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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.

You can take the capsules along with other preventive medicine (acetylsalicylic acid) or alone if you cannot tolerate acetylsalicylic acid.

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.

Children

Dipyridamol Prolonged Release Capsules should not be used for children, as there is insufficient experience with dipyridamol in children.

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'.

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 capsule can be taken with or without meals. The capsules should be swallowed whole without chewing.

Alternative dosing for intolerable headaches

If you experience intolerable headaches at the beginning of treatment with Dipyridamol Prolonged Release Capsules, you may need a different dose. Consult your doctor. As a trial, you may be dosed with 1 capsule at bedtime and a low dose of acetylsalicylic acid in the morning. Since headaches usually disappear with regular dosing, you are strongly advised to return to your normal dosage within a week.

Use in children

Dipyridamole Prolonged Release Capsules are not recommended in children.

Elders

It is not necessary to change the dose. Follow the doctor's instructions.

Reduced kidney function

It is not necessary to change the dose. Follow the doctor's instructions.

Impaired liver function

It is not necessary to change the dose. Follow the doctor's instructions.

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.

You may experience symptoms of overdose, such as a feeling of warmth, flushing, sweating, restlessness, weakness, dizziness, and headache, if you have taken too much Dipyridamol Prolonged Release Capsules. You may also experience rapid pulse, rapid breathing, low blood pressure, heart cramps, unconsciousness, stomach discomfort, weakened breathing with bluish lips and nails, prolonged bleeding time, and yellowing of the skin.

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.

The most common side effects are nausea and headache. In most cases, these side effects disappear with continued use.

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
- Feeling dizzy
- Diarrhoea
- 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
- Lowering of blood pressure
- Hot flushes
- Tightening of the chest and shortness of breath
- Pale, raised, itchy areas of skin with red edges, swelling of the tongue, lips, and face.
- 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.
- Increased bleeding during or after surgery.
- Bronchospasm (breathing difficulties, asthma-like attacks)

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 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) [simeticone, 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
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Dwight Road
Watford, WD18 9SS
United Kingdom

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320 mm

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Dimension: 160 x 320 mm

Front Page

Dimension: 160 x320 mm

Back Page

MFG. LOCATION: PONDY

ARTWORK DETAIL LABEL

Non printing colour

Product	Dipyridamole PR 200 mg Capsules				
Buyer/Country	SPUK	Component	Pack insert		
Dimension	160 x 320 mm	Pack	--		
New Item Code	1052913	Old Item Code	1047825		
Colour Shades	BLACK	No. of Colours	1		
Change Control No.	PC-PYF/2025/278 – Record Number: 472135			Artwork Version	2.0
Design/Style	Front & Back Printing. To be supplied in the folded size of 160 x 40 mm.				
Substrate	60 GSM Maplitho paper				
Special Instructions	PRINTING CLARITY TO BE CLEAR AND SHARP.				
Autocartonator Requirements	NA				
Caution to the printer: Before processing, please ensure that the ARTWORK received for printing is exactly in line with APPROVED ARTWORK provided to you. In case of any FONTS/DESIGN are Mis-matching with the APPROVED ARTWORK, please inform PDC for further action. DO NOT MAKE ANY CHANGE TO THE ARTWORK WITHOUT WRITTEN INSTRUCTIONS FROM PDC.					

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