Bijsluiter: Informatie voor de patiënt

Dipperam 5 mg/80 mg, filmomhulde tabletten
Dipperam 5 mg/160 mg, filmomhulde tabletten
Dipperam 10 mg/160 mg, filmomhulde tabletten

amlodipine (as amlodipine besylate) /valsartan

Read all of 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.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What [Nationally completed name] is and what it is used for

[Nationally completed name] tablets contain two substances called amlodipine and valsartan. Both of these substances help to control high blood pressure.
- **Amlodipine** belongs to a group of substances called "calcium channel blockers". Amlodipine stops calcium from moving into the blood vessel wall which stops the blood vessels from tightening.
- **Valsartan** belongs to a group of substances called "angiotensin-II receptor antagonists". Angiotensin II is produced by the body and makes the blood vessels tighten, thus increasing the blood pressure. Valsartan works by blocking the effect of angiotensin II.

This means that both of these substances help to stop the blood vessels tightening. As a result, the blood vessels relax and blood pressure is lowered.

[Nationally completed name] is used to treat high blood pressure in adults whose blood pressure is not controlled enough with either amlodipine or valsartan on its own.

2. What you need to know before you take [Nationally completed name]

Do not take [Nationally completed name]
- if you are **allergic to amlodipine** or to **any other calcium channel blockers**. This may involve itching, reddening of the skin or difficulty in breathing.

- if you are **allergic to valsartan** or any of the other ingredients of this medicine (listed in section 6). If you think you may be allergic, talk to your doctor before taking [Nationally completed name].
- if you have **severe liver problems** or **bile problems** such as **biliary cirrhosis** or **cholestasis.**
- if you are **more than 3 months pregnant.** (It is also better to avoid [Nationally completed name] in early pregnancy, see Pregnancy section).
- if you have **severe low blood pressure** (hypotension).
- if you have **narrowing of the aortic valve** (aortic stenosis) or **cardiogenic shock** (a condition where your heart is unable to supply enough blood to the body).
- if you suffer from **heart failure after a heart attack.**
- if you have **diabetes** or **impaired kidney function** and you are treated with a blood pressure lowering medicine containing **aliskiren.**

If any of the above applies to you, do not take [Nationally completed name] and talk to your doctor.

Warnings and precautions
Talk to your doctor before taking [Nationally completed name]:
- if you have been sick (**vomiting** or **diarrhoea**).
- if you have **liver or kidney problems.**
- if you have had a **kidney transplant** or if you had been told that you **have a narrowing of your kidney arteries.**
- if you have a **condition affecting the renal glands** called "primary hyperaldosteronism".
- if you have had **heart failure** or **have experienced a heart attack.**
  Follow your doctor's instructions for the starting dose carefully. Your doctor may also check your kidney function.
- if your doctor has told you that you **have a narrowing of the valves in your heart** (called "aortic or mitral stenosis") or **that the thickness of your heart muscle is abnormally increased** (called "obstructive hypertrophic cardiomyopathy").
- if you have **experienced swelling, particularly of the face and throat**, while taking other medicines (including angiotensin converting enzyme inhibitors).
  If you get these symptoms, **stop taking [Nationally completed name]** and **contact your doctor straight away.**
  You should **never take [Nationally completed name] again**.
- if you are taking any of the following medicines used to treat high blood pressure:
  - **an ACE inhibitor** (for example enalapril, lisinopril, ramipril), in particular if you have diabetes-related kidney problems.
  - **aliskiren.**

Your doctor may check your kidney function, blood pressure, and the amount of electrolytes (e.g. potassium) in your blood at regular intervals.

See also information under the heading "Do not take [Nationally completed name]".

If any of these apply to you, tell your doctor before taking [Nationally completed name].

Children and adolescents
The use of [Nationally completed name] in children and adolescents is not recommended (aged below 18 years old).

