Patient Information Leaflet for ACTICLOP 75

Read all of this leaflet carefully before you start taking ACTICLOP 75

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine 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: S3

NAME OF THE PRODUCT: ACTICLOP 75 film coated tablets

1. WHAT ACTICLOP 75 CONTAINS

Active ingredients: Each tablet contains 75 mg clopidogrel as the active ingredient.

In addition, ACTICLOP 75 contains the following inactive ingredients:

Microcrystalline cellulose, spray-dried mannitol, hydroxypropylcellulose, crospovidone, citric acid, PEG 6000, stearic acid & talc.

2. WHAT ACTICLOP 75 IS USED FOR

Clopidogrel, the active ingredient in ACTICLOP 75 tablets, belongs to a group of medicines called antiplatelet medicinal products. Platelets are very small structures, smaller than red or white blood cells, which clump together during blood clotting. By preventing this clumping, antiplatelet medicinal products reduce the chances of blood clots forming (a process called thrombosis).

ACTICLOP 75 is taken to prevent blood clots (thrombi) forming in hardened blood vessels (arteries), a process known as atherothrombosis, which can lead to artherosclerotic events (such as stroke, heart attack, or death) due to a disease of the blood vessels in patients with a history of:

- symptomatic atherosclerotic disease (hardening of the arteries) defined by ischaemic stroke (clot in an artery of the brain) - (from 7 days until less than 6 months)
- myocardial infarction (heart attack) - (from a few days until less than 35 days) or
- established peripheral arterial disease (disease of the blood vessels).

3. BEFORE TAKING ACTICLOP 75

Do not take ACTICLOP 75:

- If you are allergic (hypersensitive) to clopidogrel or any of the other ingredients of ACTICLOP 75;
- If you suffer from severe liver disease;

- If you have a medical condition that is currently causing bleeding such as a stomach ulcer or bleeding in the head or brain;
- If you are younger than 18 years;
- If you are pregnant or breast-feeding;
- If you suffer from thrombocytopenia (decreased number of blood platelets)
- If you have platelet dysfunction (a blood disorder)

Take special care with ACTICLOP 75:

The presence of other medical problems may affect the use of ACTICLOP 75. Talk to your doctor, pharmacist or healthcare professional before taking ACTICLOP 75:

- about thrombotic thrombocytopenic purpura (TTP) which might occur (mostly within the first 2 weeks of treatment) and about the signs and symptoms of TTP, such as thrombocytopenia (decreased number of blood platelets with symptoms such as bruising easily and nose bleeds), haemolytic anaemia (low number of red blood cells in your blood), neurological (nervous system) symptoms, renal (kidney) dysfunction and fever. ACTICLOP 75 should be stopped and TTP should be treated promptly.
- about the risk of increased blood loss during dental and surgical procedures and tell your doctor about any recent or planned surgery (including dental). In certain cases treatment with ACTICLOP 75 may need to be stopped 7 days before the procedure.
- about any bleeding or any other medical condition you currently have, such as a stomach ulcer or bleeding in the head, brain, or eyes, as these may put you at risk. If you are at risk of increased bleeding from trauma, surgery or other conditions, as ACTICLOP 75 should then be used with caution and you should be monitored carefully for any signs of bleeding
- about you taking other medicines that might increase the risk of bleeding (e.g. anticoagulants; NSAIDs including Cox-2 inhibitors and other anticoagulants, acetylsalicylic acid). The risk of bleeding and undesirable effects on your blood; blood tests and /or other tests should be done during your treatment if any symptoms show any signs of bleeding. It might take longer than usual to stop bleeding when you are taking ACTICLOP 75 (alone or in combination with acetylsalicylic acid), and you should report any unusual bleeding (site or duration) to your doctor.
- tell your doctor, dentist, pharmacist and health care professional that you are taking ACTICLOP 75 before any surgery and before any new medicine is taken.
- tell your doctor or pharmacist if you have kidney disease as ACTICLOP 75 should be used with caution in these circumstance
- tell your doctor or pharmacist if you have liver disease as, ACTICLOP 75 should then be used with caution

Take special care if you are taking other medicines with ACTICLOP 75:
In particular, you should check with your doctor, pharmacist or other healthcare professional if you are taking any of the medicines mentioned below to be sure that it is safe to take ACTICLOP 75 at the same time. *(see Taking other medicines with ACTICLOP 75.)*

Taking ACTICLOP 75 with food and drink:
ACTICLOP 75 may be taken with or without food.

Pregnancy and breast-feeding:
Do not take ACTICLOP 75 if you are pregnant or breast-feeding.
If you are pregnant or suspect that you are pregnant, you should tell your doctor or your pharmacist before taking ACTICLOP 75. If you become pregnant while taking ACTICLOP 75, consult your doctor immediately.
If you are a mother breast-feeding a baby, you should not take ACTICLOP 75.

Driving and using machinery:
Almost all patients can, but you should not perform tasks which may require special attention (for example, driving an automobile or operating dangerous machinery) until you know how you tolerate ACTICLOP 75.

Important information about some of the ingredients of ACTICLOP 75:
ACTICLOP 75 contains mannitol. If you have been told not to take mannitol, contact your doctor before taking ACTICLOP 75.

