Perindopril/Amlodipine 4 mg / 5 mg tablets

Perindopril/Amlodipine 8 mg / 5 mg tablets

Perindopril/Amlodipine 8 mg / 6 mg tablets

What is this leaflet about?

1. What Perindopril/Amlodipine is and what it is used for

Perindopril/Amlodipine is a combination of two medicines used to treat high blood pressure, a condition where the blood supply to the heart is reduced or blocked.

- You may need to read 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.
- Ask your doctor or pharmacist if you do not understand any part.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

2. Before you take Perindopril/Amlodipine

Do not take Perindopril/Amlodipine if:

- you are allergic to any of the active ingredients of this medicine listed in section 6 or any other ACE inhibitor, amlodipine besylate or any of the other ingredients of this medicine.
- you have a sign of an allergic reaction (shock). This is an emergency. Stop taking this medicine immediately and seek medical advice immediately.

You must tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicine, even those that you buy without prescription.

- If you have a history of diabetes or if you have had diabetes-related kidney problems, telmisartan, irbesartan, then Perindopril/Amlodipine is not recommended in elderly patients, and must not be taken if you are more than 75 years of age, as well as other medicines for high blood pressure, including diuretics (medicines which increase the amount of urine produced by the kidneys),
- non-steroidal anti-inflammatory drugs (such as ibuprofen, aspirin, or any other medicine that is used to treat pain, inflammation or swelling),
- aliskiren, an angiotensin II receptor blocker (ARB) also used to treat high blood pressure, includingaxifen,
- high dose acetylsalicylic acid (ASA),
- medicines to treat mental disorders such as depression, anxiety, schizophrenia etc. (e.g., trifluoperazine, antipsychotics, anticonvulsants, tricyclic antidepressants, venlafaxine),
- immunosuppressants (medicines which reduce the defence mechanism of the body) used for the treatment of autoimmune disorders or following organ transplantation (e.g., ciclosporin),
- treatment of auto-immune disorders or following organ transplantation (e.g., ciclosporin),
- for the treatment of an irregular heartbeat (e.g., diltiazem, verapamil),
- other medicines containing potassium (e.g., potassium-sparing diuretics (spironolactone, eplerenone),
- antiepileptic agents such as carbamazepine, primidone, phenobarbital, phenytoin, fosphenytoin,
- non-steroidal anti-inflammatory drugs (such as ibuprofen, aspirin, or any other medicine that is used to treat pain, inflammation or swelling),
- estrogens (used in hormone replacement therapy that are used to treat cancer),
- aliskiren, an angiotensin II receptor blocker (ARB) also used to treat high blood pressure, includingaxifen,
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If you take too many tablets, contact your nearest doctor immediately. The most likely symptoms of overdose are loss of consciousness, severe dizziness, falling, difficulty breathing.

If you feel any experience of the following, stop taking the medicinal product at once and tell your doctor immediately:

- symptoms of allergic reactions such as swelling of the face, throat, difficulty breathing.
- severe dizziness or fainting.
- unusual fast or irregular heart beat.

As the treatment with Perindopril/Amlodipine is long-term, you should discuss with your doctor before you stop taking the tablets.

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

Possible side effects

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

If you experience any of the following, stop taking the medicinal product at once and tell your doctor immediately:

- dry mouth.
- sweating.
- abdominal pain, taste disturbances, dyspepsia
- muscle cramps, feeling of tiredness, oedema
- weakness or tiredness.
- joint pain, chest pain, increased need to urinate especially during the night, malaise (general feeling of illness), fever,conjunctivitis (red eye)
- blood in urine or stool, pain and redness in the eye.
- tongue or lip swelling.
- prolonged bruising.
- unusual fast or irregular heart beat.

Common side effects (occur in less than 1 in 10 people):

- skin irritation, sweating.
- headache, dizziness, vertigo, pins and needles.
- infection of the skin, upset stomach.
- urinary tract infection, vaginal infection.
- abdominal pain, taste disturbances, dyspepsia
- muscle cramps, feeling of tiredness, oedema
- weakness or tiredness.

Other side effects include:

- confusion, cardiovascular disorders (irregular heart beat).
- skin disorders (dryness, itching, erythroderma, psoriasis), alopecia.
- other skin disorders (abnormal pigmentation, skin rash, folliculitis, paronychia, pruritus, eczema).
- abdominal pain, taste disturbances, dyspepsia
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- weakness or tiredness.

If you stop taking Perindopril/Amlodipine

Do not take a dose to make up for a missed dose.

Each tablet contains 4 mg perindopril tert-butylamine (equivalent to 3.34 mg perindopril) and 5 mg amlodipine (as besilate).

Each tablet contains 8 mg perindopril tert-butylamine (equivalent to 6.68 mg perindopril) and 10 mg amlodipine (as besilate).

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This leaflet was last revised 02/2015

Perindopril/Amlodipine 8 mg/10 mg tablets: this medicinal product is presented as white to almost white, round, biconvex tablets with bevelled edges and a score line on one side.

This leaflet can be expanded into a fold out page.

The tablets are available in cartons of 7, 10, 14, 28, 30, 50, 56, 60 and 100 tablets in blister packs. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Consilient Health (UK) Ltd., 75 High Street, Braintree, CM7 3BY, England.

Distributed by: Consilient Health (UK) Ltd., 18501 Novo mesto, Slovenia

Marketing Authorisation Holder

KRKA, d.d., Novo mesto, Šmarješka cesta 6, 2149, Slovenia.

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