

## **PACKAGE INFORMATION LEAFLET**

### **HETSOLID 110**

#### **(Dabigatran Etexilate Capsules 110 mg)**

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or 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 or pharmacist or Nurse. This includes any possible side effects not listed in this leaflet. See section 4

#### **What is in this leaflet**

1. What Dabigatran Etexilate Capsules is and what it is used for
2. Before you take Dabigatran Etexilate Capsules
3. How to take Dabigatran Etexilate Capsules
4. Possible side effects
5. How to store Dabigatran Etexilate Capsules
6. Further information

#### **1. What Dabigatran Etexilate Capsules is and what it is used for**

Dabigatran Etexilate Capsules contains the active substance dabigatran etexilate and belongs to a group of medicines called anticoagulants. It works by blocking a substance in the body which is involved in blood clot formation.

Dabigatran Etexilate Capsules is used in adults to:

- prevent blood clots in the brain (stroke) and other blood vessels in the body if you have a form of irregular heart rhythm called nonvalvular atrial fibrillation and at least one additional risk factor.
- treat blood clots in the veins of your legs and lungs and to prevent blood clots from reoccurring in the vein of your legs and lungs.

#### **2. Before you take Dabigatran Etexilate Capsules**

##### **Do not take Dabigatran Etexilate Capsules**

- if you are allergic to dabigatran etexilate or any of the other ingredients of this medicine (listed in section 6).
- if you have severely reduced kidney function.

- if you are currently bleeding.
- if you have a disease in an organ of the body that increases the risk of serious bleeding (e.g. stomach ulcer, injury or bleeding in the brain, recent surgery of the brain or eyes).
- if you have an increased tendency to bleed. This may be inborn, of unknown cause or due to other medicines.
- if you are taking medicines to prevent blood clotting (e.g. warfarin, rivaroxaban, apixaban or heparin), except when changing anticoagulant treatment, while having a venous or arterial line and you get heparin through this line to keep it open or while your heart beat is being restored to normal by a procedure called catheter ablation for atrial fibrillation.
- if you have a severely reduced liver function or liver disease which could possibly cause death.
- if you are taking oral ketoconazole or itraconazole, medicines to treat fungal infections.
- if you are taking oral cyclosporine, a medicine to prevent organ rejection after transplantation.
- if you are taking dronedarone, a medicine used to treat abnormal heart beat.
- if you are taking a combination product of glecaprevir and pibrentasvir, an antiviral medicine used to treat hepatitis C.
- if you have received an artificial heart valve which requires permanent blood thinning.

### **Warnings and precautions**

Talk to your doctor before taking Dabigatran Etextilate Capsules. You may also need to talk to your doctor during treatment with Dabigatran Etextilate Capsules if you experience symptoms or if you have to undergo surgery.

**Tell your doctor** if you have or have had any medical conditions or illnesses, in particular any of those included in the following list:

- if you have an increased bleeding risk, such as:
  - if you have been recently bleeding.
  - if you have had a surgical tissue removal (biopsy) in the past month.
  - if you have had a serious injury (e.g. a bone fracture, head injury or any injury requiring surgical treatment).
  - if you are suffering from an inflammation of the gullet or stomach.
  - if you have problems with reflux of gastric juice into the gullet.
  - if you are receiving medicines which could increase the risk of bleeding. See 'Other medicines and Dabigatran Etextilate Capsules' below.

- if you are taking anti-inflammatory medicines such as diclofenac, ibuprofen, piroxicam.
- if you are suffering from an infection of the heart (bacterial endocarditis).
- if you know you have impaired kidney function, or you are suffering from dehydration (symptoms include feeling thirsty and passing reduced amounts of dark-coloured (concentrated) urine).
- if you are older than 75 years.
- if you weigh 50 kg or less.

- if you have had a heart attack or if you have been diagnosed with conditions that increase the risk to develop a heart attack.

-if you have a liver disease that is associated with changes in the blood tests. The use of Dabigatran Etextilate Capsules is not recommended in this case.

