Package leaflet: Information for the patient

Barnidipine HCl Sigillata 10 mg, harde capsules met gereguleerde afgifte
Barnidipine HCl Sigillata 20 mg, harde capsules met gereguleerde afgifte
barnidipine hydrochloride

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 [Product Name] is and what it is used for

The active substance of [Product Name] belongs to the group of medicines called calcium antagonists. [Product Name] causes blood vessels to dilate thereby lowering blood pressure. [Product Name] capsules are made in a 'prolonged-release' form. This means that the active substance gets absorbed into your system gradually and has a longer lasting effect. That is why taking the dose once daily is sufficient.

[Product Name] is used to treat high blood pressure.

2. What you need to know before you take [Product Name]

Do not take [Product Name]:
- if you are allergic to barnidipine or any of the other ingredients of this medicine (listed in section 6)
- if you are allergic to dihydropyridines (found in medicines to treat high blood pressure)
- if you suffer from liver disease
- if you suffer from severe kidney disease
- if you suffer from these specific heart diseases: untreated heart failure, certain forms of pain on the chest (unstable angina pectoris) or acute cardiac arrest
- if you use one of the following other medicines: protease blockers (medicines used to treat AIDS), ketoconazole or itraconazole (medicines to treat yeast infections), erythromycin or clarithromycin (antibiotics, see Other medicines and [Product Name]).

Warnings and precautions
Talk to your doctor or pharmacist before taking [Product Name]
- if you suffer from a kidney disease
- if you suffer from a heart disease.

Children and adolescents
[Product Name] is not to be used in children or adolescents under 18 years.

Other medicines and [Product Name]

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

This is especially important if you use one of the following medicines as they **MUST not** be used together with [Product Name] (see Do not take [Product Name]):
- protease blockers (medicines used to treat AIDS)
- ketoconazole or itraconazole (medicines to treat yeast infections)
- erythromycin or clarithromycin (antibiotics).

Also inform your doctor if you are taking:
- other medicines to treat high blood pressure as they may cause your blood pressure to fall even more
- cimetidine (medicine against stomach problems) as they may increase the effect of [Product Name]
- phenytoin or carbamazepine (medicines used to treat epilepsy), or rifampicin (an antibiotic) as higher dose of [Product Name] may be needed. If you stop treatment with these medicines, your doctor may lower the dose of [Product Name].

[Product Name] with drink and alcohol
Take special care when drinking alcohol or grapefruit juice, as these may cause an increase in the effect of [Product Name].

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

You should not use [Product Name] during pregnancy unless clearly necessary.
Do not use [Product Name] if you breast feed. Barnidipine may get into your breast milk.

Driving and using machines
There is no information to suggest that barnidipine affects your ability to drive or use machines. However, [Product Name] may cause dizziness, so make sure you know how this medicine affects you before you drive or use machines.

[Product Name] contains sucrose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take [Product Name]

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual starting dose is 10 mg once a day. Your doctor may increase this dose to 1 capsule of 20 mg once a day or 2 capsules of 10 mg once a day.

If you are older you can use the normal dosage. Your doctor will most likely monitor you more closely at the start of the treatment.

Instructions for use
- Take the capsule once daily, in the morning. It is advisable to associate taking the capsule with something you do on a daily basis, like brushing your teeth or having breakfast.
- Swallow the capsules whole, preferably with a glass of water. You can take [Product Name] before, during or after a meal, according to your preference.
- Even though you may not feel any signs or symptoms of high blood pressure, it is important to continue to take [Product Name] every day to get the full benefits of blood pressure reduction.

If you take more [Product Name] than you should
If you have accidentally taken a large amount of capsules at once, you should **immediately** contact your doctor or have someone bring you to the hospital emergency room. Possible symptoms followed by an overdose are weakness, slow or faster heart rate, drowsiness, confusion, nausea, vomiting and convulsions.

