PATIENT INFORMATION LEAFLET
ATACAND PLUS 16/12,5 mg; 32/12,5 mg & 32/25 mg

Read all of this leaflet carefully before you start taking ATACAND PLUS

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

SCHEDULING STATUS: **S 3**

NAME OF MEDICINAL PRODUCT (and dosage form):
Atacand® PLUS 16/12,5 mg; Atacand® PLUS 32/12,5 mg; Atacand® PLUS 32/25 mg (Tablet)

1. WHAT ATACAND PLUS CONTAINS:

One ATACAND PLUS 16/12,5 mg tablet contains 16 mg candesartan cilexetil and 12,5 mg hydrochlorothiazide.
One ATACAND PLUS 32/12.5 mg tablet contains 32 mg candesartan cilexetil and 12,5 mg hydrochlorothiazide.
One ATACAND PLUS 32/25 mg tablet contains 32 mg candesartan cilexetil and 25 mg hydrochlorothiazide.

The active substance is candesartan cilexetil and hydrochlorothiazide.

The other ingredients are Carmellose calcium, hydroxypropyl cellulose, iron oxide yellow (E172), iron oxide red (E172) (only 32/25 mg), magnesium stearate, water purified, maize starch and macrogol. Calcium carboxymethylcellulose, iron oxide reddish brown (E172) (only 16/12,5 mg), polyethylene glycol, lactose monohydrate.

Contains sugar.

2. WHAT ATACAND PLUS IS USED FOR:

Candesartan cilexetil is a type of medicine called an angiotensin II receptor antagonist, which by blocking the effects of the hormone angiotensin II, causes relaxation of the blood vessels and results in a lowering of the blood pressure.

Hydrochlorothiazide belongs to a class of medicines called diuretics. Its effects promote the urinary excretion of sodium, chloride and water and results in a lowering of the blood pressure.

ATACAND PLUS 16/12,5; 32/12,5 and 32/25 is used for treating hypertension (high blood pressure) in patients stabilised on the same doses of both components given concomitantly.

3. BEFORE TAKING ATACAND PLUS:

Do not take ATACAND PLUS:

- If you are pregnant, think you might be pregnant or considering becoming pregnant.
- If you are breast-feeding.
- If you are allergic to any of the ingredients in ATACAND PLUS or to medicines closely related to hydrochlorothiazide (i.e. medicines that belong to a medicine class called sulphonamides).
- If you have a moderate to severe liver disease.
- If you have moderate to severe kidney disease.
- If you have a condition known as bilateral renal artery stenosis or stenosis in the presence of a single kidney. This is a narrowing of the kidney arteries supplying blood to the kidney/s, leading to a reduced blood flow, resulting in impaired kidney function and high blood pressure.
- If you have a condition known as Hypertrophic Obstructive Cardiomyopathy. This is a condition associated with thickening of the heart muscle, leading to stiffening of the heart walls and abnormal heart valve function, both of which may hinder normal blood flow out of the heart.

- If you previously have developed angioedema (swelling similar to hives, but the swelling is beneath the skin rather than on the surface) after taking ATACAND PLUS or any medicine in the same class called angiotensin receptor blockers (ARB's) or ACE inhibitors (a different class of blood pressure lowering medicines).
- If you have had gout.
- If you have a potassium deficiency (hypokalaemia) or excess calcium (hypercalcaemia).
- If you have porphyria, an inherited blood disorder.
- If you have Addsion's disease (hormone disorder of the adrenal gland).
- If you are on lithium therapy.

Important: You should not take ATACAND PLUS if you have had problems in the past when taking medicines containing candesartan cilexetil or hydrochlorothiazide.

Take special care with ATACAND PLUS

Please talk to your doctor or pharmacist before taking ATACAND PLUS.

- If you are taking other medicines to help lower your blood pressure.
- If you are taking any other medicines including those you have bought without a prescription.
- If you have any heart, liver or kidney problems.
- If you suffer from lactose intolerance.
- If you are you taking digitalis glycosides, antiarrhythmics, NSAIDs, colestipol, cholestyramine, lithium, other kaliuretic diuretics, laxatives, amphotericin, carbenoxolone, salicylic acid derivatives, potassium-sparing diuretics, potassium supplements or salt substitutes.
- If you are diabetic.
- If you are going to have an operation, tell your doctor or dentist that you are taking ATACAND PLUS. If combined with some anaesthetics, it may cause a drop in blood pressure.

