For the medical profession only

Perindopril tert-butylamine and amlodipine besilate tablets

COVERSAM™

4mg/5mg

COMPOSITION

Each uncoated scored tablet contains
perindopril tert-butylamine "Ph. Eur." 4mg
amlodipine besilate "Ph. Eur." 5mg
excipients ..... q.s.

THERAPEUTIC CLASS

Perindopril is an angiotensin converting enzyme (ACE) inhibitor.
Amlodipine besilate is a calcium channel blocker.

INDICATIONS

Essential hypertension

CONTRAINDICATIONS

This medicine SHOULD NOT BE used in the following cases:

- Patients with known allergy to perindopril and/or amlodipine
- Children under 15 years of age

SIDE EFFECTS

As with active products, this drug may cause undesirable effects of varying severity in certain patients. The reported side-effects include headache, oedema, fatigue, somnolence, feeling of dizziness, flushing, palpitations, dizziness, mood and/or sleep disturbances, gastro-intestinal pain, taste disturbances and dry cough.

For any persistent or any unpleasant experience the patients should contact the doctor.

SPECIAL PRECAUTIONS FOR USE

Due to the presence of lactose, this drug should not be used in the case of congenital galactosemia, the syndrome of malabsorption of glucose and galactose or a deficit in lactase (rare metabolic diseases).

Caution should be exercised while prescribing **COVERSAM**™ to patients with impaired hepatic and renal functions. Assess renal function before and during treatment where appropriate. In patients with renovascular hypertension, surgery/anaesthesia, renal failure, the dose should be cautiously adjusted in accordance with the creatinine clearance. There is a risk of allergic reactions and angioneurotic oedema. The doctor should be informed about the treatment if the patient has to undergo haemodialysis.

COVERSAM™ does not contain a beta-bloker and therefore gives no protection against the dangers of abrupt beta-blocker withdrawal; any such withdrawal should be performed by gradual reduction of the dose of beta-blocker.

Combination with beta-blockers must be avoided in patients with markedly impaired left ventricular function. Combination with neuroleptics or imipramine-type drugs may increase the hypotensive effect. Serum lithium concentrations may rise during lithium therapy.

Acute hypotension has rarely been reported with Amlodipine. Nonetheless, caution should be exercised when administering **COVERSAM**™ as with any other peripheral vasodilator particularly in patients with severe aortic stenosis. In general, calcium channel blockers should be used with caution in patients with heart failure. Symptomatic hypotension is rarely seen but is more likely in volume-depleted patients, those receiving diuretics, or with the first two doses. A diuretic may later be given in association if necessary; potassium-sparing diuretics are not recommended.

CO-ADMINISTRATION WITH OTHER HYPERTENSIVES AND/OR ANTIANGINAL DRUGS

COVERSAM™ can be co-administered with other hypertensive (potassium-sparing diuretics are not recommended) and/or antianginal drugs. However care should be exercised before prescribing to avoid any possibility of hypotension.

INTERACTIONS WITH OTHER MEDICINES

Special attention is needed while prescribing other medications such as lithium salts, estramustine, potassium salts or a potassium-sparing diuretic and drugs that are likely affect the drug displacements and potentiate the drug action.

PREGNANCY AND LACTATION

As with other medicines, use of this medicine is contraindicated during pregnancy. There are no data about the passage of this medicine into maternal milk. Consequently, administration of this medicine is not recommended in women who are breast-feeding.

DRIVERS AND MACHINERY OPERATORS

Drivers and machine operators should take special care due to the risk of dizziness.

DOSAGE AND ADMINISTRATION

COVERSAM™ one tablet once daily.

The usual dose of **COVERSAM**™ is Perindopril 4mg and amlodipine 5mg. The maximum daily dose is Perindopril 8mg and Amlodipine 10mg. The increments in the dosage should be adjusted to each patient's need to attain the control of the elevated blood pressure. The increments should be spaced over the time intervals of 1 to 2 weeks.

OVERSDOSAGE

Hypotension is the most likely result of overdosage.
If significant hypotension occurs, it may be countered by making the patient lie down with the legs elevated. Gastric lavage should be performed if necessary.
For any emergency the doctor should be contacted immediately.

PRESENTATION

Rod-shaped uncoated scored tablet.
Box of 10 tablets.

INSTRUCTIONS FOR USE AND HANDLING

Keep medicines away from children.
Do not use after the printed expiry date on the carton.
Protect from direct light, heat & moisture.

SERVIER

Manufactured by:
Servier Research & Pharmaceuticals [Pakistan] (Pvt.) Ltd.
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