### **Take special care with Dabigatran Etextilate Capsules**

- if you need to have an operation:

In this case Dabigatran Etextilate Capsules will need to be stopped temporarily due to an increased bleeding risk

during and shortly after an operation. It is very important to take Dabigatran Etextilate Capsules before and after the

operation exactly at the times you have been told by your doctor.

- if an operation involves a catheter or injection into your spinal column (e.g. for epidural or spinal anaesthesia or pain reduction):

- it is very important to take Dabigatran Etextilate Capsules before and after the operation exactly at the times you have been told by your doctor.
- tell your doctor immediately if you get numbness or weakness of your legs or problems with your bowel or bladder after the end of anaesthesia, because urgent care is necessary.

- if you fall or injure yourself during treatment, especially if you hit your head. Please seek urgent medical attention You may need to be checked by a doctor, as you may be at increased risk of bleeding.

- if you know that you have a disease called antiphospholipid syndrome (a disorder of the immune system that causes an increased risk of blood clots), tell your doctor who will decide if the treatment may need to be changed.

### **Children and adolescents**

Dabigatran Etexilate Capsules is not recommended in children and adolescents below 18 years old.

### **Other medicines and Dabigatran Etexilate Capsules**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. **In particular you should tell your doctor before taking Dabigatran Etexilate Capsules , if you are taking one of the medicines listed below:**

- Medicines to reduce blood clotting (e.g. warfarin, phenprocoumon, acenocoumarol, heparin, clopidogrel, prasugrel, ticagrelor, rivaroxaban, acetylsalicylic acid)
- Medicines to treat fungal infections (e.g. ketoconazole, itraconazole), unless they are only applied to the skin
- Medicines to treat abnormal heart beats (e.g. amiodarone, dronedarone, quinidine, verapamil).

If you are taking verapamil containing medicines, your doctor will tell you to use a reduced dose of Pradaxa. See section 3.

- Medicines to prevent organ rejection after transplantation (e.g. tacrolimus, cyclosporine)
- A combination product of glecaprevir and pibrentasvir (an antiviral medicine used to treat hepatitis C)
- Anti-inflammatory and pain reliever medicines (e.g. acetylsalicylic acid, ibuprofen, diclofenac)
- St. John's wort, a herbal medicine for depression
- Antidepressant medicines called selective serotonin re-uptake inhibitors or serotonin-norepinephrine re-uptake inhibitors
- Rifampicin or clarithromycin (two antibiotics)
- Anti-viral medicines for AIDS (e.g. ritonavir)
- Certain medicines for treatment of epilepsy (e.g. carbamazepine, phenytoin)

### **Pregnancy and breast-feeding**

The effects of Dabigatran Etexilate Capsules on pregnancy and the unborn child are not known. You should not take Dabigatran Etexilate Capsules if you are pregnant unless your doctor advises you that it is safe to do so. If you are a woman of child-bearing age, you should avoid becoming pregnant while you are taking Dabigatran Etexilate Capsules .

You should not breast-feed while you are taking Dabigatran Etexilate Capsules .

### **Driving and using machines**

Dabigatran Etextilate Capsules has no known effects on the ability to drive or use machines.

### **3. How to take Dabigatran Etextilate Capsules**

Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure. The recommended dose is 300 mg taken as one **150 mg capsule twice a day**.

If you are **80 years or older**, the recommended dose of Dabigatran Etextilate Capsules is 220 mg taken as **one 110 mg capsule twice daily**.

If you are taking **verapamil containing medicines**, you should be treated with a reduced Dabigatran Etextilate Capsules dose of 220 mg taken as **one 110 mg capsule twice a day**, because your bleeding risk may be increased.

If you have a **potentially higher risk for bleeding**, your doctor may decide to prescribe a dose of Dabigatran Etextilate Capsules 220 mg taken as **one 110 mg capsule twice a day**.

You can continue to take Dabigatran Etextilate Capsules if your heart beat needs to be restored to normal by a procedure called cardioversion or by a procedure called catheter ablation for atrial fibrillation. Take Dabigatran Etextilate Capsules as your physician has told you.

