

Xydrel 75 mg Film-coated Tablets

Clopidogrel

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 any further questions, ask your doctor or your pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

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

1 What Xydrel is and what it is used for

Xydrel belongs to a group of medicines called antiplatelet medicinal products. Platelets are very small structures in the blood, which clump together during blood clotting. By preventing this clumping, antiplatelet medicinal products reduce the chances of blood clots forming (a process called thrombosis).

Xydrel is taken to prevent blood clots (thrombi) forming in hardened blood vessels (arteries), a process known as atherothrombosis, which can lead to atherothrombotic events (such as stroke, heart attack, or death).

You have been prescribed Xydrel to help prevent blood clots and reduce the risk of these severe events because:

- You have a condition of hardening of arteries (also known as atherosclerosis), and
- You have previously experienced a heart attack, stroke or have a condition known as peripheral arterial disease, or
- You have experienced a severe type of chest pain known as 'unstable angina' or 'myocardial infarction' (heart attack). For the treatment of this condition your doctor may have placed a stent in the blocked or narrowed artery to restore effective blood flow. You should also be given acetylsalicylic acid (a substance present in many medicines used to relieve pain and lower fever as well as to prevent blood clotting) by your doctor.
- You have an irregular heartbeat, a condition called 'atrial fibrillation', and you cannot take medicines known as 'oral anticoagulants' (vitamin K antagonists) which prevent new clots from forming and prevent existing clots from growing. You should have been told that 'oral anticoagulants' are more effective than acetylsalicylic acid or the combined use of Xydrel and acetylsalicylic acid for this condition. Your doctor should have prescribed Xydrel plus acetylsalicylic acid if you cannot take 'oral anticoagulants' and you do not have a risk of major bleeding.

2 Before you take Xydrel

Do not take Xydrel

- if you are allergic (hypersensitive) to clopidogrel, soya oil, peanut oil or any of the other ingredients of Xydrel (See section 6 for list of ingredients)
- if you have a medical condition that is currently causing bleeding such as a stomach ulcer or bleeding within the brain
- if you suffer from severe liver disease

If you think any of these apply to you, or if you are in any doubt at all, consult your doctor before taking Xydrel.

Take special care with Xydrel

If any of the situations mentioned below apply to you, you should tell your doctor before taking Xydrel:

- if you have a risk of bleeding such as
 - a medical condition that puts you at risk of internal bleeding (such as a stomach ulcer)
 - a blood disorder that makes you prone to internal bleeding (bleeding inside any tissues, organs or joints of your body).
 - a recent serious injury
 - a recent surgery (including dental)
 - a planned surgery (including dental) in the next seven days

- if you have had a clot in an artery of your brain (ischaemic stroke) which occurred within the last seven days
- if you have kidney or liver disease

While you are taking Xydrel:

- You should tell your doctor if a surgery (including dental) is planned.
- You should also tell your doctor immediately if you develop a medical condition (also known as Thrombotic Thrombocytopenic 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').
- If you cut or injure yourself, it may take longer than usual for bleeding to stop. This is linked to the way your medicine works as it prevents the ability of blood clots to form. For minor cuts and injuries, e.g. cutting yourself shaving, this is usually of no concern. However, if you are concerned by your bleeding, you should contact your doctor straightaway (see section 4 'POSSIBLE SIDE EFFECTS').
- Your doctor may order blood tests.

Xydrel is not intended for use in children or adolescents.

Taking other medicines:

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Some other medicines may influence the use of Xydrel or vice versa.

You should specifically tell your doctor if you take

- oral anticoagulants, medicines used to reduce blood clotting,
- a non-steroidal anti-inflammatory medicine, usually used to treat painful and/or inflammatory conditions of muscle or joints
- heparin or any other injectable medicine used to reduce blood clotting,
- omeprazole, esomeprazole or cimetidine, medicines to treat an upset stomach,
- fluconazole, voriconazole, ciprofloxacin, or chloramphenicol, medicines to treat bacterial and fungal infections,
- fluoxetine, fluvoxamine, or moclobemide, medicines to treat depression,
- carbamazepine, or oxcarbazepine, medicines to treat some forms of epilepsy,
- ticlopidine, other antiplatelet agent.

If you have experienced severe chest pain (unstable angina or heart attack), you may be prescribed Xydrel in combination with acetylsalicylic acid, a substance present in many medicines used to relieve pain and lower fever. An occasional use of acetylsalicylic acid (no more than 1,000 mg in any 24 hour period) should generally not cause a problem, but prolonged use in other circumstances should be discussed with your doctor.

Taking Xydrel with food and drink

Xydrel may be taken with or without food.

Pregnancy and breast-feeding

It is preferable not to take this product during pregnancy.

If you are pregnant or suspect that you are pregnant, you should tell your doctor or your pharmacist before taking Xydrel. If you become pregnant while taking Xydrel, consult your doctor immediately as it is recommended not to take clopidogrel while you are pregnant.

You should not breastfeed while taking this medicine.

If you are breastfeeding or planning to breastfeed, talk to your doctor before taking this medicine.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Xydrel is unlikely to affect your ability to drive or to use machines.

Important information about some of the ingredients of Xydrel

Xydrel contains lactose. If you have been told by your doctor that you have intolerance to some sugars (e.g. lactose), contact your doctor before taking this medicine. Xydrel contains soya oil. If you are allergic to peanut or soya, do not take this medicine.

