PATIENT INFORMATION LEAFLET

CLOPIDOGREL UNICORN 75

Please read this leaflet carefully before taking CLOPIDOGREL UNICORN 75

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or your pharmacist.
- **CLOPIDOGREL UNICORN 75** 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.

Scheduling Status: Schedule 3

Proprietary name, Strength and Pharmaceutical Form:

CLOPIDOGREL UNICORN 75 (Film Coated Tablet)

1. WHAT CLOPIDOGREL UNICORN 75 CONTAINS

Each **CLOPIDOGREL UNICORN 75** film-coated tablet contains clopidogrel hydrogen sulphate equivalent to 75 mg of clopidogrel as the active ingredient.

CLOPIDOGREL UNICORN 75 tablets contain the following inactive ingredients: Anhydrous lactose, castor oil hydrogenated, hypromellose, macrogol 6000, microcrystalline cellulose, pregelatinised starch, propylene glycol, purified talc and the colourants titanium dioxide & iron oxide red.

2. WHAT CLOPIDOGREL UNICORN 75 ARE USED FOR

CLOPIDOGREL UNICORN 75 is used to lessen the chance of experiencing a heart attack, a stroke or death due to atherosclerotic disease of the blood vessels. Atherosclerosis is caused by narrowing and hardening of the blood vessels of the heart, brain and extremities due to blockage by cholesterol and fats and the resultant inflammation of the inner lining of blood vessels.

CLOPIDOGREL UNICORN 75 is given to people who have a history of experiencing the warning signs of blood vessel disease; these would include those who have had a heart attack or stroke or to people with confirmed problems of reduced blood circulation to the arms and legs.

3. BEFORE YOU TAKE CLOPIDOGREL UNICORN 75:

Do not take CLOPIDOGREL UNICORN 75:

- If you are hypersensitive (allergic) to clopidogrel or any of the other ingredients of **CLOPIDOGREL UNICORN 75** tablets (see "**WHAT CLOPIDOGREL UNICORN 75 CONTAINS**").
- If you have bleeding problems (such as bleeding stomach ulcer).
- If your liver function is severely impaired.
- If you are pregnant or breastfeeding.
- **CLOPIDOGREL UNICORN 75** should not be given to patients younger than 18 years

Take special care with CLOPIDOGREL UNICORN 75:

- If you have a serious blood disorder called thrombotic thrombocytopenic purpura [TTP].
- If you are going to have surgery or have dental work done. **CLOPIDOGREL UNICORN 75** may increase the risk of serious bleeding during surgery or dental procedures. Therefore, treatment may have to be stopped about 7 days before the operation or dental work is done.
- Tell all medical doctors, dentists, nurses and pharmacists you go to that you are taking **CLOPIDOGREL UNICORN 75**.
- **CLOPIDOGREL UNICORN 75** tablets contain 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 (see **"WHAT CLOPIDOGREL UNICORN 75 CONTAINS**)

Taking CLOPIDOGREL UNICORN 75 tablets with food or drink:

CLOPIDOGREL UNICORN 75 tablets may be taken with food or on an empty stomach. **CLOPIDOGREL UNICORN 75** tablets should be swallowed whole with water, do not chew or crush the tablets.

Pregnancy and breast-feeding:

If you are pregnant or breast feeding your baby while taking **CLOPIDOGREL UNICORN 75**, please consult your doctor, pharmacist or other health care professional for advice. Safety in pregnancy and breast-feeding has not been established.

Driving and using machinery:

CLOPIDOGREL UNICORN 75 will most likely not affect your ability to drive or perform tasks that require concentration. Take care until you know how **CLOPIDOGREL UNICORN 75** affects you.

Using other medicines with CLOPIDOGREL UNICORN 75 tablets:

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of **CLOPIDOGREL UNICORN 75** tablets with these medicines may cause undesirable interactions. Tell your doctor or pharmacist if you are taking any other medicines, including any you have bought at your pharmacy, supermarket or health food shop. Please consult your doctor, pharmacist or other healthcare professional for advice if you are using any of the following products:

- Non-Steroidal Anti-Inflammatory Agents (such as aspirin, ibuprofen, indomethacin, diclofenac etc.)
- Heparin or warfarin (medicines used to prevent blood clots)
- Phenytoin (a medicine used to treat epilepsy or seizures)
- Tolbutamide (a medicine used to treat diabetes [high blood sugar])
- Tamoxifen (medicine used to treat breast cancer)
- Fluvastatin (medicine used to treat high cholesterol)
- Aspirin (pain killer)
- Omeprazole or esomeprazole (medicine used to treat ulcers and to prevent reflux of the stomach acid into the throat)

4. HOW TO TAKE CLOPIDOGREL UNICORN 75

Always take **CLOPIDOGREL UNICORN 75** exactly as your doctor has instructed you. You should check with your doctor if you are unsure.

