SCHEDULING STATUS S4

INNOKLOD 2,5 mg Film-coated Tablets.

INNOKLOD 5 mg Film-coated Tablets

Apixaban

INNOKLOD tablets contain sugar.

INNOKLOD 2,5 mg tablet contains 50,25 mg anhydrous lactose and the film coat (in Opadry II) contains 28,00 % w/w lactose monohydrate.

INNOKLOD 5 mg tablet contains 100,50 mg anhydrous lactose and the film coat (in Opadry II) contains 28,00 % w/w lactose monohydrate.

For fill list of excipients: **see section 6**

Sugar free

Read all this leaflet carefully before you are given INNOKLOD

- 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.
- **INNOKLOD** 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 **INNOKLOD** is and what it is used for

2. What you need to know before you take **INNOKLOD**

3. How to take **INNOKLOD**

4. Possible side effects

5 How to store **INNOKLOD**

6. Contents of the pack and other information

1. What INNOKLOD is and what is it used for:

INNOKLOD contains the active substance apixaban and belongs to a group of medicines called anticoagulants. This medicine helps to prevent blood clots from forming by blocking Factor Xa, which is an important component of blood clotting.

INNOKLOD *is used in adults*

- to prevent blood clots (deep vein thrombosis [DVT]) from forming after hip or knee replacement operations. After an operation to the hip or knee you may be at a higher risk of developing blood clots in your leg veins. This can cause the legs to swell, with or without pain. If a blood clot travels from your leg to your lungs, it can block blood flow causing breathlessness, with or without chest pain. This condition (pulmonary embolism [PE]) can be life-threatening and requires immediate medical attention.

- 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 travel 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 (DVT) and in the blood vessels of your lungs (PE), 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 INNOKLOD:

Do not take INNOKLOD:

- if you are hypersensitive (allergic) to apixaban or to any of the other ingredients of **INNOKLOD** (listed in section 6)
- if you are bleeding excessively
- if you have a severe kidney disease or if you are on dialysis
- if you have a liver disease which leads to increased risk of bleeding (hepatic coagulopathy)
- if you are taking antiplatelet medicines (e.g., clopidogrel or ticagrelor) other than aspirin
- if you suffer from a condition called antiphospholipid syndrome (APS) with persistent positivity for all three antiphospholipid antibodies.
- If you have a disease patch of skin or condition is considered a high risk for excessive bleeding. This may include present or recent stomach ulcers,

presence of an abnormal growth of tissue that can be malignant (cancerous) which has high risk of bleeding, recent brain or back injury, recent brain, back or eye surgery, recent bleeding within the cranium, which is the bony dome that houses and protects the brain, known or suspected enlarged veins in the oesophagus, a tangle of blood vessels that irregularly connects arteries and veins, a bulge in the wall of an artery, major within the spine or inner brain arteries and veins abnormal features.

Warnings and precautions

Take special care with INNOKLOD:

Tell your doctor before you take this medicine if you have any of the following:

- an increased risk of bleeding, such as:
    - bleeding disorders, including conditions resulting in reduced platelet activity
    - an active or a recent ulcer of your stomach or bowel
    - infection of the heart (bacterial endocarditis)
    - recent bleeding in your brain (haemorrhagic stroke)
    - very high blood pressure, not controlled by medical treatment
    - a recent operation on your brain, spinal column or eye
- have had a prosthetic heart valve inserted
- know that you have a disease called antiphospholipid syndrome (a disorder of the immune system that causes an increased risk of blood clots)

- had a tube (catheter) or an injection into your spinal column (for anaesthesia or pain reduction), your doctor will tell you to take **INNOKLOD** 6 hours or more after catheter removal
- a liver problem or a history of liver problems. Your doctor will perform a test on your liver function before you take **INNOKLOD** and it will be used with caution in patients with signs of altered liver function
- a severe kidney disease or if you are on dialysis

If you need to undergo surgery your doctor might ask you to temporarily stop taking **INNOKLOD**.

Children and adolescents

INNOKLOD is not recommended in children and adolescents under 18 years of age.

Other medicines and INNOKLOD

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 **INNOKLOD**, and some may decrease its effects. Your doctor will decide if you should be treated with **INNOKLOD** when taking these medicines and how closely you should be monitored.

*The following medicines may increase the effects of **INNOKLOD** and increase the chance for unwanted bleeding*

- some medicines for fungal infections (ketoconazole, etc.)
- medicines used to treat infections (antibiotics) (e.g. clarithromycin)
- some antiviral medicines for HIV / AIDS (e.g. ritonavir)
- other medicines that are used to reduce blood clotting (e.g. enoxaparin, etc.)
- anti-inflammatory or pain medicines [e.g. aspirin or non-steroidal anti-inflammatory drugs (NSAIDS)]
- medicines for high blood pressure or heart problems (e.g. diltiazem)

*The following medicines may reduce the ability of **INNOKLOD** to help prevent blood clots from forming*

- medicines to prevent epilepsy or seizures (e.g. phenytoin)
- St John's Wort (a herbal supplement used for depression)
- medicines to treat tuberculosis or other infections (e.g. rifampicin)

If you are taking any of these medicines, your doctor may change your **INNOKLOD** therapy if you are using **INNOKLOD** for treatment or prevention of DVT or PE.

