blood vessels in your body);
- if you are taking medicines to prevent blood clotting (such as enoxaparin, dalteparin, fondaparinux, warfarin, rivaroxaban, dabigatran or heparin), except when changing

anticoagulant treatment, while having a venous or arterial line and you get heparin through this line to keep it open, or if a tube is inserted into your blood vessel (catheter ablation) to treat an irregular heartbeat (dysrhythmia);

- if you suffer from a condition called antiphospholipid syndrome (APS) with persistent positivity for all three antiphospholipid antibodies.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking ZYQUIS if you have any of the following:

- an increased risk of bleeding, such as:
  - you are older than 65 years
  - you weigh 60 kg or less
- a prosthetic heart valve;
- if your doctor determines that your blood pressure is unstable, or another treatment or surgical procedure to remove the blood clot from your lungs is planned;
- if you have been diagnosed with cancer, a severe kidney disease or if you are on dialysis treatment;
- a liver problem or a history of liver problems; ZYQUIS will be used with caution in patients with signs of altered liver function;
- if you have fractured your hip and you require surgery.

Take special care with ZYQUIS:

- if you know that you have a disease called antiphospholipid syndrome (a disorder of the immune system that causes an increased risk of blood clots), tell your doctor who will decide if your treatment may need to be changed;
- if you need to have surgery or a procedure which may cause bleeding, your doctor might ask you to temporarily stop taking ZYQUIS for a short while. If you are not sure whether a procedure may cause bleeding, ask your doctor;
- if you need to have spinal or epidural anaesthesia or puncture before a surgical procedure.

Children and adolescents

ZYQUIS is not indicated for use in children and adolescents under 18 years of age.

Other medicines and ZYQUIS

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

Some medicines may increase the effects of ZYQUIS and some may decrease its effects. Your doctor will decide if you should be treated with ZYQUIS when taking these medicines and how closely you should be monitored.

Do not take ZYQUIS with any of the following medicines:

The following medicines may increase the effects of ZYQUIS and increase the chance for unwanted bleeding:

- ketoconazole, itraconazole, voriconazole, posaconazole (used to treat fungal infections);
- some antiviral medicines, such as ritonavir (used to treat human immunodeficiency virus [HIV] or acquired immunodeficiency syndrome [AIDS]);
- diltiazem, verapamil (used to treat high blood pressure, chest pain or irregular heartbeat);
- naproxen (used to treat pain and inflammation);
- aspirin (used to treat pain and inflammation or used to thin your blood and prevent blood clot formation);
- clarithromycin (used to treat bacterial infection);
- amiodarone, quinidine (used to treat an irregular heartbeat);
- enoxaparin, clopidogrel or other medicines that are used to reduce blood clotting;
- selective serotonin reuptake inhibitors or serotonin norepinephrine reuptake inhibitors (used to treat depression).

The following medicines may reduce the ability of ZYQUIS to help prevent blood clots from forming:

- rifampicin (used to treat tuberculosis [TB]);
- phenytoin, carbamazepine, phenobarbital (used to treat epilepsy/seizures);
- St John's wort (a herbal medicine used to treat depression);
- activated charcoal (used as a detoxing medicine).

ZYQUIS with food and drink

See section 3.

Pregnancy and breastfeeding

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 ZYQUIS.

The effects of ZYQUIS on pregnancy and your unborn child are not known. It is not known if ZYQUIS passes into human breast milk. If you are pregnant or breastfeeding your baby, you should not use ZYQUIS. Contact your doctor immediately if you become pregnant while taking ZYQUIS.

Driving and using machines

ZYQUIS is not likely to affect your ability to drive or use machines.

ZYQUIS contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking ZYQUIS.

3. How to take ZYQUIS

Do not share medicines prescribed for you with any other person.

Always take or give ZYQUIS exactly as your doctor or pharmacist has told you. You should check

with your doctor or pharmacist if you are not sure.

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

Your doctor will tell you how long your treatment with ZYQUIS will last. Do not stop treatment with ZYQUIS unless your doctor tells you to.

Swallow the tablet with a drink of water. ZYQUIS can be taken with or without food. Try to take the tablets at the same time every day to have the best treatment effect.

Your doctor might change your anticoagulant treatment as follows:

- ***Changing from ZYQUIS to anticoagulant medicines***

  Stop taking ZYQUIS. Start treatment with the anticoagulant medicines at the time you would have taken the next tablet.
- ***Changing from anticoagulant medicines to ZYQUIS***

  Stop taking the anticoagulant medicines. Start treatment with ZYQUIS at the time you would have had the next dose of anticoagulant medicine, then continue as normal.
- ***Changing from treatment with anticoagulant containing vitamin K antagonist (such as warfarin) to ZYQUIS***

  Stop taking the medicine containing a vitamin K antagonist. Your doctor needs to do blood tests and will instruct you when to start taking ZYQUIS.
- ***Changing from ZYQUIS to anticoagulant treatment containing vitamin K antagonist (such as warfarin)***

  If your doctor tells you that you have to start taking the medicine containing a vitamin K antagonist, continue to take ZYQUIS for at least 2 days after your first dose of the medicine containing a vitamin K antagonist. Your doctor needs to do blood measurements and instruct you when to stop taking ZYQUIS.

