Final approved PIL as per SAHPRA email dated 22/02/2021: submitted 26/02/2021

FINAL PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

CLOVEXA (Film coated tablets)

Clopidogrel

Contains lactose

Read all of this leaflet carefully before you start taking CLOVEXA

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

1. What CLOVEXA is and what it is used for

- CLOVEXA contains the active substance clopidogrel.
- Clopidogrel belongs to a group of medicines called anticoagulants. Platelets are very small structures in the blood, which clump together during blood clotting. By preventing this clumping, antiplatelet medicinal products

reduce the chances of blood clots forming (a process called thrombosis).

- CLOVEXA is taken by adults to prevent blood clots (thrombi) forming in hardened blood vessels (arteries), which can lead to atherosclerotic events (such as stroke, heart attack, or death).

2. What you need to know before you take CLOVEXA

Do not take CLOVEXA:

- if you are hypersensitive (allergic) to clopidogrel or any of the other ingredients of CLOVEXA (listed in section 6.1)
- If you have a medical condition that is currently causing bleeding such as a stomach ulcer or bleeding within the brain
- If you are below the age of 18 years
- if you are pregnant or breastfeeding
- if you have severe liver disease.

Warnings and precautions

CLOVEXA has been reported to cause a blood disorder called thrombotic thrombocytopenic purpura (TTP), which causes blood clots in the small blood vessels throughout the body. If you experience any of the following symptoms contact your doctor or other healthcare provider immediately:

- fever
- bruising under the skin that may appear as red pinpoint dots, with or without unexplained extreme tiredness,
- confusion,
- yellowing of the skin or eyes (jaundice).

Take special care with CLOVEXA and tell your doctor:

- if you have a risk of bleeding, such as:

  - a medical condition that puts you at risk of internal bleeding (such as a stomach ulcer)
  - a blood disorder that makes you prone to internal bleeding (bleeding inside any tissues, organs or joints of your body).
  - a recent serious injury
  - a recent surgery (including dental)
  - a planned surgery (including dental) in the next seven days
- if you have had a clot in an artery of your brain (ischaemic stroke) which occurred within the last seven days
- if you have had a heart attack recently, suffer from angina or have recently had surgery to improve blood flow to the heart.
- If you have had an allergy to any of the medicines used to treat your disease.
- If you have kidney or liver disease.

Take note that if you get cut or injure yourself, while on treatment with CLOVEXA, it may take longer for bleeding to stop. If you are concerned about the bleeding contact your doctor immediately.

Other medicines and CLOVEXA

- Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines.)
- Please talk to your doctor or pharmacist if you are taking any of the following medicines:
  - Medicines that increase the risk of bleeding such as:
    - Other oral anticoagulants like warfarin (to reduce blood clotting)
    - Non-steroidal anti-inflammatory medicines (used for pain and inflammation)
    - Heparin (injection given for blood clotting)
    - Selective serotonin reuptake inhibitors, like fluvoxamine (used to treat depression)

- Acetylsalicylic acid (also known as aspirin)
- Omeprazole and esomeprazole (used to treat stomach problems, specifically ulcers or acid reflux)
- Moclobemide (used to treat depression)
- Voriconazole, fluconazole (used to treat fungal infections)
- Ticlopidine (antiplatelet medicine)
- Carbamazepine (used to treat epilepsy)
- Efavirenz (used to treat HIV infections)
- Repaglinide (used to treat diabetes)
- Paclitaxel (used to treat cancer)

CLOVEXA with food and drink

- CLOVEXA may be taken with or without food.

Pregnancy, 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 taking this medicine.
- You should not take this medicine during pregnancy.
- You should not breast-feed while taking CLOVEXA.

Driving and using machines

- It is not always possible to predict to what extent CLOVEXA 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 CLOVEXA affects them.

CLOVEXA contains lactose

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

3. How to take CLOVEXA

- Do not share medicines prescribed for you with any other person.
- Always take CLOVEXA exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
- The usual dose is 1 tablet daily.
- Swallow the tablet whole with a glass of water.
- If you have the impression that the effect of CLOVEXA is too strong or too weak, tell your doctor or pharmacist.

