Read all of this leaflet before you start taking this medicine. If you have any further questions, ask your doctor or pharmacist. This leaflet refers to COVERSYL PLUS tablets, which are brown and white tablets containing the active ingredients perindopril and indapamide. Please keep this leaflet, even if you are not taking COVERSYL PLUS at the moment, as you may need to read it again in the future.

In this leaflet:
1. What COVERSYL PLUS is and what it is used for
2. Before you take COVERSYL PLUS
3. How to take COVERSYL PLUS
4. Possible side effects
5. What to do if you think you have had an overdose
6. Further information

What is COVERSYL PLUS?

COVERSYL PLUS is a combination of two active ingredients, perindopril and indapamide. It is an anti-hypertensive and is used in the treatment of high blood pressure (hypertension).

What is COVERSYL PLUS used for?

Perindopril belongs to a class of medicines called ACE inhibitors. These work by widening the arteries to make it easier for blood to pass through them, thus lowering the pressure. Similar to other ACE inhibitors, COVERSYL PLUS is likely to cause an increase in the amount of urine produced by the kidneys. This is because COVERSYL PLUS is a diuretic, or water pill. COVERSYL PLUS is also used to treat heart rhythm problems (e.g. quinidine, hydroquinidine, lithium (used to treat depression), allopurinol (used to treat gout), halofantrine (used to treat certain types of malaria), erythromycin (an antibiotic). If you are on a salt-restricted diet or are using medicines that contain potassium, or you have diabetes, or you are going to have desensitisation treatment to reduce the effects of an allergy to bee or wasp stings, you should tell your doctor or pharmacist before taking COVERSYL PLUS.

2. BEFORE YOU TAKE COVERSYL PLUS

Do not take COVERSYL PLUS:

- if you are allergic to any of its ingredients, or if you are taking a different medicine that contains any of these ingredients.
- medicines to treat mental disorders such as depression, anxiety, schizophrenia...(e.g. tricyclic antidepressants, neuroleptics (such as amisulpride, sulpiride, sulothpride, liapride, haloperidol, droperidol)), or hypertrophic cardiomyopathy (heart muscle disease) or renal artery stenosis (narrowing of the artery supplying the kidney with blood).

Before you start taking COVERSYL PLUS:

Tell your doctor or pharmacist if you:
- have had liver problems or problems with your kidneys;
- have had an allergic reaction to any of the ingredients in COVERSYL PLUS;
- have had a collagen disease or skin disease such as systemic lupus erythematosus or rheumatoid arthritis;
- have had encephalopathy (degenerative disease of the brain);
- have had hypokalaemia (low potassium) or hyperkalaemia (high potassium);
- have had Raynaud's phenomenon (painful episodes of the fingers);
- have had Addison's disease;
- have ever been breast-feeding;
- have a history of gout;
- have had a history of certain types of anaemia (e.g. thalassaemia, sickle cell anaemia);
- have had a history of sickle cell crisis;
- are taking any medicine that contains potassium, or you have diabetes;
- have a history of infection of the pancreas;
- have had a history of heart problems;
- are using a medicine that causes an increased risk of bone problems or fractures;
- are using a medicine that causes an increased risk of skin cancer;
- are using a medicine that increases the risk of forming blood clots;
- are using a medicine that increases the risk of formation of gallstones;
- are using a medicine that causes the blood to clot more quickly;
- are using a medicine that causes the blood to clot more slowly;
- are using a medicine that causes an inactivity of some enzymes, consult your doctor before taking this medicine; or
- have a history of angina or strokes.

3. HOW TO TAKE COVERSYL PLUS

Always take COVERSYL PLUS exactly as your doctor has prescribed. You should check with your doctor or pharmacist if you are unsure about how to take this medicine. The usual dose is one tablet a day. Your doctor may decide to modify the dosage regimen if you suffer from renal or hepatic insufficiency or if you have some other medical condition. You may also need to take your tablet before a meal. If you forget to take COVERSYL PLUS:

It is very important that you always take your tablet on time. If you forget to take a tablet of COVERSYL PLUS, take it as soon as you remember. However, if you forget to take a tablet at bedtime, you do not need to take it; simply take the next one at your usual time. If you take too many tablets, contact your doctor or nearest hospital casualty department. If you stop taking COVERSYL PLUS:

- you should always finish taking your tablets even if you feel better, as your doctor or pharmacist will be able to tell you if it is safe to stop.
- if you are just about to have a heart operation or diagnostic test, you may need to stop taking COVERSYL PLUS a few days before the operation. Your doctor may give you a substitute treatment for a few days before the operation.

4. POSSIBLE SIDE EFFECTS

Use of ACE inhibitors, COVERSYL PLUS can cause side effects, although not everybody gets them.

4.1 Common side effects that may affect more than 1 in 10 people:

- headache, feelings of dizziness, vertigo, pins and needles, swelling of the legs, raised can help
- anorexia, vomiting, abdominal pain, faecal disturbances, dry mouth, dyspepsia or diarrhoea,
- coughing, swallowing or sticking in the throat;
- feeling of tiredness, weakness (in relation to the decrease in blood pressure)

4.2 Less common (less than 1 in 10 people but more than 1 in 100 people):

- skin reaction (e.g. redness, itching, burning sensations), hives, yellowing of the skin or whites of the eyes, severe skin reactions such as systemic lupus erythematosus or rheumatoid arthritis, or symptoms of a sensitivity reaction to a medicine (anaphylactic shock), persistent dry skin, sweats,
- skin appearance) after exposure to the sun or artificial UVA have also been reported.
- coldness or numbness in the hands or feet, tingling sensations (paresthesias), numbness in the fingers or toes;
- swelling of the face, lips, mouth, tongue, throat, difficulty in breathing;
- swelling in the hands or feet;
- numbness, pins and needles in the hands or feet;
- swelling of the face, lips, tongue, throat, difficulty in breathing;
- feeling of fatigue, weakness, reduction in red blood cell count;
- feeling of coldness, numbness, pins and needles in the hands or feet;
- feeling of dizziness, vertigo, pins and needles, swelling of the legs, raised can help
- feeling of tiredness, weakness (in relation to the decrease in blood pressure)

4.3 Very rare (occurring less than 1 in 10,000 users):

- pruritus (itching), angioedema (symptoms such as wheezing, swelling of the face, lips, mouth, tongue, throat, difficulty in breathing);
- any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, you should tell your doctor or pharmacist.

5. WHAT TO DO IF YOU THINK YOU HAVE HAD AN OVERDOSE

If you think you have taken too much of COVERSYL PLUS, contact your doctor or the Poison Control centre at your local hospital immediately.

6. FURTHER INFORMATION

This leaflet refers to COVERSYL PLUS tablets, which are brown and white tablets containing the active ingredients perindopril and indapamide. The active substances are perindopril tert-butylicarboxamide and indapamide. The other ingredients in this product include lactose, magnesium stearate (E470B), colloidal anhydrous silica and microcrystalline cellulose.

COVERSYL PLUS tablets are orange, oval, white tablets. These tablets contain 4 mg indapamide and 4 mg perindopril. These tablets are available in bottles of 30.

Manufactured by:

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"COVERSYL" PLUS tablets
perindopril tert-butylicarboxamide

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