

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S3**

ACELOREL 75/75 film-coated tablets

Clopidogrel and acetylsalicylic acid (aspirin)

Contains sugar (2,8 mg lactose monohydrate and 64 mg mannitol per tablet).

Contains hydrogenated castor oil (3 mg per tablet).

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

- 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.
- ACELOREL 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 ACELOREL is and what it is used for
2. What you need to know before you take ACELOREL
3. How to take ACELOREL
4. Possible side effects
5. How to store ACELOREL
6. Contents of the pack and other information.

1. What ACELOREL is and what it is used for

ACELOREL contains the active substances clopidogrel and acetylsalicylic acid (aspirin), which belongs to a group of medicines called antiplatelet medicines.

ACELOREL is used to treat people who have suffered a severe type of chest pain called angina, or who have had a heart attack.

ACELOREL helps to prevent platelets from sticking together and forming a clot that can block an artery. Platelets are normal blood components involved in the clotting of blood.

ACELOREL is used to lower your chance of having another serious problem with your heart or blood vessels.

2. What you need to know before you take ACELOREL

Do not take ACELOREL:

- If you are hypersensitive (allergic) to clopidogrel, aspirin or any of the other ingredients of ACELOREL, listed in section 6.
- If you develop a skin rash while taking ACELOREL.
- If you have a history of gastrointestinal bleeding, gastrointestinal ulcer or gastrointestinal perforation related to previous use of a medicine called a nonsteroidal anti-inflammatory drug (NSAID).
- If you have a medical condition that is currently causing bleeding such as a stomach ulcer, haemophilia or bleeding within the brain or bowel or a history of such a condition.
- If you suffer from severe liver disease.
- If you suffer from a dysfunction of, or reduction in, blood platelets which increases risk of bleeding and bruising.
- If you are allergic to other products called nonsteroidal anti-inflammatory drugs, usually used to treat painful and/or inflammatory conditions of muscles and joints.
- If you have a medical condition that include the combination of asthma, nasal discharge (runny nose) and polyps (a type of growth in the nose).
- If you have a medical condition called mastocytosis. The use of ACELOREL may cause a severe hypersensitivity (allergic) reaction.
- If you suffer from severe kidney disease.
- If you have heart problems which can cause shortness of breath or ankle swelling (heart failure).
- If you are pregnant and/or breastfeeding.
- If you have haemophilia (a bleeding disorder), whether you were born with it or developed it

later, or if you have ever had haemophilia caused by a medicine.

Do not take ACELOREL if any of the above applies to you. If you are not sure, talk to your doctor before taking ACELOREL.

Warnings and precautions

Tell your doctor or health care provider before taking ACELOREL:

- 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.
 - a planned spinal, epidural anaesthetic or lumbar puncture in the next seven days.
- If you have had a clot in an artery of your brain (ischaemic stroke) which occurred in the last seven days.
- If you have a history of asthma or allergic reactions.
- If you have gout.
- If you have a history of heart problems which can cause shortness of breath or ankle swelling (heart failure) or high blood pressure.
- If you are an elderly person.
- If you consume alcohol, because of the increased risk of bleeding or gastrointestinal injury.
- If you have a condition known as glucose-6-phosphate dehydrogenase (G6PD) deficiency (a condition where your red blood cells are broken down prematurely), because of the risk of a particular form of anaemia.
- If you develop symptoms or signs of a condition called drug reaction with eosinophilia and systemic symptoms (DRESS) which may include flu-like symptoms and a rash with fever, enlarged lymph nodes and increase in a type of white blood cell (eosinophilia). Other abnormal blood test results may include (but are not limited to) increased levels of liver

enzymes.

- If you have a history of inflammation of the colon which causes abdominal pain or diarrhoea.
- If you are a CYP2C19 poor metaboliser (you have very little or no function of the CYP2C19 enzyme, used to break down medicines in your body).
- If you are hypersensitive (allergic) to other antiplatelet medicines used to prevent clots (such as ticlopidine or prasugrel).
- If you have a kidney or liver disease.
- If you are taking any other type of medicine (see Other medicines with ACELOREL).

Take special care with ACELOREL:

- You should tell your doctor and anaesthetist that you take ACELOREL:
 - if surgery (including dental) is planned.
 - if you have any stomach or abdominal pain or bleeding in the stomach or bowels (red stools or black stools).
- You should also tell your doctor immediately if you develop a medical condition (also known as thrombotic thrombocytopenic purpura or TTP) that includes fever and 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) (see section 4).
- If you cut or injure yourself, it may take longer than usual for bleeding to stop. This is linked to the way your medicine works as it prevents the ability of blood clots to form. For minor cuts and injuries, e.g. cutting yourself while shaving, this is usually of no concern. However, if you are concerned by your bleeding, you should contact your doctor immediately (see section 4).