Follow your doctor's instructions or the directions on the label. The following information includes only the average doses of this medicine. If your dose is different, do not change it unless your doctor tells you to do so.

The adult dosage is one tablet daily, with or without food.

If you take more CLOPIDOGREL UNICORN 75 than you should:

When an overdosage is suspected contact your doctor or pharmacist as soon as possible. If neither is available, seek help at the nearest hospital or poison centre. Take this leaflet and any remaining tablets with you, so that the doctor knows what the person has taken.

If you forget to take CLOPIDOGREL UNICORN 75:

If you missed a dose, take it as soon as you remember. If it is almost time for you next dose, skip the missed dose and continue to take the tablet at the usual time. **Do not** take a double or larger dose to make up for the forgotten individual doses.

5. POSSIBLE SIDE-EFFECTS

CLOPIDOGREL UNICORN 75 can cause side-effects.

Not all side effects reported for CLOPIDOGREL UNICORN 75 are included in this leaflet. Should your general health worsen while taking CLOPIDOGREL UNICORN 75, please consult your doctor, pharmacist or other health care professional for advice.

If any of the following happen, you should stop taking ***CLOPIDOGREL UNICORN 75*** *immediately and tell your doctor or go to the casualty department at your nearest hospital:*

- rash or itching
- swelling of the hands, feet, ankles, face, lips, mouth or throat, difficulty in swallowing or breathing.

These are all very serious side effects, if you have them you may have had a serious allergic reaction to **CLOPIDOGREL UNICORN 75** and you may need urgent medical attention or hospitalisation.

The following side-effects have been reported:

Consult your doctor or pharmacist as soon as possible if you experience the following serious side-effects as they require immediate medical attention,

- Unusual bleeding or bruising or sudden weakness.
- Chest pain, irregular heartbeat.
- High blood pressure
- A feeling of sadness accompanied by tiredness, trouble sleeping, appetite changes, irritability and or thoughts of suicide.
- Yellow colouring of the skin accompanied by a decrease in appetite and feeling unwell, can lead to confusion and coma

If the following side-effects persist or are bothersome, consult your doctor or pharmacist :

- Blistering, flaking, or peeling of skin.
- Fever, chills, or sore throat; headache (sudden, severe).
- Ulcers, sores, or white spots in mouth; diarrhoea or constipation; flatulence; mild abdominal or stomach pain; vomiting or nausea
- Runny nose or sneezing
- Fainting, dizziness
- Frequent urination or painful or difficult urination.
- Joint pain, muscle rigidness or stiffness
- Swelling of feet or lower legs
- Loss of taste
- Anxiety, trouble in sleeping, tiredness
- Difficulty breathing
- Cough or highly productive cough

- Confusion
- Hearing, feeling or seeing things that are not there
- Decreased sense of touch or a tingling, numb feeling on the skin.

6. STORING AND DISPOSING OF CLOPIDOGREL UNICORN 75

- Store at or below 25 °C.
- KEEP ALL MEDICINES OUT OF REACH OF CHILDREN
- Do not use the tablets after the expiry date printed on the label or blister.
- Return all unused medicine to your pharmacist
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets)

7. PRESENTATION OF CLOPIDOGREL UNICORN 75

CLOPIDOGREL UNICORN 75 tablets are packed in OPA/AL/PVC film and heat sealing aluminium blister strips. Each strip containing seven or ten tablets. The blister strips are packed in an outer carton.

8. IDENTIFICATION OF CLOPIDOGREL UNICORN 75

Pink, round, slightly biconvex, film-coated tablet.

9. REGISTRATION NUMBER

CLOPIDOGREL UNICORN 75: 42/8.2/0250

10. NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE REGISTRATION CERTIFICATE

Unicorn Pharmaceuticals (Pty) Ltd.

Corner Searle and Pontac Streets

Cape Town

8001

11. DATE OF PUBLICATION

31 July 2014