Taking other medicines with ACTICLOP 75:
If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of ACTICLOP 75 with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional, for advice.
In particular, you should check with your doctor, pharmacist or other healthcare professional if you are taking any of the following medicines to be sure that it is safe to take ACTICLOP 75 at the same time:

- Acetylsalicylic acid (ASA), since using it at the same time may increase the risk of bleeding
- Glycoprotein IIb/IIIa inhibitors,
- Heparin (used to reduce blood clotting), since it may increase the risk of bleeding
- Warfarin (used to reduce blood clotting), as it may increase the intensity of bleedings
- Non-steroidal anti-inflammatory medicines including aspirin and Cox-2 inhibitors, (used to treat painful and/or inflammatory conditions of muscle or joints), since there is a potential risk of gastro-intestinal bleeding

4. HOW TO TAKE ACTICLOP 75

Always take ACTICLOP 75 exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

If you have the impression that the effect of ACTICLOP 75 is too strong or too weak, talk to your doctor or pharmacist.

The usual dose of ACTICLOP 75 is 1 tablet of ACTICLOP 75 per day. ACTICLOP 75 can be taken with or without food.

Take your tablet regularly at the same time each day to control your blood levels over the 24 hour period.

If you took more ACTICLOP 75 than you should:

In case of an overdose, contact your doctor or pharmacist immediately so that medical attention may be given promptly. If neither is available, seek help at the nearest hospital or poison centre.

Signs of overdose may include bleeding and other Side effects (*see Possible Side effects*)

If you forget to take ACTICLOP 75:

Try to take ACTICLOP 75 daily as prescribed. However, if you miss a dose, do not take an extra dose. Just resume your usual schedule.

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

If you forget to take a dose of ACTICLOP 75, but remember within 12 hours of your usual time, take your tablet straight away 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.

Effects when treatment with ACTICLOP 75 is stopped:

Do not stop taking ACTICLOP 75. Contact your doctor or pharmacist before stopping.

5. POSSIBLE SIDE EFFECTS

ACTICLOP 75 can cause side effects.

Check with your doctor pharmacist or health care professional if any of these unwanted effects persist or become bothersome, even if you notice a side effect not mentioned here.

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

If you develop an allergic or hypersensitivity reaction or angioedema (a serious allergic reaction involving rash, itching, swelling of the face, lips, throat and/or tongue that may cause difficulty in swallowing or breathing; or dizziness or fainting usually with irregular heart beat), stop taking ACTICLOP 75 and contact your doctor immediately or go to the nearest hospital.

The most common side effect reported with ACTICLOP 75 is bleeding such as bruising, haematoma (unusual bleeding or bruising under the skin), nose bleed, blood in the urine, bleeding in the stomach or bowels. In a small number of cases, bleeding in the eye, inside the head, the lung or the joints has also been reported.

The other side effects reported with ACTICLOP 75 are:

- Diarrhoea, abdominal pain, constipation, nausea, vomiting, indigestion or heartburn, inflammation of the mouth (stomatitis);
- Vertigo, headache, decrease in blood pressure, confusion, hallucinations;
- Skin disorders such as rashes and itching, swelling in the mouth, blisters of the skin, generalised allergic reactions;
- Joint pain, muscular pain, fever, taste disorders.
- Breathing difficulty, sometimes associated with cough.
- Tingling sensation in hands and feet.

Contact your doctor immediately if you experience:

- fever, signs of infection or extreme tiredness. These may be due to rare decrease of some blood cells.
- signs of liver problems such as yellowing of the skin and/or the eyes (jaundice), whether or not associated with bleeding and/or confusion.

If you experience prolonged bleeding when taking ACTICLOP 75

If you cut or injure yourself, it may take slightly longer than usual for bleeding to stop. This is linked to the way your medicine works. If you are in any doubt at all, you should contact your doctor straightaway.

6. STORING AND DISPOSING OF ACTICLOP 75

Store ACTICLOP 75 tablets at or below 25 °C in the original package in a safe place and out of the reach of children. Do not remove the tablets from the blister pack until you are ready to take your medicine.

Do not store near a heater or on a window sill or in a humid place, or the bathroom.

Do not use after the expiry date stated on the blister or carton.

Return all unused medicines to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF ACTICLOP 75

ACTICLOP 75 tablets are supplied in cardboard cartons containing 28 (2 blisters of 14 tablets or 4 blisters of 7 tablets) or 30 (3 blisters of 10 tablets) tablets in blister packs.

Not all pack sizes may be marketed at any one time.

8. IDENTIFICATION OF ACTICLOP 75

ACTICLOP 75 tablets are pink, round, biconvex film coated tablets of 9,1 mm diameter and 4,2 mm thickness and are packed in blister packs. The blister packs may be opaque white on aluminium colour, or all aluminium. The blister packs are labelled with the name ACTICLOP 75, the batch number and expiry date and the name of the applicant namely Activo Health (Pty) Ltd.

9. REGISTRATION NUMBER:

43/8.2/0725

10. NAME AND BUSINESS ADDRESS OF THE REGISTRATION HOLDER

Activo Health (Pty) Ltd
Block B,
Arena Office Park,
272 West Avenue,
Centurion,
0157

11. DATE OF PUBLICATION:

Date as approved by Council