Package leaflet: Information for the user

Blovarak 2.5 mg film-coated tablets

apixaban

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, 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. See section 4.

What is in this leaflet

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

1. What Blovarak is and what it is used for

Blovarak contains the active substance apixaban and belongs to a group of medicines called anticoagulants. This medicine helps to prevent blood clots from forming by blocking Factor Xa, which is an important component of blood clotting.

Blovarak is used in adults:
- to prevent blood clots (deep vein thrombosis [DVT]) from forming after hip or knee replacement operations. After an operation to the hip or knee you may be at a higher risk of developing blood clots in your leg veins. This can cause the legs to swell, with or without pain. If a blood clot travels from your leg to your lungs, it can block blood flow causing breathlessness, with or without chest pain. This condition (pulmonary embolism) can be life-threatening and requires immediate medical attention.
- to prevent a blood clot from forming in the heart in patients with an irregular heart beat (atrial fibrillation) and at least one additional risk factor. Blood clots may break off and travel to the brain and lead to a stroke or to other organs and prevent normal blood flow to that organ (also known as a systemic embolism). A stroke can be life-threatening and requires immediate medical attention.
- to treat blood clots in the veins of your legs (deep vein thrombosis) and in the blood vessels of your lungs (pulmonary embolism), and to prevent blood clots from re-occurring in the blood vessels of your legs and/or lungs.

Blovarak is used in children aged 28 days to less than 18 years to treat blood clots and to prevent re-occurrence of blood clots in the veins or in the blood vessels of the lungs.

For body weight appropriate recommended dose, see section 3.

2. What you need to know before you take Blovarak Do not

take Blovarak:
- **if you are allergic** to apixaban or any of the other ingredients of this medicine (listed in section 6);
- you are **bleeding excessively**
- if you have a **disease in an organ** of the body that increases the risk of serious bleeding (such as **an active or a recent ulcer** of your stomach or bowel, **recent bleeding in your brain**)
- if you have a **liver disease** which leads to increased risk of bleeding (hepatic coagulopathy)
- if you are **taking medicines to prevent blood clotting** (e.g. warfarin, rivaroxaban, dabigatran 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 if a tube is inserted into your blood vessel (catheter ablation) to treat an irregular heartbeat (arrhythmia).

Warnings and precautions
Talk to your doctor, pharmacist or nurse before you take this medicine if you have any of the following:
- an **increased risk of bleeding**, such as:
  - **bleeding disorders**, including conditions resulting in reduced platelet activity
  - **very high blood pressure,** not controlled by medical treatment
  - you are older than 75 years
  - you weigh 60 kg or less
- **a severe kidney disease or if you are on dialysis**
- **a liver problem or a history of liver problems**
  This medicine will be used with caution in patients with signs of altered liver function.
- **had a tube (catheter) or an injection into your spinal column** (for anaesthesia or pain reduction), your doctor will tell you to take this medicine 5 hours or more after catheter removal
- if you have a **prosthetic heart valve**
- if your doctor determines that your blood pressure is unstable or another treatment or surgical procedure to remove the blood clot from your lungs is planned.

Take special care with Blovarak
- 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.

If you need to have surgery or a procedure which may cause bleeding, your doctor might ask you to temporarily stop taking this medicine for a short while. If you are not sure whether a procedure may cause bleeding ask your doctor.

Children and adolescents
This medicine is not recommended in children and adolescents with a body weight of less than 35 kg.

Other medicines and Blovarak
Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines.

Some medicines may increase the effects of Blovarak and some may decrease its effects. Your doctor will decide, if you should be treated with Blovarak when taking these medicines and how closely you should be monitored.

The following medicines may increase the effects of Blovarak and increase the chance for unwanted bleeding:
- some **medicines for fungal infections** (e.g. ketoconazole, etc.)
- some **antiviral medicines for HIV/AIDS** (e.g. ritonavir)
- other **medicines that are used to reduce blood clotting** (e.g. enoxaparin, etc.)
- **anti-inflammatory** or **pain medicines** (e.g. acetylsalicylic acid or naproxen). Especially, if you are older than 75 years and are taking acetylsalicylic acid, you may have an increased chance of bleeding
- **medicines for high blood pressure or heart problems** (e.g. diltiazem)
- **antidepressant medicines** called **selective serotonin re-uptake inhibitors** or **serotonin norepinephrine re-uptake inhibitors.**

The following medicines may reduce the ability of Blovarak to help prevent blood clots from forming:
- **medicines to prevent epilepsy or seizures** (e.g. phenytoin, etc.)
- **St John's Wort** (a herbal supplement used for depression)
- **medicines to treat tuberculosis** or **other infections** (e.g. rifampicin).

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor, pharmacist or nurse for advice before taking this medicine.

The effects of Blovarak on pregnancy and the unborn child are not known. You should not take this medicine if you are pregnant. **Contact your doctor immediately** if you become pregnant while taking this medicine.

It is not known if Blovarak passes into human breast milk. Ask your doctor, pharmacist or nurse for advice before taking this medicine while breast-feeding. They will advise you whether to stop breast-feeding or to stop/not start taking this medicine.

Driving and using machines
Blovarak has not been shown to impair your ability to drive or use machines.

Blovarak contains lactose (a type of sugar) and sodium.
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Blovarak

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

Dose
Swallow the tablet with a drink of water. Blovarak can be taken with or without food. Try to take the tablets at the same times every day to have the best treatment effect.

If you have difficulty swallowing the tablet whole, talk to your doctor about other ways to take Blovarak.

The tablet may be crushed and mixed with water, or 5% glucose in water, or apple juice or apple puree, immediately before you take it.

Instructions for crushing:
- Crush the tablets with a pestle and mortar.
- Transfer all the powder carefully into a suitable container then mix the powder with a little e.g. 30 mL (2 tablespoons), water or one of the other liquids mentioned above to make a mixture.
- Swallow the mixture.
- Rinse the pestle and mortar you used for crushing the tablet and the container, with a little water or one of the other liquids (e.g. 30 mL), and swallow the rinse.

If necessary, your doctor may also give you the crushed Blovarak tablet mixed in 60 mL of water or 5% glucose in water, through a nasogastric tube.

Take Blovarak as recommended for the following:

<u>To prevent blood clots from forming after hip or knee replacement operations.</u>
The recommended dose is one tablet of Blovarak 2.5 mg twice a day. For example, one in the morning and one in the evening.
You should take the first tablet 12 to 24 hours after your operation.

If you have had a major **hip** operation you will usually take the tablets for 32 to 38 days.
If you have had a major **knee** operation you will usually take the tablets for 10 to 14 days.

<u>To prevent a blood clot from forming in the heart in patients with an irregular heart beat and at least one additional risk factor.</u>
The recommended dose is one tablet of Blovarak **5 mg** twice a day.

The recommended dose is one tablet of Blovarak **2.5 mg** twice a day if:
- you have **severely reduced kidney function**
- **two or more of the following apply to you:**
  - your blood test results suggest poor kidney function (value of serum creatinine is 1.5 mg/dL (133 micromole/L) or greater)
  - you are 80 years old or older
  - your weight is 60 kg or lower.

The recommended dose is one tablet twice a day, for example, one in the morning and one in the evening.
Your doctor will decide how long you must continue treatment for.

<u>To treat blood clots in the veins of your legs and blood clots in the blood vessels of your lungs</u>
The recommended dose is **two tablets** of Blovarak **5 mg** twice a day for the first 7 days, for example, two in the morning and two in the evening.
After 7 days the recommended dose is **one tablet** of Blovarak **5 mg** twice a day, for example, one in the morning and one in the evening.

<u>For preventing blood clots from re-occurring following completion of 6 months of treatment</u>
The recommended dose is one tablet of Blovarak **2.5 mg** twice a day for example, one in the morning and one in the evening.
Your doctor will decide how long you must continue treatment for.

<u>Use in children and adolescents</u>

For treating blood clots and to prevent re-occurrence of blood clots in the veins or in the blood vessels of your lungs.

Always take or give this medicine exactly as your or the child's doctor or pharmacist has told you. Check with your or the child's doctor, pharmacist or nurse if you are not sure.

Try to take or give the dose at the same times every day to have the best treatment effect.

The dose of Blovarak depends on the body weight, and will be calculated by the doctor.

The recommended dose for children and adolescents weighing at least 35 kg is **four tablets** of Blovarak **2.5 mg** twice a day for the first 7 days, for example, four in the morning and four in the evening.

After 7 days the recommended dose is **two tablets** of Blovarak **2.5 mg** twice a day, for example, two in the morning and two in the evening.

For parents or caregivers: please observe the child to ensure that the full dose is taken.

It is important to keep scheduled doctor's visits because the dose may need to be adjusted as the weight changes.

Your doctor might change your anticoagulant treatment as follows:

Changing from Blovarak to anticoagulant medicines
Stop taking Blovarak. Start treatment with the anticoagulant medicines (for example heparin) at the time you would have taken the next tablet.