Other medicines and [Nationally completed name]

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Your doctor may need to change your dose and/or to take other precautions. In some cases you may have to stop taking one of the medicines. This applies especially to the medicines listed below:
- **ACE inhibitors** or **aliskiren** (see also information under the headings "Do not take [Nationally completed name]" and "Warnings and precautions");
- **diuretics** (a type of medicine also called "water tablets" which increases the amount of urine you produce);
- **lithium** (a medicine used to treat some types of depression);
- **potassium-sparing diuretics**, **potassium supplements**, **salt substitutes containing potassium** and **other substances** that **may increase potassium levels;**
- certain types of **painkillers** called non-steroidal anti-inflammatory medicines (NSAIDs) or selective cyclooxygenase-2 inhibitors (COX-2 inhibitors). Your doctor may also check your kidney function;
- **anticonvulsant agents** (e.g. carbamazepine, phenobarbital, phenytoin, fosphenytoin, primidone);
- **St. John's wort;**
- **nitroglycerin** and **other nitrates**, or other substances called "vasodilators";
- **medicines used for HIV/AIDS** (e.g. ritonavir, indinavir, nelfinavir);
- **medicines used to treat fungal infections** (e.g. ketoconazole, itraconazole);
- **antibiotics** (such as rifampicin, erythromycin, clarithromycin, talithromycin);
- **verapamil, diltiazem** (heart medicines);
- **simvastatin** (a medicine used to control high cholesterol levels);
- **dantrolene** (infusion for severe body temperature abnormalities);
- **medicines used to protect against transplant rejection** (ciclosporin).

[Nationally completed name] with food and drink
Grapefruit and grapefruit juice should not be consumed by people who are taking [Nationally completed name]. This is because grapefruit and grapefruit juice can lead to an increase in the blood levels of the active substance amlodipine, which can cause an unpredictable increase in the blood pressure lowering effect of [Nationally completed name].

Pregnancy and breast-feeding
Pregnancy
You must tell your doctor if you think you are (or might become) pregnant. Your doctor will normally advise you to stop taking [Nationally completed name] before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of [Nationally completed name]. [Nationally completed name] is not recommended in early pregnancy (first 3 months), and must not be taken when more than 3 months pregnant, as it may cause serious harm to your baby if used after the third month of pregnancy.

Breast-feeding
Tell your doctor if you are breast-feeding or about to start breast-feeding. [Nationally completed name] is not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breast-feed, especially if your baby is newborn, or was born prematurely.

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

Driving and using machines
This medicine may make you feel dizzy. This can affect how well you can concentrate. So, if you are not sure how this medicine will affect you, do not drive, use machinery, or do other activities that you need to concentrate on.

3. How to take [Nationally completed name]

Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure. This will help you get the best results and lower the risk of side effects.

The usual dose of [Nationally completed name] is one tablet per day.
- It is preferable to take your medicine at the same time each day.
- Swallow the tablets with a glass of water.
- You can take [Nationally completed name] with or without food. Do not take [Nationally completed name] with grapefruit or grapefruit juice.

Depending on how you respond to the treatment, your doctor may suggest a higher or lower dose.

Do not exceed the prescribed dose.

[Nationally completed name] and elderly (age 65 years or over)
Your doctor should exercise caution when increasing your dose.

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

If you take more [Nationally completed name] than you should
If you have taken too many tablets of [Nationally completed name], or if someone else has taken your tablets, consult a doctor immediately.

Excess fluid may accumulate in your lungs (pulmonary oedema) causing shortness of breath that may develop up to 24-48 hours after intake.

If you forget to take [Nationally completed name]
If you forget to take this medicine, take it as soon as you remember. Then take your next dose at its usual time. However, if it is almost time for your next dose, skip the dose you missed. Do not take a double dose to make up for a forgotten tablet.

If you stop taking [Nationally completed name]
Stopping your treatment with [Nationally completed name] may cause your disease to get worse. Do not stop taking your medicine unless your doctor tells you to.