If you have the impression that the effect of ZYQUIS is too strong or too weak, tell your doctor or pharmacist.

If you take more ZYQUIS than you should

In the event of overdosage, consult your doctor or pharmacist without delay. If neither is available, contact the nearest hospital or poison centre. You or a child in your care may may require medical attention. Take the medicine pack with you.

If you take more ZYQUIS than recommended, you may have an increased risk of bleeding.

If you forget to take ZYQUIS

If you forget a dose, take it as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose. Then continue with your normal schedule. Do not take a double dose to make up for a forgotten dose.

If you stop taking ZYQUIS

Do not stop taking ZYQUIS without talking to your doctor first, because the risk of developing a blood clot could be higher if you stop treatment too early. If you have any further questions on the use of ZYQUIS, ask your doctor or pharmacist.

4. Possible side effects

ZYQUIS can have side effects.

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

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

- swelling of your hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing;
- rash, hives or itching;
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to

ZYQUIS. 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:

- reduced number of platelets in your blood (which can affect clotting and cause unexplained bleeding or bruising);
- bleeding, including:
  - bleeding in your brain or in your spinal column,
  - bleeding in your eyes,
  - bleeding occurring after your operation including bruising and swelling, blood or liquid leaking from the surgical wound/incision (wound secretion) or injection site,
  - bleeding in your stomach or bowel,
  - bleeding from your nose, from your gums, in your mouth or blood in your spit when coughing,
  - vomiting of blood,
  - dark, tarry stools,
  - bleeding from a haemorrhoid,
  - bleeding from your rectum,
  - bright/red blood in the stools,
  - bleeding in your muscle/s,
  - blood in your urine,
  - abnormal bleeding from your vagina,
  - positive test results showing blood in the stools,
  - bruising and swelling.
- abnormal liver function test results (can cause yellowing of your skin and eyes).

The following side effects are known if you take ZYQUIS to prevent a blood clot from forming in the heart in patients with an irregular heartbeat (atrial fibrillation) and at least one additional risk factor

Tell your doctor if you notice any of the following:

Frequent side effects:

- anaemia (paleness, tiredness, weakness);
- low blood pressure (dizziness or light-headedness);
- nausea (feeling sick).

Less frequent side effects:

- hair loss.

The following side effects are known if you take ZYQUIS to prevent blood clots from forming in the veins of your legs (deep vein thrombosis) and in the blood vessels of your lungs (pulmonary embolism)

Tell your doctor if you notice any of the following:

Frequent side effects:

- anaemia (paleness, tiredness, weakness);
- nausea (feeling sick).

Less frequent side effects:

- low blood pressure (dizziness or light-headedness);
- hair loss.

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. This includes any possible side effects not listed in this leaflet. 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 ZYQUIS.

5. How to store ZYQUIS

- Store at or below 25 °C.
- Keep the blister strips in the outer carton until required for use.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use after the expiry date printed on the carton or container.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What ZYQUIS contains

The active substance in ZYQUIS is apixaban.

ZYQUIS 2,5: Each film-coated tablet contains 2,5 mg apixaban.

ZYQUIS 5: Each film-coated tablet contains 5 mg apixaban.

The other ingredients are:

Tablet core:

Croscarmellose sodium (E468)

Hypromellose (E464)

Lactose anhydrous

Magnesium stearate (E572)

Microcrystalline cellulose (E460)

Stearic acid (E570)

Tetrahydrofuran.

Film-coating:

ZYQUIS 2,5:

Opadry White (containing hypromellose [E464], lactose monohydrate, titanium dioxide [E171] and triacetin).

ZYQUIS 5:

Opadry Beige (containing hypromellose [E464], lactose monohydrate, titanium dioxide [E171], triacetin, iron oxide yellow [E172] and iron oxide red [E172]).

What ZYQUIS looks like and contents of the pack

ZYQUIS 2,5: White to off-white coloured, round shaped, film-coated tablets, debossed with “1181” on one side and plain on the other side.

ZYQUIS 5: Beige coloured, oval shaped, film-coated tablets, debossed with “1182” on one side and plain on the other side.

Clear transparent PVC/PVDC/aluminium blister strips containing 10 tablets, packed into an outer container.

Pack sizes: 30 or 60 tablets.

Holder of certificate of registration

Zydus Healthcare SA (Pty) Ltd

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