

# Molita 200 mg/25 mg Modified-Release Capsules, Hard

## Dipyridamole and aspirin

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. 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.

### In this leaflet

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### 1. What Molita is and what it is used for

The name of your medicine is Molita. It contains two different medicines called dipyridamole and aspirin. Both belong to a group of medicines called 'anti-thrombotic medicines'. Aspirin is also a type of medicine called a 'Non-Steroidal Anti-inflammatory Drug' (NSAID).

Molita belongs to a group of medicines called 'anti-thrombotic agents'. They are used to stop blood clots forming. Molita is used for people who have had a

- Stroke
- Transient Ischaemic Attack (TIA)

which are caused by a clot in the brain. This medicine reduces the risk of them happening again.

### 2. What you need to know before you take Molita

Do not take Molita if you:

- are **allergic** to **dipyridamole, aspirin** or any other medicines containing aspirin (also called 'salicylates') or any of the other ingredients of this medicine (listed in section 6)
- are **allergic** to **peanut or soya**
- have any **bleeding problems**
- have ever had an **ulcer in your stomach or gut** (duodenum)
- have **severe kidney or liver problems**
- are taking **methotrexate** at doses higher than 15 mg/week
- have ever had **abnormal bleeding** in the **brain**
- have had **stomach pain** when previously taking this medicine
- are in the last three months of pregnancy.

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Molita.

#### Warnings and precautions

Talk to your doctor or pharmacist before taking Molita if you:

- have an **increased risk of bleeding** as you might require careful follow up by your doctor
- have **angina or other heart problems** (including heart valve or circulation problems)
- have **myasthenia gravis** (a rare muscle problem)
- have **asthma, hayfever or nasal polyps** (a type of growth in the nose)
- have **kidney or liver problems**
- need treatment to lower your blood sugar
- have something called '**glucose-6-phosphate dehydrogenase deficiency**'. This is a problem of the red blood cells which can cause anaemia
- are in the first six months of pregnancy, likely to get pregnant or are breast-feeding
- are about to have **surgery** such as having a tooth removed. Your doctor may want you to stop taking this medicine up to 7 days before
- you regularly drink alcohol.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Molita.

#### Other medicines and Molita

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:

- **aspirin** or medicines containing aspirin (or planning to for any condition)
- medicines for **high blood pressure**
- medicines for **gout**

- medicines to **thin the blood** such as warfarin, heparin, coumarins, clopidogrel, ticlopidine and anagrelide. If you attend an anticoagulant clinic tell them at your next visit
- medicines for depression called '**selective serotonin reuptake inhibitors**' such as fluoxetine, paroxetine or sertraline
- other **Non-Steroidal Anti-inflammatory Drugs** (such as **ibuprofen**) for another condition
- **steroids** such as prednisolone
- **methotrexate** - used for joint problems or cancer. The risk of side effects may be increased. Your doctor may want to do some blood tests. **Do not take** this medicine if your dose of methotrexate is higher than 15 mg/week
- **adenosine injection** - used for heart problems or tests on the heart
- **spironolactone** - a water tablet
- **valproic acid** - used for the over excited and 'high' feeling (manic episodes) that people with bipolar disorder get
- **phenytoin** - used to treat epilepsy (seizures).

#### If you are having heart tests

Molita contains dipyridamole. 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 Molita.

#### Pregnancy and breast-feeding

Do not take Molita if you are in the last three months of pregnancy. If you are in the first six months of pregnancy, likely to get pregnant or are breast-feeding, talk to your doctor before taking this medicine.

#### Driving and using machines

You may feel dizzy or confused while taking Molita. If this happens do not drive or use any tools or machines.

#### Molita contains lactose.

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

Molita also contains methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216) and colourings ponceau 4R (E124) and sunset yellow (E110), which may cause allergic reactions.

### 3. How to take Molita

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

#### The recommended dose is

- One capsule twice a day.
- Usually one in the morning and one in the evening.
- It is best to take it with food.
- Swallow the capsule whole with a glass of water.
- **Do not** crush or chew it.

If you get a severe migraine-like headache at the start of your treatment tell your doctor as they may need to change your dose for a short period of time. **DO NOT** take painkillers containing aspirin to treat your headache.

#### Use in children

This medicine should not be given to children.

#### If you take more Molita than you should

If you take more of this medicine than you should, talk to a doctor or go to a hospital straight away. Take the medicine pack with you, even if there are no capsules left.

#### If you forget to take Molita

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

#### If you stop taking Molita

Do not stop treatment without talking to your doctor first.

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. The following side effects may happen with this medicine.

#### Bleeding

Bleeding at different sites within the body can occur which in some cases may be serious. The following have been seen with Molita.