INNOKLOD with food and drink

INNOKLOD can be taken with or without food.

Pregnancy and breastfeeding and fertility:

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 provider for advice before using this medicine.

Pregnancy:

The effects of **INNOKLOD** on pregnancy and the unborn child are not known. Treatment may increase the risk of bleeding during pregnancy and delivery.

You should not take **INNOKLOD** if you are pregnant.

Contact your doctor immediately if you become pregnant while taking **INNOKLOD**.

Breastfeeding:

It is not known if **INNOKLOD** passes into human breast milk. Do not take **INNOKLOD** while breastfeeding.

Driving and using machines:

INNOKLOD has not been shown to impair your ability to drive or use machines

It is not always possible to predict to what extent **INNOKLOD** 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 **INNOKLOD** affects them.

INNOKLOD contains lactose

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

Contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per dosage unit, that is to say essentially ‘sodium-free’.

3. How to use INNOKLOD:

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

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

INNOKLOD can be taken with or without food.

Swallow the tablet with a drink of water.

Take one tablet twice a day, every day, for as long as your doctor tells you to take **INNOKLOD**.

Dose

To prevent blood clots (deep vein thrombosis (DVT)) from forming after hip or knee replacement operations or 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

The recommended dose is one tablet twice a day, for example, one in the morning and one in the evening. Take the tablets at the same time every day.

To treat blood clots in the veins of your legs and blood clots in the blood vessels of your lungs

The recommended dose is two 5 mg tablets twice a day for the first 7 days, for example, two in the morning and two in the evening. After 7 days the recommended dose is one 5 mg tablet twice a day.

For preventing blood clots from re-occurring following completion of 6 months of treatment

The recommended dose is one 2,5 mg tablet twice a day for example, one in the morning and one in the evening. Your doctor will decide how long you must continue your treatment.

If you are undergoing cardioversion

If your abnormal heartbeat needs to be restored to normal by a procedure called cardioversion, take **INNOKLOD** at the times your doctor tells you, to prevent blood clots in blood vessels in your brain and other blood vessels in your body.

If you are unable to swallow whole tablets, you may crush the tablets and add it to water, apple juice or mix it with applesauce. This should be taken immediately.

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

If you take more INNOKLOD than you should

Tell your doctor immediately if you have taken more than the prescribed dose of **INNOKLOD**. Take the medicine pack with you, even if there are no tablets left.

If you take more **INNOKLOD** than recommended, you may have an increased risk of bleeding. If bleeding occurs, surgery or blood transfusions may be required.

Your doctor may administer activated charcoal to you which may be useful if you have taken **INNOKLOD** accidently or taken more than you should have.

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 INNOKLOD

Take the tablet as soon as you remember. Take the next tablet of **INNOKLOD** at the usual time and then continue as normal.

Do not take a double dose to make up for forgotten individual doses.

If you are not sure what to do or have missed more than one dose, ask your doctor, pharmacist or other health care provider.

If you stop taking INNOKLOD

Do not stop taking **INNOKLOD** 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 **INNOKLOD**, ask your doctor, pharmacist or other health care provider.

4. Possible side effects

INNOKLOD can have side effects.

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

INNOKLOD can be given for different medical conditions. The known possible side effects and how frequently they occur for each of these medical conditions may differ and are listed separately below.

The most common general possible side effect of **INNOKLOD** is bleeding which may be potentially life-threatening and require immediate medical attention.

*The following side effects are known if you take **INNOKLOD** to prevent blood clots (deep vein thrombosis (DVT)) from forming after hip or knee replacement operations.*

Tell your doctor if you notice any of the following:

Frequent side effects:

- Anaemia which may cause tiredness or paleness.
- Bleeding including bruising and swelling
- Nausea (feeling sick)

Less frequent side effects:

- Reduced number of platelets in your blood (which can affect clotting)
- Itching
- Low blood pressure which may make you feel faint or have a quickened heartbeat.
- Bleeding including:
    - bleeding from your nose
    - bleeding in your stomach, bowel or blood in the stools
    - blood found in the urine (that stains the urine pink or red)
    - bleeding from your vagina
    - bleeding occurring after your operation including bruising and swelling, blood or liquid leaking from the surgical wound/incision (wound secretion)
    - in your eyes
    - from your gums and blood in your spit when coughing
    - from your rectum
    - into a muscle
- Blood tests may show:
    - abnormal liver function
    - an increase in some liver enzymes

    - an increase in bilirubin, a breakdown product of red blood cells
    - which can cause yellowing of the skin and eyes
- Allergic reactions (hypersensitivity) which may cause swelling of the face, lips, mouth, tongue and/or throat and difficulty breathing. Contact your doctor immediately if you experience any of these symptoms
- Hair loss

Other side effects

- Angioedema (swelling of areas of tissue under your skin)
- Bleeding:
    - in your brain or in your spinal column
    - in your lungs or your throat
    - in your mouth
    - into your abdomen or space behind your abdominal cavity
    - from a haemorrhoid
    - tests showing blood in the stools or in the urine
- Skin rash

