Patient Information Leaflet

Information for the Patient about

CIPLA-WARFARIN 1 mg Tablets
CIPLA-WARFARIN 3 mg Tablets

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

- **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:

S4

PROPRIETARY NAME AND DOSAGE FORM:

CIPLA-WARFARIN 1 mg Tablets
CIPLA-WARFARIN 3 mg Tablets

WHAT CIPLA-WARFARIN CONTAIN:

The active substance is warfarin.

CIPLA-WARFARIN 1 mg and 3 mg contain 1 mg and 3 mg of warfarin sodium, respectively.

WHAT CIPLA-WARFARIN IS USED FOR:

- CIPLA-WARFARIN belongs to a group of medicines called anticoagulants. Warfarin is a coumarin-type anticoagulant and acts by depressing synthesis of Vitamin K dependent coagulation factors in the liver.

- It is used for the prevention and management of deep vein thrombosis and pulmonary embolism.
- Prevention of thromboembolism in:

1. Artrial fibrillation,
2. Prosthetic heart valves
3. Post-myocardial infarction.

- It is also used in the treatment of transient ischaemic attacks

BEFORE YOU USE CIPLA-WARFARIN:

Do not take CIPLA-WARFARIN if you:

- Haemorrhagic states;
- Peptic ulcers or other gastrointestinal disease involving bleeding;
- Conditions involving bleeding from respiratory or genito-urinary tract;
- Severe wounds (including surgical);
- Infective endocarditis;
- Impaired liver function;
- Impaired kidney function;
- Hypertension;
- Cerebrovascular haemorrhage;
- Aneurysm - cerebral, aortic;
- Pericarditis, pericardial effusion;
- Neuro- or ophthalmic surgery - recent or contemplated;
- Surgery involving large exposed raw surfaces;
- Polyarthritis;

- Vitamin C deficiency;
- Major regional block anaesthesia;
- Inadequate laboratory facilities or lack of patient co-operation;
- Breast feeding mothers;
- Threatened abortion;
- Known hypersensitivity to warfarin or similar product.
- Safety in children younger than 18 years has not been established.

Take special care with CIPLA-WARFARIN :

Tell your doctor if you have any of the following as you may then require a lower dose or special precaution:

- Carcinoma, collagen disease, congestive heart failure, diarrhoea, elevated temperature, hepatic disorders, infectious hepatitis, jaundice, poor nutritional state.
- Diabetes mellitus, oedema, hereditary resistance to warfarin therapy, hyperlipidaemia, hypothyroidism.

Taking CIPLA-WARFARIN with food and drinks:

Tablets can be taken without regard to meals. Each tablet should be swallowed whole with fluid. Do not divide, crush, chew or place the tablets in water. See **"HOW TO TAKE CIPLA-WARFARIN"**.

Use in pregnancy and breast feeding:

The safety of **CIPLA WARFARIN** in pregnancy and lactation has not been established. Thus use in pregnancy and lactation is not recommended.

If you are pregnant or breast feeding your baby while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

Use in children: Safety and efficacy in individuals below 18 years of age has not been established and as such use is not recommended.

Taking other medicines with CIPLA WARFARIN tablets?

See **"BEFORE YOU TAKE CIPLA WARFARIN TABLETS"**

If you are taking other medicines on a regular basis, use of this medicine wit other medicines may cause undesirable interactions.

Please consult your doctor or pharmacist.

HOW TO TAKE CIPLA WARFARIN TABLETS:

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

Please consult your doctor before abruptly discontinuing CIPLA WARFARIN as your doctor will advise you on the tapered dose to minimise the risk of discontinuation symptoms.

If you take more CIPLA WARFARIN than you should:

In the event of an overdosage (if you take too many tablets), or

if someone else has taken your medicine by mistake, you, or this other person, may experience excessive bleeding. General and supportive measures are recommended. Contact your doctor or pharmacist immediately. If neither is available, seek help at the nearest hospital or poison control centre.

If you forget to take CIPLA WARFARIN

Take CIPLA WARFARIN as prescribed. If you miss a dose of this medicine, take it as soon as possible. However, if you do not remember the missed dose until the next day, skip the missed dose and go back to your regular dosing schedule. Do not take a double dose to compensate for the forgotten individual dose.

POSSIBLE SIDE-EFFECTS:

What undesirable effects may CIPLA WARFARIN have?

- CIPLA WARFARIN can have side-effects. As with any medicine, CIPLA WARFARIN may have unintended or undesirable effects.

The following side-effects have been reported:

Body as a whole:

Less Frequent:	Alopecia, fever

Gastrointestinal System Disorders:

Frequent:	Diarrhoea, nausea, vomiting.

Haematological and Lymphatic System Disorders:

Frequent:	Haemorrhage from almost any organ of the body with the consequent effects of haematomas as well as anaemia.

Metabolic and nutritional:

Frequent:	Purple toe syndrome - a reversible, sometimes painful, bluish discoloration of the toes may occur.

Skin and appendages:

Frequent:	Hypersensitivity reactions and skin reactions. Skin necrosis may occur

STORAGE AND DISPOSING OF CIPLA WARFARIN TABLETS:

Store this medicine out of reach of children.

Store below 25°C.

Keep the blisters in the outer carton until required for use.

Do not use after the expiry date stated on the packaging material.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems, for example toilets.

PRESENTATION OF CIPLA WARFARIN TABLETS:

CIPLA-WARFARIN 1 mg (TABLET): Supplied in white, opaque PVC/PVDC and aluminium foil blister strips of 10 tablets, packed in 30's, 60's or 100's in a carton.

CIPLA-WARFARIN 3 mg (TABLET): Supplied in white, opaque PVC/PVDC and aluminium foil blister strips of 10 tablets, packed in 30's, 60's or 100's in a carton.

IDENTIFICATION OF CIPLA WARFARIN TABLETS:

CIPLA-WARFARIN 1 mg (TABLET): Light brown coloured, circular, flat, beveled tablets with a breakline on one side. 'W' and '1' engraved on breakline side and plain on the other side of tablet.

CIPLA-WARFARIN 3 mg (TABLET): Light blue coloured, circular, flat, beveled tablets with a breakline on one side. 'W' and '3' engraved on breakline side and plain on the other side of tablet.

REGISTRATION NUMBER:

To be allocated.

NAME AND BUSINESS ADDRESS OF THE HOLDER CERTIFICATE OF REGISTRATION:

CIPLA MEDPRO (PTY) LTD

Rosen Heights

Pasita Street

Rosen Park, Bellville

7530

DATE OF PUBLICATION OF THIS PATIENT LEAFLET: