

# ARTWORK FOR SUBMISSION

## Dipyridamole Leaflet

160 mm

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**Package Leaflet: Information for the patient**  
**Dipyridamole 200mg Prolonged Release Capsules, Hard**

**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 Dipyridamole Prolonged Release Capsules are and what they are used for
2. What you need to know before you take Dipyridamole Prolonged Release Capsules
3. How to take Dipyridamole Prolonged Release Capsules
4. Possible side effects
5. How to store Dipyridamole Prolonged Release Capsules
6. Contents of the pack and other information

**1. What dipyridamole prolonged release capsules are and what they are used for**  
You must talk to a doctor if you do not feel better or if you feel worse after a few days.  
Dipyridamole 200mg Prolonged Release Capsules contain a medicine called dipyridamole. Dipyridamole belongs to a group of medicines called antithrombotic agents which are used to stop blood clots forming.  
Dipyridamole Prolonged Release Capsules are used:

- After a stroke to prevent blood clots in the brain
- To prevent blood clots forming after having a heart valve replaced.

**2. What you need to know before you take dipyridamole prolonged release capsules**  
**Do not take Dipyridamole Prolonged Release Capsules:**

- If you are allergic to dipyridamole, or any of the other ingredients in this medicine (listed in Section 6).

**Warnings and precautions**  
Talk to your doctor or pharmacist or nurse before taking Dipyridamole Prolonged Release Capsules if you have:

- Angina or other heart problems (including heart valve or circulation problems) or have recently had a heart attack
- Myasthenia gravis (a rare muscle problem)
- Bleeding problems
- Or if you are pregnant, planning to become pregnant or breast-feeding.

**Other medicines and Dipyridamole Prolonged Release Capsules**  
Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines. This includes medicines obtained without a prescription, herbal medicine, strong vitamins and minerals. This is because Dipyridamole Prolonged Release Capsules can affect the way some other medicines work. Also some other medicines can affect the way Dipyridamole Prolonged Release Capsules work.

**Tell your doctor or pharmacist if you are taking medicines for:**

- High blood pressure
- Heart problems or irregular heartbeat (e.g. adenosine)
- Blood clots (e.g. warfarin, aspirin)
- Myasthenia gravis, a disease which causes muscle weakness (e.g. cholinesterase inhibitors).

**If you are having heart tests**  
Always tell your doctor that you are taking Dipyridamole Prolonged Release Capsules before having a test of your heart function (myocardial imaging). Treatment with Dipyridamole Prolonged Release Capsules may affect the results. You may need to stop taking Dipyridamole Prolonged Release Capsules before you have the test. Dipyridamole is also sometimes given as an injection during tests to see if the heart is working properly (also called 'myocardial imaging'). This means that the test and your medicine may contain the same substance. If you are going to have an injection of dipyridamole, tell the doctor that you are taking Dipyridamole Prolonged Release Capsules.

**Dipyridamole Prolonged Release Capsules with alcohol**  
You should avoid alcohol when taking the capsules.

**Pregnancy, breast-feeding and fertility**  
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.

*Pregnancy*  
If you are pregnant you are not recommended to take Dipyridamole Prolonged Release Capsules. Ask your doctor for advice.

*Breast-feeding.*  
If you are breast-feeding, do not take Dipyridamole Prolonged Release Capsules, as dipyridamole is excreted into breast milk. Talk to your doctor.

*Fertility*  
No data are available.

**Driving and using machines**  
You may experience dizziness whilst taking Dipyridamole Prolonged Release Capsules. If this occurs you should not drive or operate machinery.

**Other ingredients**  
Dipyridamole Prolonged Release Capsules contains sucrose and sodium benzoate.

- 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 0.02 mg sodium benzoate in each capsule.
- This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially 'sodium-free'.

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Folding: 160 x 33.75 mm

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**3. How to take dipyridamole prolonged release capsules**  
Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

**Use in adults**  
The recommended dose is one capsule twice daily. Usually one in the morning and one in the evening. The capsules should be swallowed whole without chewing.

**Use in children**  
Dipyridamole Prolonged Release Capsules are not recommended in children.

**If you take more Dipyridamole Prolonged Release Capsules than you should**  
Tell your doctor, hospital or pharmacist straight away if you have taken more Dipyridamole Prolonged Release Capsules than listed here or more than the doctor has prescribed and you feel unwell. Take the medicine pack with you, even if there are no capsules left.

**If you forget to take Dipyridamole Prolonged Release Capsules**  
If you forget a dose, take it as soon as you remember it. However, if it is time for the next dose, skip the missed dose. Do not take a double dose to make up for a forgotten dose.

**If you stop taking Dipyridamole Prolonged Release Capsules**  
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.

**If you experience any of the following side effects after you have taken your medicine, see your doctor immediately.** These side effects are rare but serious:

- **Severe allergic reaction** which may include a red and lumpy skin rash, difficulty breathing, swelling of face, mouth, lips or eyelids, unexplained high temperature (fever) and feeling faint. If the swelling affects your throat and makes breathing and swallowing difficult, stop taking your medicine and go to hospital straight away.

**Very common** (may affect more than 1 in 10 people)

- Headache
- Diarrhoea
- Feeling dizzy
- Feeling sick (nausea).

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

- Worsening of the symptoms of heart disease such as chest pain and shortness of breath
- Being sick (vomiting)
- Muscle pain.

**Not known** (frequency cannot be estimated from available data)

- Increased heart rate
- Hot flushes
- Pale, raised, itchy areas of skin with red edges
- A blood problem called "thrombocytopenia" which can cause bruising and prolong bleeding from wounds or during and after surgery
- Gallstone pain (in the centre or right of your stomach). In people who have gallstones, the dipyridamole in this medicine can be absorbed into the gallstones.

**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. You can also report side effects directly via the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

**5. How to store dipyridamole prolonged release capsules**  
Keep this medicine out of the sight and reach of children.  
Do not store above 25°C.  
Keep the container tightly closed in order to protect from moisture.  
Do not open the container until you are ready to start taking the capsules. If you have any capsules left after six weeks, these should not be taken.  
Do not use this medicine after the expiry date which is stated on the label and 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 Dipyridamole Prolonged Release Capsules contain**  
The active substance is dipyridamole. Each capsule contains dipyridamole 200mg.  
The other ingredients are: tartaric acid pellets [tartaric acid, sucrose and povidone], hypromellose, talc, acacia, spray-dried, triacetin, povidone, simeticone emulsion (30 % W/V) [simethicone, cetostearyl alcohol and ethoxylate, sodium benzoate], methacrylic acid - ethyl acrylate copolymer, hypromellose phthalate P55.  
Capsule shells: gelatin, titanium dioxide (E171), red and yellow iron oxides (E172).

**What Dipyridamole Prolonged Release Capsules look like and contents of the pack**  
Hard gelatin capsules consisting of a red cap and an orange body. Dimension 7,66 mm x 23,1 mm.  
The capsule contains yellow coloured slow release pellets.  
HDPE bottle with polypropylene child resistant closure, containing desiccant in a canister.  
Packs contain 60 capsules.

**Marketing Authorisation Holder and Manufacturer**  
**Strides Pharma UK Ltd**  
Unit 4, The Metro Centre,  
Dwight Road  
Watford, WD18 9SS  
United Kingdom

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