Package Leaflet: Information for the user
Fluidoro 10 mg film-coated tablets

prasugrel

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.
- 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. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Fluidoro is and what it is used for

Fluidoro, which contains the active substance prasugrel, belongs to a group of medicines called antiplatelet agents. Platelets are very small cell particles that circulate in the blood. When a blood vessel is damaged, for example if it is cut, platelets clump together to help form a blood clot (thrombus). Therefore, platelets are essential to help stop bleeding. If clots form within a hardened blood vessel such as an artery they can be very dangerous as they can cut off the blood supply, causing a heart attack (myocardial infarction), stroke or death. Clots in arteries supplying blood to the heart may also reduce the blood supply, causing unstable angina (a severe chest pain).

Fluidoro inhibits the clumping of platelets and so reduces the chance of a blood clot forming.

You have been prescribed Fluidoro because you have already had a heart attack or unstable angina and you have been treated with a procedure to open blocked arteries in the heart. You may also have had one or more stents placed to keep open a blocked or narrowed artery supplying blood to the heart. Fluidoro reduces the chances of you having a further heart attack or stroke or of dying from one of these atherothrombotic events. Your doctor will also give you acetylsalicylic acid (e.g. aspirin), another antiplatelet agent.

2. What you need to know before you take Fluidoro

Do not take Fluidoro
- If you are allergic to prasugrel or any of the other ingredients of this medicine (listed in section 6). An allergic reaction may be recognised as a rash, itching, a swollen face, swollen lips or shortness of breath. If this has happened to you, tell your doctor **immediately**.

- If you have a medical condition that is currently causing bleeding, such as bleeding from your stomach or intestines.
- If you have ever had a stroke or a transient ischaemic attack (TIA). - If you have severe liver disease.

Warnings and precautions

- **Before you are taking Fluidoro :**

Talk to your doctor before taking Fluidoro.

You should tell your doctor before taking Fluidoro if any of the situations mentioned below apply to you:

- If you have an increased risk of bleeding such as:
  - age of 75 years or older. Your doctor should prescribe a daily dose of 5 mg as there is a greater risk of bleeding in patients older than 75 years
  - a recent serious injury
  - recent surgery (including some dental procedures)
  - recent or recurrent bleeding from the stomach or intestines (e.g. a stomach ulcer or colon polyps)
  - body weight of less than 60 kg. Your doctor should prescribe a daily dose of 5 mg of Fluidoro if you weigh less than 60 kg
  - renal (kidney) disease or moderate liver problems
  - taking certain types of medicines (see 'Other medicines and Fluidoro ' below)
  - planned surgery (including some dental procedures) in the next seven days. Your doctor may wish you to stop taking Fluidoro temporarily due to the increased risk of bleeding
- If you have had allergic reactions (hypersensitivity) to clopidogrel or any other anti-platelet agent please tell your doctor before starting treatment with Fluidoro. If you then take Fluidoro and experience allergic reactions that may be recognised as a rash, itching, a swollen face, swollen lips or shortness of breath you need to tell your doctor **immediately.**

- **While you are taking Fluidoro:**

You should tell your doctor immediately if you develop a medical condition called Thrombotic Thrombocytopaenic Purpura (or TTP) that includes fever and bruising under the skin that may appear as red pinpoint dots, with or without unexplained extreme tiredness, confusion, yellowing of the skin or eyes (jaundice) (see section 4 'Possible side effects').

Children and adolescents
Fluidoro should not be used in children and adolescents below 18 years of age.

Other medicines and Fluidoro
Tell your doctor if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription, dietary supplements and herbal remedies.

It is particularly important to tell your doctor if you are being treated with:

- clopidogrel (an anti-platelet agent),
- warfarin (an anti-coagulant),
- "non steroidal anti inflammatory drugs" for pain and fever (such as ibuprofen, naproxen, etoricoxib).

If given together with Fluidoro these medicines may increase the risk of bleeding.

Tell your doctor if you are taking morphine or other opioids (used to treat severe pain).

Only take other medicines while you are on Fluidoro if your doctor tells you that you can.

Pregnancy and breast-feeding
Tell your doctor if you become pregnant or are trying to become pregnant while you are taking Fluidoro. You should use Fluidoro only after discussing with your doctor the potential benefits and any potential risks to your unborn child.
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines
Fluidoro is unlikely to affect your ability to drive or use machines.