If you take more CLOVEXA than you should

In the event of overdosage consult your doctor or pharmacist. If neither is available, contact your nearest hospital or poison centre. You may be at risk of increased bleeding.

If you forget to take CLOVEXA

If you miss a dose within less than 12 hours after the scheduled time, take the dose immediately and then take the next dose at the regular time.

If more than 12 hours have elapsed, take the next dose at the regular time. Do not take a double dose to make up for a forgotten dose. Do not take more than the daily amount of CLOVEXA that has been prescribed for you in one day.

4. Possible side effects

- CLOVEXA can have side effects.
- Not all side effects reported for CLOVEXA are included in this leaflet. Should your general health worsen or if

you experience any untoward effects while taking CLOVEXA, please consult your doctor, pharmacist or other healthcare professional for advice.

- If any of the following happens, stop taking CLOVEXA and tell your doctor immediately or go to the casualty department at your nearest hospital:
    - Difficulty breathing
    - Severe skin rash or itching
    - Swollen tongue or lips

These are all very serious side effects. If you have them, you may have had a serious reaction to CLOVEXA. 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:
    - fever
    - bruising under the skin that may appear as red pinpoint dots, with or without unexplained extreme tiredness,
    - confusion,
    - yellowing of the skin or eyes (jaundice).

- Tell your doctor if you notice any of the following:
    - <u>Frequent side effects</u>
        - Haematoma (pain, swelling, redness)
        - Nosebleeds
        - Appearance of blood in stool, diarrhoea, stomach pain or discomfort
        - Bruising
        - Bleeding at site where blood sample is taken

- Less frequent side effects
  - Changes in blood results, which your doctor will identify
  - Serum sickness (fever, general ill feeling, hives, itching, joint pain, rash)
  - Hallucination, confusion
  - Headache, tingling feeling in hands or feet, dizziness, changes in taste or loss of taste
  - Bleeding in the eye
  - Feeling off balance
  - Chest pain
  - Bleeding from wounds, fever, fatigue, weight loss, muscle and joint pain, low blood pressure
  - Coughing up blood, difficulty breathing, cough, chest pain
  - Stomach ulcers, vomiting, nausea, constipation, gas (flatulence), appearance of blood in stool or vomit, sores in the mouth
  - Liver problems (your doctor will perform tests to determine this)
  - Rash, itchy rash on skin, bleeding under the skin (you will see purplish, red spots on skin), blisters on the skin, painful rash, painful lesions on skin
  - Pain, swelling of joints caused by bleeding into joints, pain in joints and muscles
  - Blood or protein in urine (your doctor will do a test to determine this)
  - Swelling of breast tissue in males
  - Fever

- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. 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 CLOVEXA.

5. How to store CLOVEXA

- Store all medicines out of reach of children.
- Store at or below 25 °C.

6. Contents of the pack and other information

What CLOVEXA contains

- The active substance is clopidogrel.
- Each film coated tablet contains 75 mg clopidogrel.
- The other ingredients are:
    - *Anhydrous lactose, low substituted hydroxypropyl cellulose, hydroxypropyl cellulose, microcrystalline cellulose, hydrogenated castor oil, colloidal anhydrous silica*
    - *Film coating (Opadry II pink):* lactose monohydrate, Hypromellose, titanium dioxide, glycerol triacetate, iron oxide red

What CLOVEXA looks like and contents of the pack

- CLOVEXA: Pink coloured, round, biconvex, film coated tablet, plain on both sides.
- CLOVEXA is packed in Alu-Alu blister packs comprising aluminium foil (hard tempered) with HSL coating on bright side. The forming material is cold formable Alu-Alu triple laminated foil. The blisters are further packed in a cardboard carton in pack sizes of 7, 14, 28, 30, 50, 84, 90 and 100 tablets per pack. (Not all pack sizes will be marketed).

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HOLDER OF CERTIFICATE OF REGISTRATION

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Rivonia

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South Africa

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