



NormiGore[®]

Clopidogrel 75 mg

Film - coated tablets

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 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.

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1. What NormiGore is and what it is used for

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

NormiGore 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 **NormiGore** 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.

2. Before you take NormiGore

Do not take NormiGore:

- If you are allergic (hypersensitive) to clopidogrel or any of the other ingredients of **NormiGore**;
- 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 **NormiGore**.

Take special care with NormiGore:

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

- 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 (ischemic stroke) which occurred within the last seven days.
- if you are taking another type of medicine (see 'Taking other medicines').
- if you have kidney or liver disease.

While you are taking **NormiGore**:

- 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 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 '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 'Possible side effects').
- Your doctor may order blood tests.
- You should tell your doctor or pharmacist if you notice any side effect not listed in the 'Possible side effects' section of this leaflet or if you notice that a side effect gets serious.

NormiGore is not intended for use in children or adolescents.

Taking other medicines

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

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

The use of oral anticoagulants (medicines used to reduce blood clotting) with **NormiGore** is not recommended.

You should specifically tell your doctor if you take a non steroidal anti-inflammatory drug, usually used to treat painful and/or inflammatory conditions of muscle or joints, or if you take heparin or any other medicine used to reduce blood clotting. If you have experienced severe chest pain (unstable angina or heart attack), you may be prescribed **NormiGore** 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 1000 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 NormiGore with food and drink

Food/meals have no influence. **NormiGore** may be taken with or without food.

Pregnancy and breast-feeding

It is preferable not to use this product during pregnancy and breast feeding.

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

While taking **NormiGore**, consult your doctor about the breast feeding of a baby. Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

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

Important information about some of the ingredients of NormiGore

NormiGore contains lactose and hydrogenated castor oil.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Hydrogenated castor oil may cause stomach upset or diarrhea.

3. How to take NormiGore

Always take **NormiGore** 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 **NormiGore** (4 tablets of 75 mg) once at the start of treatment. Then, the usual dose is one 75 mg tablet of **NormiGore** per day to be taken orally with or without food, and at the same time each day.

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

If you take more NormiGore than you should:

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

If you forget to take NormiGore:

If you forget to take a dose of **NormiGore**, 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.

If you stop taking NormiGore:

Do not stop the treatment. 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, **NormiGore** can cause side effects, although not everybody gets them.

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 'Take special care with **NormiGore**').
- 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 (affects 1 to 10 patients in 100) **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 NormiGore

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 'Take special care with **NormiGore**').

Other side effects reported with NormiGore are:

Common side effects (affects 1 to 10 patients in 100): Diarrhea, abdominal pain, indigestion or heartburn.

Uncommon side effects (affects 1 to 10 patients in 1000): Headache, stomach ulcer, vomiting, nausea, constipation, excessive gas in stomach or intestines, rashes, itching, dizziness, abnormal touch sensation.

Rare side effect (affects 1 to 10 patients in 10,000): Vertigo.

Very rare side effects (affects less than 1 patient in 10,000): jaundice; severe abdominal pain with or without back pain; fever, breathing difficulties sometimes associated with cough; generalized 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; taste disorders.

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 NormiGore

Keep all medicines out of reach of children.

Do not use **NormiGore** after the expiry date which is stated on the carton and on the blister.
Do not use **NormiGore** if you notice any visible sign of deterioration.

Store below 30°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 NormiGore contains

The active substance is: Clopidogrel bisulfate equivalent to 75 mg of clopidogrel.

The other ingredients are: Mannitol (E421), hydrogenated castor oil, microcrystalline cellulose with addition of silica, low-substituted hydroxypropylcellulose and pregelatinised starch in the tablet core, and lactose monohydrate, hypromellose (E464), triacetin (E1518), red iron oxide (E172), yellow iron oxide (E172), black iron oxide (E172) and titanium dioxide (E171) in the tablet coating.

What NormiGore looks like and contents of the pack

NormiGore 75 mg tablets are round, biconvex, pink, unscored film-coated tablets. They are supplied in carton box containing 28 tablets in aluminum / aluminum blisters.

Manufactured by: Zakład Farmaceutyczny Adamed Pharma S.A.
Ksawerów, Poland

For: ARWAN Pharmaceutical Industries Lebanon s.a.l.
Jadra, Lebanon

THIS IS A MEDICAMENT

- Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of the reach of children.

Council of Arab Health Ministers, Union of Arab Pharmacists