Changing from anticoagulant medicines to Blovarak
Stop taking the anticoagulant medicines. Start treatment with Blovarak at the time you would have had the next dose of anticoagulant medicine, then continue as normal.

Changing from treatment with anticoagulant containing vitamin K antagonist (e.g. warfarin) to Blovarak
Stop taking the medicine containing a vitamin K antagonist. Your doctor needs to do blood-measurements and instruct you when to start taking Blovarak.

Changing from Blovarak to anticoagulant treatment containing vitamin K antagonist (e.g. warfarin).
If your doctor tells you that you have to start taking the medicine containing a vitamin K antagonist, continue to take Blovarak for at least 2 days after your first dose of the medicine containing a vitamin K antagonist. Your doctor needs to do blood-measurements and instruct you when to stop taking Blovarak.

Patients undergoing cardioversion
If your abnormal heartbeat needs to be restored to normal by a procedure called cardioversion, take this medicine at the times your doctor tells you, to prevent blood clots in blood vessels in your brain and other blood vessels in your body.

If you take more Blovarak than you should
Tell your doctor immediately if you have taken more than the prescribed dose of this medicine. Take the medicine pack with you, even if there are no tablets left.

If you take more Blovarak than recommended, you may have an increased risk of bleeding. If bleeding occurs, surgery, blood transfusions or other treatments that may reverse anti-factor Xa activity may be

required.

If you forget to take Blovarak
- If you miss a morning dose, take it as soon as you remember and it may be taken together with the evening dose.
- A missed evening dose can only be taken during the same evening. Do not take two doses the next morning, instead continue to follow the dosing schedule twice daily as recommended on the next day.

If you are not sure what to do or have missed more than one dose, ask your doctor, pharmacist or nurse.

If you stop taking Blovarak
Do not stop taking this medicine without talking to your doctor first, because the risk of developing a blood clot could be higher if you stop treatment too early.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Blovarak can be given for three different medical conditions. The known side effects and how frequently they occur for each of these medical conditions may differ and are listed separately below. For these conditions, the most common general side effect of this medicine is bleeding which may be potentially life threatening and require immediate medical attention.

<u>The following side effects are known if you take Blovarak to prevent blood clots from forming after hip or knee replacement operations.</u>

Common side effects (may affect up to 1 in 10 people)
- Anaemia which may cause tiredness or paleness
- Bleeding including: bruising and swelling
- Nausea (feeling sick).

Uncommon side effects (may affect up to 1 in 100 people)
- Reduced number of platelets in your blood (which can affect clotting)
- Bleeding:
  - occurring after your operation including bruising and swelling, blood or liquid leaking from the surgical wound/incision (wound secretion) or injection site
  - in your stomach, bowel or bright/red blood in the stools
  - blood in the urine
  - from your nose
  - from the vagina.

- Low blood pressure which may make you feel faint or have a quickened heartbeat
- Blood tests may show:
  - abnormal liver function
  - an increase in some liver enzymes
  - an increase in bilirubin, a breakdown product of red blood cells, which can cause yellowing of the skin and eyes.
- Itching.

Rare side effects (may affect up to 1 in 1,000 people)
- Allergic reactions (hypersensitivity) which may cause: swelling of the face, lips, mouth, tongue and/or throat and difficulty breathing. **Contact your doctor immediately** if you experience any of these symptoms.
- Bleeding:
  - into a muscle
  - in your eyes
  - from your gums and blood in your spit when coughing
  - from your rectum.
- Hair loss.

Not known (frequency cannot be estimated from the available data)
- Bleeding:
  - in your brain or in your spinal column
  - in your lungs or your throat
  - in your mouth
  - into your abdomen or space behind your abdominal cavity
  - from a haemorrhoid
  - tests showing blood in the stools or in the urine
- Skin rash which may form blisters and looks like small targets (central dark spots surrounded by a paler area, with a dark ring around the edge) *(erythema multiforme)*.
- Blood vessel inflammation (vasculitis) which may result in skin rash or pointed, flat, red, round spots under the skin's surface or bruising.
- Bleeding in the kidney sometimes with presence of blood in urine leading to inability of the kidneys to work properly (anticoagulant-related nephropathy).

The following side effects are known if you take Blovarak to prevent a blood clot from forming in the heart in patients with an irregular heart beat and at least one additional risk factor.