3 How to take Xydrel

Always take Xydrel exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

If you have experienced severe chest pain (unstable angina or heart attack), your doctor may give you 300 mg of Xydrel once at the start of treatment. Then, the usual dose is one 75-mg tablet of Xydrel per day to be taken orally with or without food, and at the same time each day.

You should take Xydrel for as long as your doctor continues to prescribe it.

If you take more Xydrel than you should

Contact your doctor or the nearest hospital emergency department because of the increased risk of bleeding.

If you forget to take Xydrel

If you forget to take a dose of Xydrel, but remember within 12 hours of your usual time, take your tablet straightaway and then take your next tablet at the usual time.

If you forget for more than 12 hours, simply take the next single dose at the usual time. Do not take a double dose to make up for the forgotten individual doses.

You can check the day on which you last took a tablet of Xydrel by referring to the calendar printed on the blister.

If you stop taking Xydrel

Do not stop the treatment unless your doctor tells you so. Contact your doctor or pharmacist before stopping.

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

4 Possible side effects

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

The frequency of possible side effects listed below is defined using the following convention:

- very common (affects more than 1 user in 10)
- common (affects 1 to 10 users in 100)
- uncommon (affects 1 to 10 users in 1,000)
- rare (affects 1 to 10 users in 10,000)
- very rare (affects less than 1 user in 10,000)
- not known (frequency cannot be estimated from the available data)

Contact your doctor immediately if you experience:

- fever, signs of infection or extreme tiredness. These may be due to rare decrease of some blood cells.
- signs of liver problems such as yellowing of the skin and/or the eyes (jaundice), whether or not associated with bleeding which appears under the skin as red pinpoint dots and/or confusion (see section 2 "Take special care with Xydrel").
- swelling in the mouth or skin disorders such as rashes and itching, blisters of the skin. These may be the signs of an allergic reaction.

The most common side effect reported with clopidogrel is bleeding.

Bleeding may occur as bleeding in the stomach or bowels, bruising, haematoma (unusual bleeding or bruising under the skin), nose bleed, blood in the urine. In a small number of cases, bleeding in the eye, inside the head, the lung or the joints has also been reported.

If you experience prolonged bleeding when taking Xydrel

If you cut or injure yourself, it may take longer than usual for bleeding to stop. This is linked to the way your medicine works as it prevents the ability of blood clots to form. For minor cuts and injuries, e.g. cutting yourself shaving, this is usually of no concern. However, if you are concerned by your bleeding, you should contact your doctor straightaway (see section 2 "Take special care with Xydrel").

Other side effects reported with clopidogrel are:

Common side effects: Diarrhoea, abdominal pain, indigestion or heartburn.

Uncommon side effects: Headache, stomach ulcer, vomiting, nausea, constipation, excessive gas in stomach or intestines, rashes, itching, dizziness, sensation of tingling and numbness.

Rare side effect: Vertigo.

Very rare side effects: Jaundice; severe abdominal pain with or without back pain; fever, breathing difficulties sometimes associated with cough; generalised allergic reactions; swelling in the mouth; blisters of the skin; skin allergy; inflammation of the mouth (stomatitis); decrease in blood pressure; confusion; hallucinations; joint pain; muscular pain; changes in the way things taste.

In addition, your doctor may identify changes in your blood or urine test results.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5 How to store Xydrel

Keep out of the reach and sight of children.

Do not use Xydrel after the expiry date which is stated on the pack, after EXP.

Store below 25 °C

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6 Further information

What Xydrel contains

The active substance is clopidogrel as besylate. Each tablet contains 75 mg of clopidogrel.

The other ingredients are:

- Tablet core: lactose anhydrous, microcrystalline cellulose, crospovidone Type A, glycerol dibehenate, talc.
- Tablet coating: polyvinyl alcohol, talc, macrogol 3350, lecithin (soya oil) (E322), titanium dioxide (E171), iron oxide red (E172).

What Xydrel looks like and contents of the pack

Film-coated tablet.

Pink 9 mm round, biconvex, film-coated tablet, engraved with "II" on one face.

Pack sizes:

Blisters: 28 tablets.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Remidix Limited, 26 Upper Pembroke St, Dublin 2, Ireland

Manufacturer:

Actavis Ltd, Bulebel Industrial Estate, Zejtun, Malta.

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

Austria:	Clopidogrel Actavis 75 mg Filmtabletten
Denmark:	Clopidogrel Actavis
Finland:	Clopidogrel Actavis 75 mg tabletti, kalvopäällysteinen
France:	Clopidogrel Actavis 75 mg comprimé pelliculé
Germany:	Clopidogrel Actavis 75 mg Filmtabletten
Greece:	Clopidogrel Actavis
Ireland:	Clopidogrel Actavis 75 mg Film-coated Tablets
Italy:	Clopidogrel Actavis 75 mg compreste rivestite con film
Malta:	Clopidogrel Actavis
Netherlands:	Clopidogrel Actavis 75 mg
Norway:	Clopidogrel Actavis
Portugal:	Clopidogrel Actavis
Spain:	Clopidogrel Actavis 75 mg comprimidos recubiertos con película EFG
Sweden:	Clopidogrel Actavis
United Kingdom:	Clopidogrel Actavis 75 mg Film-coated Tablets

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