Your doctor may order blood tests.

Children and adolescents

ACELOREL is not intended for use in children or adolescents less than 18 years of age. There is an association between aspirin and Reye's syndrome when products containing aspirin are given to children or adolescents with a viral infection. Reye's syndrome is a very rare disease which can be fatal.

Other medicines with ACELOREL

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

Some other medicines may influence the use of ACELOREL or vice versa.

You should tell your doctor if you take:

- Medicines that may increase your risk of bleeding such as:
 - ticlopidine or prasugrel or other antiplatelet medicines used to reduce blood clotting
 - oral anticoagulants, medicines used to reduce blood clotting
 - heparin or any other injectable medicines used to reduce blood clotting
 - aspirin or another nonsteroidal anti-inflammatory medicines usually used to treat painful and/or inflammatory conditions of muscle or joints
 - rifampicin (a medicine used to treat severe infections)
 - a selective serotonin reuptake inhibitor (SSRI) (e.g. fluoxetine or fluvoxamine), medicines usually used to treat depression.
- nicorandil (a medicine to treat cardiac chest pain)
- omeprazole or esomeprazole (medicines to treat upset stomach or to prevent gastric reflux [heartburn])
- repaglinide (a medicine to treat diabetes)
- paclitaxel (a medicine to treat cancer)
- rosuvastatin (a medicine used to lower your cholesterol level)
- medicines used to treat gout
- methotrexate (a medicine used to treat severe joint disease [rheumatoid arthritis] or skin disease [psoriasis])
- metamizole (a medicine used to treat pain, muscle spasms and fever)
- corticosteroids (medicines to treat some inflammatory diseases)
- metamizole (a medicine to treat pain, muscle spasms and fever)
- acetazolamide (a medicine to treat glaucoma)

- the varicella vaccine (a medicine to prevent chickenpox or shingles, within 6 weeks of taking ACELOREL, or if you have an active chickenpox or shingles infection)
- levothyroxine (a medicine to treat low thyroid activity)
- valproic acid (a medicine used to treat some forms of epilepsy)
- tenofovir (an antiretroviral medicine used in the treatment of HIV)
- opioids: while you are treated with clopidogrel, you should inform your doctor before being prescribed any opioids [medicine used to treat severe pain, e.g. morphine]).

Alcohol: The consumption of alcohol may affect how well ACELOREL works; it may increase blood loss and stomach irritation. Please ask your doctor for more information. Alcohol should be used with caution if you are taking ACELOREL.

You should stop other clopidogrel treatments while you are taking ACELOREL.

Contact your doctor before taking other aspirin-containing medicines concomitantly with ACELOREL.

ACELOREL with food, drink and alcohol

Alcohol should be used with caution if you are taking ACELOREL (see Other medicines with ACELOREL).

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 ACELOREL.

You should not take ACELOREL if you are pregnant or breastfeeding (see section 2).

Driving and using machines

ACELOREL should not affect your ability to drive or to use machines. It is not always possible to

predict to what extent ACELOREL may interfere with your daily activities. You should ensure that you do not engage in activities requiring mental alertness, judgement and/or sound coordination and vision, e.g. driving, riding, flying, sailing, operating machines/equipment until you are aware of the measure to which ACELOREL affects you.

ACELOREL contains lactose and castor oil

ACELOREL contains lactose. If you have been told by your doctor that you have intolerance to some sugars (e.g. lactose), contact your doctor before taking ACELOREL.

ACELOREL also contains hydrogenated castor oil which may cause stomach upset and diarrhoea.

3. How to take ACELOREL

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

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

The usual dose is one tablet of ACELOREL per day to be taken orally with a glass of water, with or without food.

You should take your medicines at the same time each day.

You should take ACELOREL for as long as your doctor continues to prescribe it.

If you take more ACELOREL than you should

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 ACELOREL

If you forget to take a dose of ACELOREL, but remember within 12 hours of your usual time, take your tablet immediately and then take your next tablet at the usual time.

If you forget for more than 12 hours, simply take the next single dose at the usual time. Do not take a double dose to make up for the forgotten individual doses.

If you stop taking ACELOREL

Do not stop the treatment unless your doctor tells you so. Contact your doctor or pharmacist before stopping.

If you have been told by your doctor to stop treatment temporarily, ask your doctor when to restart the treatment.

If you have any further questions on the use of ACELOREL, ask your doctor or pharmacist.

4. Possible side effects

ACELOREL can have side effects.

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

If any of the following happens, stop taking ACELOREL 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 or itching
- fainting.