Common side effects (may affect up to 1 in 10 people)
- Bleeding including:
  - in your eyes
  - in your stomach or bowel
  - from your rectum - blood in the urine
  - from your nose
  - from your gums
  - bruising and swelling
- Anaemia which may cause tiredness or paleness
- Low blood pressure which may make you feel faint or have a quickened heartbeat
- Nausea (feeling sick)
- Blood tests may show:
  - an increase in gamma-glutamyltransferase (GGT)

Uncommon side effects (may affect up to 1 in 100 people)

- Bleeding:
  - in your brain or in your spinal column
  - in your mouth or blood in your spit when coughing
  - into your abdomen, or from the vagina
  - bright/red blood in the stools
  - bleeding occurring after your operation including bruising and swelling, blood or liquid leaking from the surgical wound/incision (wound secretion) or injection site
  - from a haemorrhoid
  - tests showing blood in the stools or in the urine
- Reduced number of platelets in your blood (which can affect clotting)
- Blood tests may show:
  - abnormal liver function
  - an increase in some liver enzymes
  - an increase in bilirubin, a breakdown product of red blood cells, which can cause yellowing of the skin and eyes
- Skin rash
- Itching
- Hair loss
- Allergic reactions (hypersensitivity) which may cause: swelling of the face, lips, mouth, tongue and/or throat and difficulty breathing. **Contact your doctor immediately** if you experience any of these symptoms.

Rare side effects (may affect up to 1 in 1,000 people)
- Bleeding:
  - in your lungs or your throat
  - into the space behind your abdominal cavity
  - into a muscle.

Very rare side effects (may affect up to 1 in 10,000 people)
- Skin rash which may form blisters and looks like small targets (central dark spots surrounded by a paler area, with a dark ring around the edge) *(erythema multiforme)*.

Not known (frequency cannot be estimated from the available data)
- Blood vessel inflammation (vasculitis) which may result in skin rash or pointed, flat, red, round spots under the skin's surface or bruising.
- Bleeding in the kidney sometimes with presence of blood in urine leading to inability of the kidneys to work properly (anticoagulant-related nephropathy).

<u>The following side effects are known if you take Blovarak to treat or prevent re-occurrence of blood clots in the veins of your legs and blood clots in the blood vessels of your lungs.</u>

Common side effects (may affect up to 1 in 10 people)
- Bleeding including:
  - from your nose
  - from your gums
  - blood in the urine
  - bruising and swelling
  - in your stomach, your bowel, from your rectum
  - in your mouth
  - from the vagina
- Anaemia which may cause tiredness or paleness
- Reduced number of platelets in your blood (which can affect clotting)

- Nausea (feeling sick)
- Skin rash
- Blood tests may show:
  - an increase in gamma-glutamyltransferase (GGT) or alanine aminotransferase (ALT)

Uncommon side effects (may affect up to 1 in 100 people)
- Low blood pressure which may make you feel faint or have a quickened heartbeat
- Bleeding:
  - in your eyes
  - in your mouth or blood in your spit when coughing
  - bright/red blood in the stools
  - tests showing blood in the stools or in the urine
  - bleeding occurring after your operation including bruising and swelling, blood or liquid leaking from the surgical wound/incision (wound secretion) or injection site
  - from a haemorrhoid
  - into a muscle.
- Itching
- Hair loss
- Allergic reactions (hypersensitivity) which may cause: swelling of the face, lips, mouth, tongue and/or throat and difficulty breathing. **Contact your doctor immediately** if you experience any of these symptoms.
- Blood tests may show:
  - abnormal liver function
  - an increase in some liver enzymes
  - an increase in bilirubin, a breakdown product of red blood cells, which can cause yellowing of the skin and eyes.

Rare side effects (may affect up to 1 in 1,000 people)
- Bleeding:
  - in your brain or in your spinal column
  - in your lungs.

Not known (frequency cannot be estimated from the available data)
- Bleeding:
  - into your abdomen or the space behind your abdominal cavity
- Skin rash which may form blisters and looks like small targets (central dark spots surrounded by a paler area, with a dark ring around the edge) (*erythema multiforme*).
- Blood vessel inflammation (vasculitis) which may result in skin rash or pointed, flat, red, round spots under the skin's surface or bruising.
- Bleeding in the kidney sometimes with presence of blood in urine leading to inability of the kidneys to work properly (anticoagulant-related nephropathy).

<u>Additional side effects in children and adolescents</u>

Tell the child's doctor immediately if you observe any of these symptoms;
- Allergic reactions (hypersensitivity) which may cause: swelling of the face, lips, mouth, tongue and/or throat and difficulty breathing. The frequency of these side effects is common (may affect up to 1 in 10 people).