If a medical device (stent) has been deployed in a blood vessel to keep it open in a procedure called percutaneous coronary intervention with stenting, you can be treated with Dabigatran Etextilate Capsules after your physician has decided that normal control of blood coagulation is achieved. Take Dabigatran Etextilate Capsules as your physician has told you.

### **How to take Dabigatran Etextilate Capsules**

Dabigatran Etextilate Capsules can be taken with or without food. The capsule should be swallowed whole with a glass of water, to ensure delivery to the stomach. Do not break, chew, or empty the pellets from the capsule since this may increase the risk of bleeding.

### **Change of anticoagulant treatment**

Without specific guidance from your doctor do not change your anticoagulant treatment.

**If you take more Dabigatran Etextilate Capsules than you should**

Taking too much Dabigatran Etexilate Capsules increases the risk of bleeding. Contact your doctor immediately if you have taken too many Dabigatran Etexilate Capsules capsules. Specific treatment options are available.

### **If you forget to take Dabigatran Etexilate Capsules**

A forgotten dose can still be taken up to 6 hours prior to the next due dose.

A missed dose should be omitted if the remaining time is below 6 hours prior to the next due dose. Do not take a double dose to make up for a forgotten dose.

### **If you stop taking Dabigatran Etexilate Capsules**

Take Dabigatran Etexilate Capsules exactly as prescribed. Do not stop taking Dabigatran Etexilate Capsules without talking to your doctor first,

because the risk of developing a blood clot could be higher if you stop treatment too early.

Contact your doctor if you experience indigestion after taking Dabigatran Etexilate Capsules .

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

## **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Dabigatran Etexilate Capsules affects blood clotting, so most side effects are related to signs such as bruising or bleeding. Major or severe bleeding may occur, these constitute the most serious side effects and, regardless of location, may become disabling, life-threatening or even lead to death. In some cases these bleedings may not be obvious.

If you experience any bleeding event that does not stop by itself or if you experience signs of excessive bleeding (exceptional weakness, tiredness, paleness, dizziness, headache or unexplained swelling) consult your doctor immediately. Your doctor may decide to keep you under closer observation or change your medicine.

Tell your doctor immediately, if you experience a serious allergic reaction which causes difficulty in breathing or dizziness.

Possible side effects are listed below, grouped by how likely they are to happen. Prevention of brain or body vessel obstruction by blood clot formation developing after abnormal heart beats.

Common (may affect up to 1 in 10 people):

- Bleeding may happen from the nose, into the stomach or bowel, from penis/vagina or urinary tract (incl. blood in the urine that stains the urine pink or red), or under the skin
- A fall in the number of red cells in the blood

- Belly ache or stomach ache
- Indigestion
- Frequent loose or liquid bowel movements
- Feeling sick

Uncommon (may affect up to 1 in 100 people):

- Bleeding
- Bleeding may happen from piles, from the rectum, or in the brain
- Haematoma formation
- Coughing of blood or blood stained sputum
- A fall in the number of platelets in the blood
- A fall in the amount of haemoglobin in the blood (the substance in the red blood cells)
- Allergic reaction
- Sudden change of the skin which affects its colour and appearance
- Itching
- Ulcer in the stomach or bowel (incl. ulcer in the gullet)
- Inflammation of the gullet and stomach Reflux of gastric juice into the gullet
- Vomiting
- Difficulty in swallowing
- Unusual laboratory test results on liver function

Rare (may affect up to 1 in 1,000 people):

- Bleeding may happen into a joint, from a surgical incision, from an injury, from the site of entry of an injection or from the site of entry of a catheter into a vein
- Serious allergic reaction which causes difficulty in breathing or dizziness
- Serious allergic reaction which causes swelling of the face or throat
- Skin rash notable for dark red, raised, itchy bumps caused by an allergic reaction
- A decrease in the proportion of red cells in the blood
- Liver enzymes increased
- Yellowing of the skin or whites of the eyes, caused by liver or blood problems

Not known (frequency cannot be estimated from the available data):

- Difficulty in breathing or wheezing

- Decreases in the number or even lack of white blood cells (which help to fight infections)
- Hair loss

In a clinical trial the rate of heart attacks with Dabigatran Etxilate Capsules was numerically higher than with warfarin. The overall occurrence was low.

