

# ACTAPIN TABLET

Amlodipine Besylate (5mg, 10mg)

---

## What is in this leaflet

1. What Actapin is used for
2. How Actapin works
3. Before you use Actapin
4. How to use Actapin
5. While you are using Actapin
6. Side effects
7. Storage and disposal of Actapin
8. Product description
9. Manufacturer and Product Registration Holder
10. Date of Revision

## What Actapin is used for

Actapin is used to treat high blood pressure (hypertension) and angina pectoris.

## How Actapin works

Actapin contains the active substance amlodipine which belongs to a group of medicines called calcium antagonists.

In patients with high blood pressure, Actapin works by relaxing blood vessels, so that blood passes through them easily.

In patients with angina, Actapin works by improving blood supply to the heart muscle which then receives more oxygen and as a result chest pain is prevented. Actapin does not provide immediate relief of chest pain from angina.

## Before you use Actapin

### When you must not use it

- if you are allergic (hypersensitive) to amlodipine, or any of the other ingredients of Actapin or to any other calcium antagonists. This may be itching, reddening of the skin or difficulty in breathing.

- if you have severe low blood pressure (hypotension).

### Before you start to use it

You should inform your doctor if you have or have had any of the following conditions:

- Recent heart attack
- Heart failure
- Severe increase in blood pressure (hypertensive crisis)
- Liver disease

### Taking other medicines

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

Actapin may affect or be affected by other medicines, such as:

- ketoconazole, itraconazole (anti-fungal medicines)
- ritonavir (so called protease inhibitors used to treat HIV)
- rifampicin (antibiotics)
- hypericum perforatum (St John's wort)
- diltiazem (heart medicines)

Actapin may lower your blood pressure even more if you are already taking other medicines to treat your high blood pressure.

## How to use Actapin

### How much to use

Always take your medicine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The usual initial dose is Actapin 5 mg once daily. The dose can be increased 10 mg once daily.

### When to use it

You should take your medicine at the same time each day with a drink of water. Do not take Actapin with grapefruit juice.

It is important to keep taking the tablets. Do not wait until your tablets are finished before seeing your doctor.

### How long to use it

Your doctor will advise you how long to take your medicine. Your condition may return if you stop using your medicine before you are advised.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

### If you forget to use it

Do not worry. If you forget to take a tablet, leave out that dose completely. Take your next dose at the right time. Do not take a double dose to make up for a missed dose.

### If you use too much (overdose)

Taking too many tablets may cause your blood pressure to become low or even dangerously low. You may feel dizzy, lightheaded, faint or weak. If blood pressure drop is severe enough shock can occur.

Your skin could feel cool and clammy and you could lose consciousness. Seek immediate medical attention if you take too many Actapin tablets.

## While you are using Actapin

### Things you must do

If you think you might be pregnant, or are planning to get pregnant, you must tell your doctor before you take Actapin.

If you are breast-feeding or about to start breastfeeding you must tell your doctor before taking Actapin.

Ask your doctor or pharmacist for advice before taking any medicine.

### Things you must not do

- Do not stop taking the medicine unless advised by your doctor or pharmacist.
- Do not take any new medicines without consulting your doctor or pharmacist.
- Do not give Actapin to anyone else, even if they have the same symptoms or condition as you.

### Things to be careful of

Actapin may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

## Side effects

Like all medicines Actapin can cause side effects, although not everybody gets them.

Visit your doctor **immediately** if you experience any of the following very rare, severe side effects after taking this medicine.

- Sudden wheeziness, chest pain, shortness of breath or difficulty in breathing
- Swelling of eyelids, face or lips
- Swelling of the tongue and throat which causes great difficulty breathing
- Severe skin reactions including intense skin rash, hives, reddening

of the skin over your whole body, severe itching, blistering, peeling and swelling of the skin, inflammation of mucous membranes (Stevens Johnson Syndrome) or other allergic reactions

- Heart attack, abnormal heart beat
- Inflamed pancreas which may cause severe abdominal and back pain accompanied with feeling very unwell

The following **common side-effects** have been reported. If any of these cause you problems or if they **last for more than one week**, you should **contact your doctor**.