In general, the side effects observed in children and adolescents treated with Blovarak were similar in type to those observed in adults and were primarily mild to moderate in severity. Side effects that were observed more often in children and adolescents were nose bleed and abnormal vaginal bleeding.

Very Common side effects (may affect more than 1 in 10 people)
- Bleeding including:
- from the vagina;
- from the nose.

Common side effects (may affect up to 1 in 10 people)
- Bleeding including:
    - from the gums;
    - blood in the urine;
    - bruising and swelling;
    - from the bowel or rectum;
    - bright/red blood in the stools;
    - bleeding after an operation including bruising and swelling, blood or liquid leaking from the surgical wound/incision (wound secretion) or injection site;
- Hair loss;
- Anaemia which may cause tiredness or paleness;
- Reduced number of platelets in the child's blood (which can affect clotting);
- Nausea (feeling sick);
- Skin rash;
- Itching;
- Low blood pressure which may make the child feel faint or have a quickened heartbeat;
- Blood tests may show:
    - abnormal liver function;
    - an increase in some liver enzymes;
    - an increase in alanine aminotransferase (ALT).

Not known (frequency cannot be estimated from the available data)
- Bleeding:
    - into the abdomen or the space behind the abdominal cavity;
    - in the stomach;
    - in the eyes;
    - in the mouth;
    - from a haemorrhoid;
    - in the mouth or blood in the spit when coughing;
    - in the brain or in the spinal column;
    - in the lungs;
    - into a muscle;
- Skin rash which may form blisters and looks like small targets (central dark spots surrounded by a paler area, with a dark ring around the edge) *(erythema multiforme);*
- Blood vessel inflammation (vasculitis) which may result in skin rash or pointed, flat, red, round spots under the skin's surface or bruising;
- Blood tests may show:
    - an increase in gamma-glutamyltransferase (GGT);
    - tests showing blood in the stools or in the urine.

- Bleeding in the kidney sometimes with presence of blood in urine leading to inability of the kidneys to work properly (anticoagulant-related nephropathy).

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

Ireland
HPRA Pharmacovigilance
Website: www.hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Blovarak

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and on the blister after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

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 Blovarak contains
- The active substance is apixaban. Each tablet contains 2.5 mg of apixaban.
- The other ingredients are:
  - Tablet core: mannitol (E421), cellulose, microcrystalline (E460), sodium laurilsulfate, croscarmellose sodium, magnesium stearate
  - Film coat: hypromellose type 2910/6 (E464), titanium dioxide (E171), lactose monohydrate, macrogol 3350, triacetin (E1518), iron oxide yellow (E172)

What Blovarak looks like and contents of the pack
Round, biconvex, yellow film-coated tablets.

Al//PVC/PVDC blisters. Cartons of 10, 20, 60, 168 and 200 film-coated tablets.

Not all pack sizes may be marketed.

Patient Card: handling information
Inside the Blovarak pack together with the package leaflet you will find a Patient Card or your doctor might give you a similar card.
This Patient Card includes information that will be helpful to you and alert other doctors that you are taking Blovarak. **You should keep this card with you at all times**.

1. Take the card.
2. Separate your language as needed (this is facilitated by the perforated edges).
3. Complete the following sections or ask your doctor to do it:
- Name:
- Birth Date:
- Indication:
- Dose : .....mg twice daily
- Doctor's Name:

- Doctor's telephone:

4. Fold the card and keep it with you at all times

Marketing Authorisation Holder and Manufacturer

Les Laboratoires Servier
50, rue Carnot
92284 Suresnes cedex
France

This medicinal product is authorised in the Member States of the EEA under the following names:

Belgium	Blovarak 2,5 mg comprimés pelliculés, Blovarak 2,5 mg filmomhulde tabletten, & Blovarak 2,5 mg Filmtabletten
Bulgaria	Blovarak 2.5 mg film-coated tablets & Бловарак 2,5 mg филмирани таблетки
Greece	Blovarak 2.5 mg film-coated tablets
Ireland	Blovarak 2.5 mg film-coated tablets
Luxembourg	Blovarak 2,5 mg comprimés pelliculés, Blovarak 2,5 mg filmomhulde tabletten, & Blovarak 2,5 mg Filmtabletten
Romania	Blovarak 2.5 mg film-coated tablets
Spain	Blovarak 2.5 mg comprimidos recubiertos con película EFG

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