**Common** (affects less than 1 in 10 people but more than 1 in 100 people)

- bleeding in the brain
- bleeding in the stomach or gut
- nosebleeds

**Uncommon** (affects less than 1 in 100 people but more than 1 in 1,000 people)

- bleeding in the eye

**Unknown** (incidence cannot be estimated)

- prolonged bleeding from wounds including during or after surgery or other medical procedures
- bruising or swellings where blood has collected (haematoma)

#### Allergic reactions

Allergic reactions are common. If you have an allergic reaction stop taking your medicine and **see a doctor straight away**. The signs may include difficulty breathing, rash which may be severe with itching, or swelling of the throat or face.

**Other side effects that have been reported for Molita are:**

**Very Common** (affects more than 1 in 10 people)

- headache, sometimes migraine. This is more common at the start of treatment and usually goes away as treatment continues
- feeling dizzy
- feeling sick (nausea)
- stomach ache
- indigestion or diarrhoea

**Common** (affects less than 1 in 10 people but more than 1 in 100 people)

- anaemia, which may sometimes be due to internal bleeding into the stomach
- worsening of the symptoms of heart disease such as chest pain and shortness of breath
- being sick (vomiting)
- muscle pain
- fainting

**Uncommon** (affects less than 1 in 100 people but more than 1 in 1,000 people)

- increased heart beat
- lowering of blood pressure
- hot flushes
- stomach ulcers

**Rare** (affects less than 1 in 1,000 people but more than 1 in 10,000 people)

- a blood problem called 'thrombocytopenia' which can cause bruising or prolonged bleeding
- inflammation of the stomach
- anaemia due to internal bleeding into the stomach

In addition, there are other side effects that **are known** for the active ingredients **dipyridamole and aspirin** when taken on their own. These are listed below and also apply to Molita.

#### Dipyridamole

In people who have gallstones, dipyridamole can be absorbed into the gallstones.

#### Aspirin

- blood clotting problems and bleeding gums
- severe allergic reactions especially in patients who have asthma
- high or low blood sugar levels
- increased uric acid in the blood, which may cause gout, or other changes in the composition of the blood
- feeling thirsty or becoming dehydrated
- feeling confused or restless
- feeling less alert, convulsions (fits) or swelling of the brain
- deafness or ringing in the ears
- irregular heart beats
- difficulty breathing or fast or shallow breathing
- swelling in the throat or excess fluid in the lungs
- perforated ulcers in the stomach
- blood in the stools or vomiting blood
- inflammation of the pancreas
- inflammation of the liver (hepatitis)
- Reye's syndrome – a rare disease which can be fatal especially if aspirin is given to children
- rash with blisters
- muscle breakdown
- kidney failure and other kidney problems
- possible effect on liver test results
- prolonged pregnancy or labour
- bleeding before or after birth, small baby or stillbirth
- fever or low body temperature (hypothermia)

#### Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. 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).

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

## 5. How to store Molita

Keep this medicine out of the sight and reach of children.

This medicinal product does not require any special temperature storage conditions. Store in the original package in order to protect from moisture. Keep the bottle tightly closed.

Do not use this medicine after the expiry date which is stated on the carton and the bottle label. The expiry date refers to the last day of that month.

Do not open the bottle until you are ready to start taking the capsules. If you have any capsules left in the bottle after 30 days, **these should not be taken**.

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 Molita contains

The active substances are dipyridamole and aspirin. Each capsule contains dipyridamole 200 mg in modified release form and 25 mg aspirin in standard release form.

The other ingredients are: *Dipyridamole pellets* – tartaric acid, hypromellose, acacia, talc, povidone, methacrylic acid-methyl methacrylate copolymer, hypromellose phthalate, dimethicone, triacetin, stearic acid; *Aspirin tablet* – microcrystalline cellulose, anhydrous lactose, corn starch, colloidal anhydrous silica, stearic acid, polyvinyl alcohol, titanium dioxide, talc, quinoline yellow (E104), soya lecithin (E322), xanthan gum (E415); *Capsule shells* – gelatine, methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), ponceau 4R (E124), patent blue (E131), quinoline yellow (E104), sunset yellow (E110), titanium dioxide (E171).

### What Molita looks like and contents of the pack

Capsule (size 0xEL) with orange coloured cap and white to off-white coloured body.

Molita is available in plastic bottles with child-proof closure containing 30, 50, 60 (1 x 60), 60 (2x30) or 100 (2 x 50) capsules.

Not all pack sizes may be marketed.

### Marketing Authorisation Holder and Manufacturer

Dr. Reddy's Laboratories (UK) Ltd., 6 Riverview Road, Beverley, HU17 0LD, United Kingdom

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