4. Possible side effects

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

Some side effects can be serious and need immediate medical attention:
A few patients have experienced these serious side effects **(may affect up to 1 in 1,000 people)**. **If any of the following happen, tell your doctor straight away:**
- allergic reaction with symptoms such as rash, itching, swelling of face or lips or tongue, difficulty breathing, low blood pressure (feeling of faintness, light-headedness)

Other possible side effects of [Nationally completed name]:
Common (may affect up to 1 in 10 people):
- influenza (flu)

- blocked nose, sore throat and discomfort when swallowing
- headache
- swelling of arms, hands, legs, ankles or feet
- tiredness
- asthenia (weakness)
- redness and warm feeling of the face and/or neck

Uncommon (may affect up to 1 in 100 people):
- dizziness
- nausea and abdominal pain
- dry mouth
- drowsiness, tingling or numbness of the hands or feet
- vertigo
- fast heart beat including palpitations
- dizziness on standing up
- cough
- diarrhoea
- constipation
- skin rash, redness of the skin
- joint swelling, back pain
- pain in joints

Rare (may affect up to 1 in 1,000 people):
- feeling anxious
- ringing in the ears (tinnitus)
- fainting
- passing more urine than normal or feeling more of an urge to pass urine
- inability to get or maintain an erection
- sensation of heaviness
- low blood pressure with symptoms such as dizziness, light-headedness
- excessive sweating
- skin rash all over your body
- itching
- muscle spasm

If any of these affect you severely, tell your doctor.

Side effects reported with amlodipine or valsartan alone and either not observed with [Nationally completed name] or observed with a higher frequency than with [Nationally completed name]:

Amlodipine
Consult a 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 the mucous membranes (Stevens-Johnson Syndrome, toxic epidermal necrolysis) or other allergic reactions
- heart attack, abnormal heart beat

- inflamed pancreas, which may cause severe abdominal and back pain accompanied with feeling of being very unwell

The following 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 (may affect up to 1 in 10 people):
Dizziness, sleepiness, palpitations (awareness of your heart beat), flushing, ankle swelling (oedema), abdominal pain, feeling sick (nausea)

Uncommon (may affect up to 1 in 100 people):
Mood changes, anxiety, depression, sleeplessness, trembling, taste abnormalities, fainting, loss of pain sensation, visual disturbances, visual impairment, ringing in the ears, low blood pressure, sneezing/runny nose caused by inflammation of the lining of the nose (rhinitis), indigestion, vomiting (being sick), hair loss, increased sweating, itchy 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, pain, feeling unwell, muscle pain, muscle cramps, weight increase or decrease.

Rare (may affect up to 1 in 1,000 people):
Confusion.

Very rare (may affect up to 1 in 10,000 people):
Decreased number of white blood cells, decrease in blood platelets which may result in unusual brusing or easy bleeding (red blood cell damage), excess sugar in blood (hyperglycaemia), 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, sensitivity to light, disorders combining rigidity, tremor and/or movement disorders.

Valsartan
Not known (frequency cannot be estimated from the available data):
Decrease in red blood cells, fever, sore throat or mouth sores due to infections, spontaneous bleeding or bruising, high level of potassium in the blood, abnormal liver test results, decreased renal functions and severely decreased renal functions, swelling mainly of the face and the throat, muscle pain, rash, purplish-red spots, fever, itching, allergic reaction, blistering skin (sign of a condition called dermatitis bullous).

If you experience any of these, tell your doctor straight away.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store **[Nationally completed name]**

Keep this medicine out of the sight and reach of children.

Do not use this medicine 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 30°C.

Store in the original package in order to protect from moisture.

Do not use this medicine if you notice the visible signs of deterioration.
Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What [Nationally completed name] contains

- The active substances are amlodipine (as amlodipine besylate) and valsartan.
  Each 5 mg/80 mg film-coated tablet contains 5 mg of amlodipine and 80 mg of valsartan.
  Each 5 mg/160 mg film-coated tablet contains 5 mg of amlodipine and 160 mg of valsartan.
  Each 10 mg/160 mg film coated tablet contains 10 mg of amlodipine and 160 mg of valsartan.