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

*The following side effects are known if you take **INNOKLOD** 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*

Frequent side effects

- Anaemia which may cause tiredness or paleness
- Bleeding including:
    - in your eyes
    - from your nose
    - in your stomach, bowel or dark/black blood in the stools
    - from your rectum
    - from your gums
    - blood found in the urine
    - bruising and swelling
- Low blood pressure which may make you feel faint or have a quickened heartbeat
- Nausea (feeling sick)
- Blood tests may show an increase in some liver enzymes

Less frequent side effects

- Reduced number of platelets in your blood (which can affect clotting)
- Allergic reactions (hypersensitivity) which may cause swelling of the face, lips, mouth, tongue and/or throat and difficulty breathing

- Itching
- Bleeding including:
    - in your brain or in your spinal column
    - into your abdomen, into the rectum or from the vagina
    - in your mouth or blood in your spit when coughing
    - from a haemorrhoid
    - bright/red blood in the stools - bleeding occurring after any operation including bruising and swelling, blood or liquid leaking from the surgical wound/incision (wound secretion) or injection site
    - bleeding in your lungs or your throat
    - bleeding into the space behind your abdominal cavity
    - bleeding into your muscle
- Blood tests may show:
    - abnormal liver function
    - an increase in some liver enzymes
    - an increase in bilirubin, a breakdown product of red blood cells which can cause yellowing of the skin and eyes
- Skin rash
- Hair loss

Other side effects

- Angioedema (swelling of areas of tissue under your skin)

*The following side effects are known if you take **INNOKLOD** to treat or prevent re-occurrence of blood clots in the veins of your legs and blood clots in the blood vessels of your lungs*

Frequent side effects

- Anaemia which may cause tiredness or paleness
- Reduced number of platelets in your blood (which can affect clotting)
- Bleeding including:
    - bruising and swelling
    - from your nose
    - into your abdomen
    - from your mouth
    - from your rectum
    - from your gums
    - blood in the urine
    - from the vagina
- Nausea (feeling sick)
- Blood tests may show an increase in some liver enzymes
- Skin rash

Less frequent side effects

- Allergic reactions (hypersensitivity) which may cause swelling of the face, lips, mouth, tongue and/or throat and difficulty breathing

- Itching
- Bleeding including:
    - in your eyes
    - blood in your spit when coughing
    - from a haemorrhoid
    - bright/red blood in the stools
    - into a muscle
    - bleeding including bruising and swelling, blood or liquid leaking from the surgical wound or from the injection site
    - blood found in the urine on laboratory testing
    - in your brain
    - in our lungs
- Low blood pressure which may make you feel faint or have a quickened heartbeat
- Blood tests may show:
    - abnormal liver function
    - an increase in some liver enzymes
    - an increase in bilirubin, a breakdown product of red blood cells, which can cause yellowing of the skin and eyes
- Hair loss

Other side effects

Angioedema (swelling of areas of tissue under your skin)

Bleeding into your abdomen or the space behind your abdominal cavity.

If you 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 **"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 **INNOKLOD.**

5. How to store INNOKLOD

Store all medicines out of reach of children

Store at or below 30 °C.

Do not remove blister from carton until required for use.

Do not use this medicine after the expiry date which is stated on the carton and on the blister. The expiry date refers to the last day of that month.

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 INNOKLOD contains:

The active substance in **INNOKLOD** is apixaban.

The other ingredients are

Tablet core

Anhydrous lactose

Croscarmellose sodium

Magnesium stearate

Microcrystalline cellulose

Sodium lauryl sulphate

Film coat

Hypromellose

Lactose monohydrate

Titanium dioxide

Triacetin

Yellow iron oxide (2,5 mg tablets)

Red iron oxide (5 mg tablets)

What INNOKLOD looks like and contents of the pack

INNOKLOD 2,5 mg: Yellow coloured, round shaped, film-coated tablets debossed with ‘2.5’ on one side and ‘A’ on the other side.

INNOKLOD 5 mg: Pink coloured, oval shaped, film-coated tablets debossed with ‘’5’’ on one side and ‘’A’’ on other side.

Primary Packaging components (2,5 mg Tablets)

Bottles

40 cc HDPE bottle 33 mm neck

33 mm CR closures

Flip-Off Seal, 20 mm

Blister

Triplex film 162 mm (PVC/PE/PVDC)

Plain Aluminium foil 158 x 0.025 mm

Primary Packaging components (5 mg tablets)

Bottles

40 cc HDPE bottle 33 mm neck

33 mm CR closures

Flip-Off Seal, 20 mm

Blister

Triplex film 212 mm (PVC/PE/PVDC)

Plain Aluminium foil 208 x 0.025 mm

Pack sizes: blisters of 10’s tablets (10’s x 3) & Bottles pack of 60’s tablets

Holder of Certificate of Registration

Innovata Pharmaceuticals (Pty) LTD

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South Africa

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Access to the corresponding Professional information.

A copy of the professional Information is contained in the packaging of **INNOKLOD**.