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

- bleeding or bruising more easily than normal
- frequent infections such as fever, severe chills, sore throat or mouth ulcers
- eye bleeding
- yellowing of the skin and eyes, dark urine, and tiredness which may be symptoms of liver

problems

- painful, blistering or peeling skin rash, such as Stevens-Johnson syndrome, toxic epidermal necrolysis or acute generalised exanthematous pustulosis (AGEP)
- blood in your urine or faeces (dark stool), vomiting blood
- kidney failure or inflammation of your kidneys – symptoms may include swelling of legs, ankles, feet or face due to fluid retention, reduction in your urine output, shortness of breath, fatigue, confusion
- a rare, life-threatening blood disorder known as thrombotic thrombocytopenic purpura (TTP) that causes clots to form in the small blood vessels throughout your body causing symptoms such as fever, bruising under the skin that may appear as red pinpoint dots, with or without unexplained extreme tiredness, confusion, yellowing of your skin or eyes (jaundice)
- chest pain that may radiate to your neck or left arm, pallor, sweatiness, nausea, breathlessness, low blood pressure. These symptoms may be signs of heart problems due to an allergy to clopidogrel or aspirin (Kounis syndrome)
- bleeding in your brain (also called an intracranial haemorrhage) causing symptoms such as sudden severe headache, seizures with no previous history of seizures, weakness in your arm or leg, nausea or vomiting (severe and continuing), sudden tiredness, difficulty speaking or understanding speech, loss of balance, hand tremors or loss of consciousness
- a serious skin reaction called drug rash with eosinophilia and systemic symptoms (DRESS) or drug-induced hypersensitivity syndrome (DiHS) – symptoms may include rash, often itchy, fever, inflammation of internal organs, most commonly the liver
- pancreatitis (nausea, vomiting, fever, pain in your stomach area radiating to your back)
- breathing difficulties, sometimes associated with coughing, wheezing, shortness of breath or rapid breathing, chest pain, or fever
- colitis, sometimes worsened (severe abdominal pain, diarrhoea, fever)
- ulcer perforation (where an ulcer burns through your stomach or duodenal wall, causing severe, sharp abdominal pain)
- inflammation of your blood vessels with symptoms such as fever, headache, tiredness, weight loss, general aches and pains, night sweats, rash or nerve problems such as numbness or

weakness (vasculitis).

These are serious side effects. If you have them, you may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent:

- nosebleed
- indigestion, pain in your stomach area, diarrhoea.

Less frequent:

- anaemia (feeling weak and tired, looking pale)
- feeling confused, seeing or hearing things that do not exist
- headache, dizziness
- tingling or numbness of your hands and feet (pins and needles)
- changes in the way things taste
- vertigo (sensation of spinning or swaying)
- low blood pressure
- nausea (feeling sick), flatulence (wind), constipation, vomiting (being sick)
- stomach, duodenal ulcer or oesophageal ulcer, inflammation of your stomach lining or mouth
- inflammation of the tube running from your throat to your stomach (oesophagus)
- hives, dry, itchy skin (eczema), purple, itchy, flat bumps (lichen planus)
- purple, red or brown spots and patches on your skin (purpura)
- joint pain or stiffness, pain in a muscle or group of muscles
- increased creatine levels when blood tests are done
- breast enlargement in men
- fever.

Unknown frequency:

- low sugar levels in your blood (sweating, weakness, hunger, dizziness, trembling, headache, flushing or paleness)

- gout
- ringing in the ears, hearing loss
- ulcers in your small or large colon, intestines or rectum
- intestinal perforation (a hole in your intestines).

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

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or health care provider. This includes any possible side effects not listed in this leaflet.

You can report any side effects to SAHPRA via 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 ACELOREL.

5. How to store ACELOREL

- Store at or below 25 °C.
- Keep in the original container until required for use.
- Store all medicines out of reach of children.
- Do not use after the expiry date printed on the packaging.
- 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 ACELOREL contains

The active substances are clopidogrel and acetylsalicylic acid (aspirin).

Each film-coated tablet contains 75 mg clopidogrel and 75 mg acetylsalicylic acid (aspirin).

The other ingredients are:

Core:

Hydrogenated colloidal silica [E551], hydrogenated castor oil [E1503], low-substituted hydroxypropyl cellulose, mannitol [E421], microcrystalline cellulose [E460], polyethylene glycol, stearic acid [E570] and yellow iron oxide [E172].

Coating:

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

What ACELOREL looks like and contents of the pack

Yellow coloured, oval shaped, film-coated tablets debossed with “I” on one side and plain on other side.

OPA/aluminium/desiccant PE blister strip containing 10 tablets, packed in an outer carton.

Pack sizes: 10 or 30 tablets.

Holder of Certificate of Registration

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