- The other ingredients are:
  5 mg/80 mg film-coated tablets:
  cellulose microcrystalline; crospovidone (Type A); silica, colloidal anhydrous; magnesium stearate; hypromellose (substitution type 2910 (3 mPa.s)); titanium dioxide (E 171); iron oxide, yellow (E 172); macrogol 4000; talc.
  mg/160 mg film-coated tablets:
  cellulose microcrystalline; crospovidone (Type A); silica, colloidal anhydrous; magnesium stearate; hypromellose (substitution type 2910 (3 mPa.s)); titanium dioxide (E 171); iron oxide, yellow (E 172); macrogol 4000; talc.
  10 mg/160 mg film-coated tablets:
  cellulose microcrystalline; crospovidone (Type A); silica, colloidal anhydrous; magnesium stearate; hypromellose (substitution type 2910 (3 mPa.s)); titanium dioxide (E 171); iron oxide, yellow (E 172); iron oxide, red (E 172); macrogol 4000; talc.

What [Nationally completed name] looks like and contents of the pack
5 mg/80 mg film-coated tablets:
Dark yellow and round with beveled edges, debossed with "NVR" on one side and "NV" on the other side.
Approximate size: diameter 8.20 mm.

5 mg/160 mg film-coated tablets:
Dark yellow and ovaloid with beveled edges, debossed with "NVR" on one side and "ECE" on the other side.
Approximate size: 14.2 mm (length) x 5.7 mm (width).

10 mg/160 mg film-coated tablets:
Light yellow and ovaloid with beveled edges, debossed with "NVR" on one side and "UIC" on the other side.
Approximate size: 14.2 mm (length) x 5.7 mm (width).

[Nationally completed name] is available in packs containing 7, 14, 28, 30, 56, 90, 98 or 280 film-coated tablets and in multipacks comprising 4 cartons, each containing 70 film-coated tablets, or 20 cartons, each containing 14 film-coated tablets. All packs are available with standard PVC/PVDC blisters; the 56, 98 and 280 film-coated tablet packs are additionally available with perforated unit dose PVC/PVDC blisters.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Houder van de vergunning voor het in de handel brengen
Sandoz B.V.
Veluwezoom 22
1327 AH Almere
Nederland

Fabrikant
Novartis Pharma GmbH
Roonstrasse 25
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Duitsland

Novartis Farmacéutica S.A.
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08013 Barcelona
Spanje

Novartis Pharma S.p.A.
Via Provinciale Schito, 131
80058 Torre Annunziata (NA)
Italië

In het register ingeschreven onder:
Dipperam 5 mg/80 mg, filmomhulde tabletten - RVG 119500
Dipperam 5 mg/160 mg, filmomhulde tabletten - RVG 119505
Dipperam 10 mg/160 mg, filmomhulde tabletten - RVG 119506

Dit geneesmiddel is geregistreerd in lidstaten van de EEA onder de volgende namen:

Nederland	Dipperam, 5 mg/80 mg, filmomhulde tabletten
	Dipperam, 5 mg/160 mg, filmomhulde tabletten
	Dipperam, 10 mg/160 mg, filmomhulde tabletten
Bulgarije	ДИПЕРАМ 5 mg/80 mg филмирани таблетки;
	ДИПЕРАМ 5 mg/160 mg филмирани таблетки;
	ДИПЕРАМ 10 mg/160 mg филмирани таблетки.
Estland	Dipperam
Litouwen	Dipperam 5 mg/80 mg plėvele dengtos tabletės

	Dipperam 5 mg/160 mg plėvele dengtos tabletės
	Dipperam 10 mg/160 mg plėvele dengtos tabletės
Letland	Dipperam 5 mg/80 mg apvalkotās tabletes
	Dipperam 5 mg/160 mg apvalkotās tabletes
	Dipperam 10 mg/160 mg apvalkotās tabletes
Polen	Dipperam, 5 mg + 80 mg, tabletki powlekane
	Dipperam, 5 mg + 160 mg, tabletki powlekane
	Dipperam, 10 mg + 160 mg, tabletki powlekane
Roemenië	Dipperam 5 mg/80 mg comprimate filmate
	Dipperam 5 mg/160 mg comprimate filmate
	Dipperam 10 mg/160 mg comprimate filmate
Slovenië	Dipperam 5 mg/80 mg filmsko obložene tablete
	Dipperam 5 mg/160 mg filmsko obložene tablete
	Dipperam 10 mg/160 mg filmsko obložene tablete

Deze bijsluiter is voor het laatst goedgekeurd in juni 2022.