Taking ATACAND PLUS with food and drink

It does not matter whether you take your tablet with or without food.

Pregnancy and Breast-feeding:

If you are pregnant or breast feeding your baby while taking ATACAND PLUS please consult your doctor, pharmacist or other health care professional for advice.

ATACAND PLUS is contra-indicated (should not be used) in pregnancy and breast-feeding.

Driving and using machinery:

The treatment of high blood pressure or heart failure may lead to dizziness or tiredness in some patients. Make sure you are not affected in this way before driving or operating machines.

Important information about some of the ingredients of ATACAND PLUS:

Please talk to your doctor or pharmacist before taking this medicine if you suffer from lactose intolerance.

Taking other medicines with ATACAND PLUS:

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of ATACAND PLUS with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other health care professional, for advice.

4. HOW TO TAKE ATACAND PLUS:

- It is important to keep taking ATACAND PLUS every day and as your doctor has told you to.
- The instructions on the label should remind you of what the doctor has said.
- It is best to take your tablet at the same time each day, e.g. in the morning.
- ATACAND PLUS is not normally recommended for children.

If you have the impression that the effect of ATACAND PLUS is too strong or too weak, talk to your doctor or pharmacist.

The usual dose:

The dosage prescribed to you is individualised and may differ from the information contained in this leaflet.

Adults: Take 1 ATACAND PLUS tablet once a day.

If you take more ATACAND PLUS than you should

If you take more than the recommended number of tablets, contact a doctor or pharmacist as soon as possible.

In the event of an overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take a dose

If you forget to take a dose, just carry on with the next dose as normal. Do not take an extra tablet to make up.

5. POSSIBLE SIDE EFFECTS:

ATACAND PLUS can have side effects.

If any of the following happen, stop taking ATACAND PLUS and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the face, lips, tongue and/or throat, which may cause difficulty in swallowing or breathing.
- Rash, allergic or unusual skin reactions or itching.
- Yellowing of the skin and eyes, also called jaundice.
- Easy bruising or feeling extreme fatigue.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to ATACAND PLUS. You may need urgent medical attention or hospitalisation.

Other side effects that may occur.

- Worsening of your kidney function (especially in patients with existing kidney problems or heart failure).
- Changes in your potassium, sodium and red or white blood cell levels. Such changes are usually detected by a blood test.

Not all side effects reported for ATACAND PLUS are included in this leaflet. Should your general health worsen while taking ATACAND PLUS, please consult your doctor, pharmacist or other health care professional for advice.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

6. STORING AND DISPOSING OF ATACAND PLUS:

Keep your medicine stored at or below 25 °C.
Keep well closed (bottle).
Do not remove blister from carton until required for use.
Keep all medicines out of the reach and sight of children.
Do not use after the expiry date stated on the blister strip/bottle or carton.
Return all unused medicine to your pharmacist.
Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF ATACAND PLUS:

ATACAND PLUS 16/12,5 mg; 32/12,5 mg; 32/25 mg:
Tablets are packed into white HDPE bottles containing 28 or 30 tablets per container.
ATACAND PLUS 16/12,5 mg; 32/12,5 mg; 32/25 mg:
Tablets are available in clear PVC/PVDC/aluminium blister packs of 28 or 30 tablets.

8. IDENTIFICATION OF ATACAND PLUS:

ATACAND PLUS 16/12,5 mg is a peach-coloured, oval tablet with a score line on both sides of the tablet and marked with *A/CS*.

ATACAND PLUS 32/12,5 mg tablets are yellow, oval, biconvex tablets with a score and engraving *A/CJ* on one side and a pressure sensitive bisect on the reverse side.

ATACAND PLUS 32/25 mg tablets are pink, oval, biconvex tablets with a score and engraving *A/CD* on one side and a pressure sensitive bisect on the reverse side.

The tablets can be divided into equal halves.

9. REGISTRATION NUMBERS:

ATACAND PLUS 16/12,5 mg: 35/7.1.3/0098
ATACAND PLUS 32/12,5 mg: 43/7.1.3/0922
ATACAND PLUS 32/25 mg: 43/7.1.3/0923

10. NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

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11. DATE OF PUBLICATION OF PATIENT INFORMATION LEAFLET:

30 September 2011