Treatment of blood clots in the veins of your legs and lungs including prevention of blood clots from re-occurring in the veins of your legs and/or lungs.

Common (may affect up to 1 in 10 people):

- Bleeding may happen from the nose, into the stomach or bowel, from the rectum, from penis/vagina or urinary tract (incl. blood in the urine that stains the urine pink or red), or under the skin
- Indigestion

Uncommon (may affect up to 1 in 100 people):

- Bleeding
- Bleeding may happen into a joint or from an injury
- Bleeding may happen from piles
- A fall in the number of red cells in the blood
- Haematoma formation
- Coughing of blood or blood stained sputum
- Allergic reaction
- Sudden change of the skin which affects its colour and appearance
- Itching
- Ulcer in the stomach or bowel
- Inflammation of the gullet and stomach
- Reflux of gastric juice into the gullet
- Feeling sick
- Vomiting
- Belly ache or stomach ache
- Frequent loose or liquid bowel movements
- Unusual laboratory test results on liver function
- Liver enzymes increased

Rare (may affect up to 1 in 1,000 people):

- Bleeding may happen, from a surgical incision, or from the site of entry of an injection or from the site of entry of a catheter into a vein or from the brain
- A fall in the number of platelets in the blood
- Serious allergic reaction which causes difficulty in breathing or dizziness
- Serious allergic reaction which causes swelling of the face or throat
- Skin rash notable for dark red, raised, itchy bumps caused by an allergic reaction
- Difficulty in swallowing
- A decrease in the proportion of red cells in the blood

Not known (frequency cannot be estimated from the available data):

- Difficulty in breathing or wheezing
- A fall in the amount of haemoglobin in the blood (the substance in the red blood cells)
- A fall in the number of red cells in the blood
- Decreases in the number or even lack of white blood cells (which help to fight infections)
- Yellowing of the skin or whites of the eyes, caused by liver or blood problems
- Hair loss

In the trial program the rate of heart attacks with Dabigatran Etxilate Capsules was higher than with warfarin. The overall occurrence was low. No imbalance in the rate of heart attacks was observed in patients treated with dabigatran versus patients treated with placebo.

### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

### **5. How to store Dabigatran Etxilate Capsules**

- Keep out of reach of children.
- Store below 30°C.
- Store this medicine in the original package and keep the bottle tightly closed in order to protect from moisture.
- Do not use this medicine after the expiry date which is stated on the carton after “EXP”. The expiry date refers to the last day of that month.

- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

#### 6. Contents of the pack and other information

##### What Dabigatran Etxilate Capsules contains

- The active substance is Dabigatran Etxilate mesylate. Each capsule contains Dabigatran Etxilate Mesylate equivalent to Dabigatran Etxilate 150 mg
- The other ingredients are:** Tartaric acid, Hypromellose, Talc, Sugar Spheres, Hydroxylpropyl cellulose, Empty Hard HMPC capsule shells.

##### Empty Hard HMPC capsule shells composition

FDA/E172 Red Iron Oxide, FDA/E172 Yellow Iron Oxide, FD&C Blue #1, FD&C Red #40, Titanium Dioxide, Water, Hypromellose, Black SW-9008/SW-9009 Printing Ink.

##### What Dabigatran Etxilate Capsules looks like?

##### Dabigatran Etxilate Capsules 110

Cream opaque cap/Cream opaque body size '1' HPMC capsules imprinted with 'H' on cap and 'D16' on body with black ink, filled with mixture of off white to yellowish white pellets.

##### Supplier and Manufacturer:

| Supplier                                                                                                                                                                                                                                                                          | Manufacturer                                                                                                                                                                       |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
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