If you forget to take [Product Name]
If you forget to take [Product Name] at your usual time take the capsule as soon as possible on that same day.
If you only remember the following day, do **NOT** take a double dose to make up for a forgotten dose. Simply continue with your regular daily dose.

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

4. Possible side effects

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

If you experience serious allergic reaction, which causes difficulty in breathing or dizziness, you must inform your doctor or nurse **immediately**.

[Product Name] may cause the following:

[Product Name] 20 mg:
Very common: may affect more than 1 in 10 people
- headache
- facial redness
- fluid accumulation (oedema) in arms or legs.

Common: may affect up to 1 in 10 people
- dizziness
- palpitations.

Product Name] 10 mg:
Common: may affect up to 1 in 10 people
- headache
- facial redness
- fluid accumulation (oedema) in arms or legs.
- dizziness
- palpitations.

[Product Name] 10 mg & 20 mg:
Not known: frequency cannot be estimated from the available data
- faster heart beat
- blood tests which show changes in the way the liver is working
- rash.

These side effects usually lessen or disappear during treatment (within one month for fluid accumulation and within two weeks for facial redness, headache and palpitations).

Following side effects have been observed in some of the other medicines belonging to the same group of medicines that [Product Name]:
- overgrowth of gums (gingival hyperplasia),
- pain in the left side of the chest (precordial pain) or chest pain (angina pectoris) has been rarely observed (may affect up to 1 in 1,000 people),
- increase in frequency or severity of angina pectoris attacks in patients with pre-existing angina pectoris has been very rarely observed (may affect up to 1 in 10,000 people)

- heart attack (myocardial infarction) has been observed in isolated cases

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 [Product Name]

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

Do not store above 25°C.

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 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 [Product Name] contains

- The active substance is barnidipine. Each capsule contains 10 mg or 20 mg of barnidipine hydrochloride, equivalent to 9.3 mg or 18.6 mg barnidipine, respectively.
- The other ingredients are:
  Capsule content: Sugar spheres (containing sugar syrup, corn starch and sucrose), carboxymethylethylcellulose, polysorbate 80, ethylcellulose, talc
  Capsule shell: Titanium dioxide (E171), yellow iron oxide (E172), gelatin
  Printing ink: Shellac, propylene glycol, black iron oxide (E172), potassium hydroxide.

What [Product Name] looks like and contents of the pack

[Product Name] 10 mg hard modified-release capsules are hard gelatin capsules filled with yellow to pale yellow pellets. Capsule cap is yellow with black ″1000″ imprinting and body yellow with black ″0010″ imprinting.

[Product Name] 20 mg hard modified-release capsules are hard gelatin capsules filled with yellow to pale yellow pellets. Capsule cap is yellow with black ″1000″ imprinting and body yellow with black ″0020″ imprinting.

[Product Name] is available in perforated blister packs of 28 capsules.

Houder van de vergunning voor het in de handel brengen en fabrikant
Houder van de vergunning voor het in de handel brengen
Sigillata Limited
Landscape House
Baldonnell Business Park
Baldonnell,
DUBLIN,
D22 P3K7,
Ireland
Fabrikant
Balkanpharma-Dupnitsa AD
Samokovsko Shosse Str. 3

2600 Doepnitsa
Bulgarije

In het register ingeschreven onder
Barnidipine HCl Sigillata 10 mg, harde capsules met gereguleerde afgifte – RVG 127087
Barnidipine HCl Sigillata 20 mg, harde capsules met gereguleerde afgifte – RVG 127088

Dit medicijn is geregistreerd in lidstaten van de Europese Economische Ruimte onder de volgende namen:

Italië	Barnidipina cloridrato Sigillata
Nederland	Barnidipine HCl Sigillata 10 mg, harde capsules met gereguleerde afgifte
	Barnidipine HCl Sigillata 20 mg, harde capsules met gereguleerde afgifte

Deze bijsluiter is voor het laatst goedgekeurd in april 2025.