1.6.3 Patient Information Leaflet

The Patient Information Leaflet for **Declot** (Warfarin Sodium Tablets USP 5 mg) is enclosed after this page.

PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

Declot (Warfarin Sodium Tablet USP 5mg)

Category of Distribution: Prescription Preparation (PP)

Pharmacological Classification: Anticoagulant

ATC Code: B01AA03

Read this entire leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

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

1. WHAT WARFARIN TABLET IS AND WHAT IT IS USED FOR

Warfarin is prescription medicine used to treat blood clots and to lower the chance of blood clots forming in your body. Blood clots can cause a stroke, heart attack, or other serious conditions if they form in the legs or lungs.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE WARFARIN TABLET

Do not take Warfarin tablet if you

- your risk of having bleeding problems is higher than the possible benefit of treatment. Your healthcare provider will decide if Warfarin is right for you.

- you are pregnant unless you have a m echanical heart valve. Warfarin may cause birth defects, miscarriage, or death of your unborn baby.
- you are allergic to Warfarin or any of the other ingredients in Warfarin.

Before taking Warfarin, tell your healthca re provider about all of your medical conditions, including if you:

• have bleeding problems
• fall often
• have liver problems
• have kidney problems or are undergoing dialysis
• have high blood pressure
• have a heart problem called congestive heart failure
• have diabetes
• plan to have any surgery or a dental procedure
• are pregnant or plan to become pregnant.
- Females who can becom e pregnant s hould use effective birth control during treatment, and for atleast 1 month after the last dose of Warfarin.

• are breastfeeding. You and your healthcare provider should decide if you will take Warfarin and breastfeed. Check your baby for br uising or bleeding if you take W arfarin and breastfeed.

Tell all of your health care providers and dentists that you are taking Warfarin. They should talk to the healthcare provider who prescribed Warfarin for you before you have **any** surgery or dental procedure.

Your W arfarin m ay need to be stopped for a short tim e or you m ay need your dose adjusted.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Other medicines and Warfarin Tablets

You m ay have a higher risk of bleeding if you take W arfarin and other m edicines that increase your risk of bleeding, including:

- a medicine that contains heparin
- other medicines to prevent or treat blood clots
- nonsteroidal anti-inflammatory drugs (NSAIDs)

Tell your healthcare provid er if you take any of th ese med icines. Ask your healthcare provider if you are not sure if your medicine is one listed above.

Many other medicines can interact with Warfarin and affect the dose you need or increase Warfarin side effects. Do not change or stop any of your m edicines or start any new medicines before you talk to your healthcare provider.

Do not take other medicines that contain Warfarin sodium while taking Warfarin.

Warfarin Tablets with food and drink

Some foods and beverages can interact with Warfarin and affect your treatment and dose.

Eat a norm al, balanced diet. T alk to your he althcare provider before you m ake any diet changes. Do not eat large am ounts of leafy, green vegetables. Leafy, green vegetables contain vitamin K.

Certain vegetable oils also contain large amounts of vitamin K. Too much vitamin K can lower the effect of Warfarin.

3. HOW TO TAKE WARFARIN TABLETS

• **Take Warfarin exactly as prescribed.** Your healthcare provider will adjust your dose from time to time depending on your response to Warfarin.

• **You must have regular blood tests and vi sits w ith your healthcare provider to monitor your condition.**

• Call your healthcare provider right away if you:

- take too much Warfarin
- are sick with diarrhea, an infection, or have a fever
- fall or injure yourself, especially if you hit your head. Your healthcare provider may need to check you.

If you take more Warfarin Tablets than you should

Do not take more medicine than your doctor tells you to. If you or anyone else has swallowed more tablets than doctor have prescribed, contact your nearest hospital causality department or doctor immediately. Take the medicine pack with you.

If you forget to take Warfarin Tablets

If you miss a dose of Warfarin, call your healthcare provider. Take the dose as soon as possible on the same day.

Do not take a double dose of Warfarin the next day to make up for a missed dose.

POSSIBLE SIDE EFFECTS

Warfarin can cause bleeding which can be serious and sometimes lead to death. This is because Warfarin is a blood thinner medicine that lowers the chance of blood clots forming in your body.

- You may have a higher risk of bleeding if you take Warfarin and:
  - are 65 years of age or older
  - have a history of stomach or intestinal bleeding
  - have high blood pressure (hypertension)
  - have a history of stroke, or "mini-stroke" (transient ischemic attack or TIA)
  - have serious heart disease
  - have a low blood count or cancer
  - have had trauma, such as an accident or surgery
  - have kidney problems

• **Death of skin tissue (skin necrosis or gangrene).** This can happen soon after starting Warfarin. It happens because blood clots form and block blood flow to an area of your body. Call your healthcare provider right away if you have pain, color, or temperature change to any area of your body. You may need medical care right away to prevent death or loss (amputation) of your affected body part.

• **Kidney problems.** Kidney injury may happen in people who take Warfarin. Tell your healthcare provider right away if you develop blood in your urine. Your healthcare

provider may do tests more often during treatment with Warfarin to check for bleeding if you already have kidney problems.

• **"Purple toes syndrome."** Call your healthcare provider right away if you have pain in your toes and they look purple in color or dark in color.

These are not all of the side effects of Warfarin. For more information, ask your healthcare provider or pharmacist.

HOW TO STORE WARFARIN TABLETS

• 'Store below 30°C in a dry place Protect from light'.

• Keep Warfarin in a tightly closed container.

• Follow your healthcare provider or pharmacist instructions about the right way to throw away outdated or unused Warfarin.

• Females who are pregnant should not handle crushed or broken Warfarin tablets.

Keep Warfarin and all medicines out of the reach of children.

CONTENTS OF THE PACK AND OTHER INFORMATION

What Warfarin Tablets contain

The **active** substance is Warfarin sodium

The **other** ingredients are: lactose monohydrate, Pregelatinized starch, Hydroxy propul cellulose, Isopropyl alcohol and magnesium stearate

What Warfarin Tablets looks like and contents of the pack

'Peach colored, round, biconvex, uncoated tablets debossed with 'M' and '83' separated by scoreline on one side and plain on another side.'

HDPE container of 30/100 Tablets, Such 1container is packed in a carton along with pack insert.

PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

Supplier

Macleods Pharmaceuticals Ltd.

304, Atlanta Arcade,

Marol Church Road, Andheri (East)

Mumbai- 400 059, India

Phone: +91-22-66762800

Fax: +91-22-2821 6599

E-mail: exports@macleodspharma.com

Manufacturer

Macleods Pharmaceuticals Ltd

Block N-2, Village: Theda,

PO: Lodhimajra, Tehsil Baddi,

Dist: Solan,

Himachal Pradesh – 174 101, India