### **Common:**

- Headache, dizziness, sleepiness (especially at the beginning of treatment)
- Palpitations (awareness of your heart beat), flushing
- Abdominal pain, feeling sick (nausea)
- Ankle swelling (oedema), tiredness

Other side-effects that have been reported include the following list. If any of these get serious, or if you notice any side-effects not listed in this leaflet, please tell your doctor or pharmacist.

### **Uncommon:**

- Mood changes, anxiety, depression, sleeplessness
- Trembling, taste abnormalities, fainting, weakness
- Numbness or tingling sensation in your limbs;
- Visual disturbances, double vision, ringing in the ears
- Low blood pressure
- Sneezing/running nose caused by inflammation of the lining of the nose
- Altered bowel habits, diarrhoea, constipation, indigestion, dry mouth, vomiting (being sick)
- Hair loss, increased sweating, itchy skin, red patches on skin, skin discolouration

- Disorder in passing urine, increased need to urinate at night, increased number of times of passing urine
- Inability to obtain an erection; discomfort or enlargement of the breasts in men
- Weakness, pain, feeling unwell
- Joint or muscle pain, muscle cramps, back pain
- Weight increase or decrease

### **Very rare:**

- Decreased numbers of white blood cells, decrease in blood platelets which may result in unusual bruising or easy bleeding (red blood cell damage)
- Excess sugar in blood (hyperglycaemia)
- A disorder of the nerves, which can cause weakness, tingling or numbness
- Cough, swelling of the gums
- Abdominal bloating (gastritis)
- Abnormal liver function, inflammation of the liver (hepatitis), yellowing of the skin (jaundice), liver enzyme increase which may have an effect on some medical tests
- Increased muscle tension
- Inflammation of blood vessels, often with skin rash
- Disorders combining rigidity, tremor, and/or movement disorders

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.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website [portal.bpfk.gov.my](http://portal.bpfk.gov.my) (Consumers → Reporting)

**Storage and disposal of Actapin**

Storage

Keep out of the sight and reach of children.

Do not use Actapin after the expiry date, which is stated on the carton and blister after 'EXP'. The expiry date refers to the last day of that month.

Do not store above 25°C.

Disposal

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.

**Product description**

What it looks like

Actapin 5 mg tablet

White, uncoated, round, flat, tablet (8 mm) with score on one side and embossed with AB5 on the other side. The tablet can be divided into two equal halves.

Actapin 10 mg tablet

White, uncoated, round, flat, tablet (10 mm) with score on one side and embossed with AB10 on the other side. The tablet can be divided into two equal halves.

Ingredients

Active ingredient:

Actapin 5 mg tablet

One tablet contains 5 mg amlodipine (as amlodipine besilate)

Actapin 10 mg tablet

One tablet contains 10 mg amlodipine (as amlodipine besilate).

Inactive ingredients:

Microcrystalline cellulose, calcium hydrogenphosphate dihydrate, magnesium stearate, sodium starch glycolate (type A).

**MAL number**

Actapin 5 mg Tablet  
MAL07081523A

Actapin 10 mg Tablet  
MAL07081524A

**Manufacturer**

Actavis hf  
Reykjavikurvegur 78  
IS-220 Hafnafjordur  
Iceland

**Product Registration Holder**

MILRIN PHARMACEUTICAL CO.  
(M) SDN. BHD.  
125L, 5th Floor, Wisma Getah,  
Macalister Road,  
10400 Penang, Malaysia.  
Tel: 04-2286042, 2286741, 2288644  
Fax: 04-2280757

**Date of revision**

04/11/2014

**Serial number:**

BPFK(R4/1)041114/00041