Fluidoro contains lactose and sodium
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

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

3. How to take Fluidoro

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

The usual dose of Fluidoro is 10 mg per day. You will start the treatment with a single dose of 60 mg. If you weigh less than 60 kg or are more than 75 years of age, the dose is 5 mg Fluidoro per day. Your doctor will also tell you to take acetylsalicylic acid- (s) he will tell you the exact dose to take (usually between 75 mg and 325 mg daily).

You may take Fluidoro with or without food. Take your dose at around the same time every day. Do not break or crush the tablet.

It is important that you tell your doctor, dentist and pharmacist, that you are taking Fluidoro.

If you take more Fluidoro than you should
Contact your doctor or hospital straight away, as you may be at risk of excessive bleeding. You should show the doctor your pack of Fluidoro.

If you forget to take Fluidoro
If you miss your scheduled daily dose, take Fluidoro when you remember. If you forget your dose for an entire day, just resume taking Fluidoro at its usual dose the next day. Do not take a double dose to make up for a forgotten dose.

If you stop taking Fluidoro
Do not stop taking Fluidoro without consulting your doctor; if you stop taking Fluidoro too soon, your risk of a heart attack may be higher. It is important to take special care of your doctor before stopping Fluidoro, because both risk and benefits are based on regular use.

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.

Contact your doctor immediately if you notice any of the following:
- Sudden numbness or weakness of the arm, leg or face, especially if only on one side of the body.
- Sudden confusion, difficulty speaking or understanding others.
- Sudden difficulty in walking or loss of balance or co-ordination.
- Sudden dizziness or sudden severe headache with no known cause.

All of the above may be signs of a stroke. Stroke is an uncommon side effect of Fluidoro in patients who have never had a stroke or transient ischaemic attack (TIA).

Also contact your doctor immediately if you notice any of the following:
- Fever and bruising under the skin that may appear as red pinpoint dots, with or without unexplained extreme tiredness, confusion, yellowing of the skin or eyes (jaundice) (see section 2 'What you need to know before you take Fluidoro').
- A rash, itching, or a swollen face, swollen lips/tongue, or shortness of breath. These may be signs of a severe allergic reaction (see section 2 'What you need to know before you take Fluidoro').

Tell your doctor **promptly** if you notice any of the following:

- Blood in your urine.
- Bleeding from your rectum, blood in your stools or black stools.
- Uncontrollable bleeding, for example from a cut.

All of the above may be signs of bleeding, the most common side effect with Fluidoro. Although uncommon, severe bleeding can be life-threatening.

Common side effects (may affect up to 1 in 10 people)
- Bleeding in the stomach or bowels
- Bleeding from a needle puncture site
- Nose bleeds
- Skin rash
- Small red bruises on the skin (ecchymoses)
- Blood in urine
- Haematoma (bleeding under the skin at the site of an injection, or into a muscle, causing swelling)
- Low haemoglobin or red blood cell count (anaemia)
- Bruising

Uncommon side effects (may affect up to 1 in 100 people)
- Allergic reaction (rash, itching, swollen lips/tongue, or shortness of breath)
- Spontaneous bleeding from the eye, rectum, gums or in the abdomen around the internal organs
- Bleeding after surgery
- Coughing up blood

- Blood in stools

Rare side effects (may affect up to 1 in 1,000 people)
- Low blood platelet count
- Subcutaneous haematoma (bleeding under the skin causing a swelling)

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

Bulgarian Drug Agency
8 Damyan Gruev Str,
1303 Sofia
Tel .: +359 2 8903417
website: www.bda.bg

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

5. How to store Fluidoro

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 blister and carton after EXP. The expiry date refers to the last day of that month.

For AL / AL blisters: Store below 30 ° C. Do not throw away any medicines via wastewater or household waste. Ask your doctor how to dispose of medicines no longer required. These measures will help protect the environment.

6. Contents of the pack and other information

What Fluidoro contains
- The active substance is prasugrel.

Each tablet contains 10 mg of prasugrel.

- The other ingredients are:

Tablet core: sodium docusate, hydroxypropylcellulose (EF), mannitol, microcrystalline cellulose (PH 112), croscarmellose sodium, magnesium stearate.
Film coating: hypromellose (E 464), lactose monohydrate, triacetin, iron oxide yellow (E 172), titanium dioxide (E 171), iron oxide red (E 172), iron oxide black (E 172).

What Fluidoro looks like and contents of the pack
Fluidoro 10 mg film-coated tablet: brown, oblong film-coated tablet, debossed with “L452” on one side and smooth on the other.

Fluidoro is available in aluminum foil blisters containing 28 tablets.

Marketing Authorisation Holder and Manufacturer:
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