

**PACKAGE LEAFLET**

## Package leaflet: Information for the user

Trolactin 200mg Prolonged-release Hard Capsules

dipyridamole

**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 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- The full name of this medicine is Trolactin 200mg Prolonged-release Hard Capsules but within the leaflet it will be referred to as Trolactin.

### What is in this leaflet

1. What Trolactin is and what it is used for
2. What you need to know before you take Trolactin
3. How to take Trolactin
4. Possible side effects
5. How to store Trolactin
6. Contents of the pack and other information

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

Trolactin contains the active substance dipyridamole. This belongs to a group of medicines called 'anti-thrombotic agents', which are used to stop blood clots forming.

Trolactin is used:

- To reduce the risk of having another stroke in people who have had a stroke caused by a blood clot in the brain.

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

#### Do not take Trolactin:

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

#### Warnings and precautions

Talk to your doctor or pharmacist before taking Trolactin:

- If you have angina or other heart diseases or have had a recent heart attack
- If you have myasthenia gravis (muscle weakness)
- If you have any bleeding problems.

#### If you are having heart tests

Trolactin 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 Trolactin.

### **Children and adolescents**

Trolactin should not be given to children since the safety and efficacy has not been established.

### **Other medicines and Trolactin**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes herbal medicines. This is because Trolactin can affect the way some other medicines work. Also some other medicines can affect the way Trolactin works.

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

- Medicines for high blood pressure
- Medicines for muscle weakness (myasthenia gravis), called a 'cholinesterase inhibitor'
- Adenosine, used for heart problems or tests on the heart
- Warfarin, acetylsalicylic acid or other medicines to stop blood clots forming
- Theophylline (a medicine for respiratory problems).

### **Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Trolactin should generally not be used in pregnancy.

Trolactin should only be used during breast-feeding if your doctor considers it essential, since dipyridamole is excreted in breastmilk.

### **Driving and using machines**

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

## **3. How to take Trolactin**

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.

The capsules may be taken with or without food.

Swallow the capsule whole. Do not crush or chew it.

### **If you take more Trolactin 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.

Symptoms such as feeling warm, flushes, sweating, faster pulse, restlessness, feeling of weakness, dizziness, drop in blood pressure and chest pain can be expected.

### **If you forget to take Trolactin**

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 Trolactin**

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.

##### **Allergic reactions**

If you have an allergic reaction, stop taking your medicine and see a doctor straight away. The signs may include feeling breathless, runny nose, severe rash with itching, swelling and swelling around the eyes.

Other side effects that have been reported for Trolactin are described below.

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

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

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

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

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

- Hot flushes
- Lowering of blood pressure or increased heart rate
- A blood problem called 'thrombo-cytopenia' which can cause bruising and prolonged bleeding from wounds, including during or after surgery.

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, 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 Website: [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 Trolactin**

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

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 label and carton after EXP. The expiry date refers to the last day of that month.

Shelf life after first opening: 100 days.

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 Trolactin contains**

- The active substance is dipyridamole. Each prolonged-release capsule contains dipyridamole 200mg. Trolactin is a prolonged-release capsule which releases the active substance slowly in your body over a number of hours.
- The other ingredients are: Capsule content: Tartaric acid, hypromellose, talc, hydroxypropyl cellulose, methacrylic acid – methyl methacrylate copolymer (1:2), triethyl citrate.  
Capsule shell: Gelatin, titanium dioxide (E171) and red iron oxide (E172).

### **What Trolactin looks like and contents of the pack**

Trolactin 200mg Prolonged-release Hard Capsules are reddish-brown (orange) hard capsules, 23.5mm.

Trolactin is available in packs of 60 capsules.

### **Marketing Authorisation Holder**

Accord Healthcare Limited  
Sage House  
319 Pinner Road  
North Harrow  
Middlesex  
HA1 4HF  
United Kingdom

### **Manufacturer**

Balkanpharma-Dupnitsa AD  
3 Samokovsko Shosse Str.  
2600 Dupnitsa  
Bulgaria

**This leaflet was last revised in April 2018.**

**If you would like a  
leaflet with larger text,  
please contact  
01271 385257.**

Pil Spec no

Accord Healthcare Ltd, North Harrow, HA1 4HF, UK