Package Leaflet: Information for the User

Corinfar® retard 20 mg prolonged-release tablets
Active substance: nifedipine, 20 mg

Read all of this leaflet carefully before you start taking this medicine.
- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

1. What Corinfar retard 20 mg prolonged-release tablets is and what it is used for
Corinfar retard 20 mg prolonged-release tablets is a medicine for the treatment of heart disease associated with poor oxygen supply to the heart muscle. It is also used for the treatment of high blood pressure.
Corinfar retard 20 mg prolonged-release tablets is used for:
- symptoms of angina pectoris (e.g. pain or tightness in the chest area, caused by poor oxygen supply to the heart muscle):
  - on exertion: chronic stable angina (exertional angina)
  - due to narrowing of the blood vessels: vasospastic angina (Prinzmetal’s angina, variant angina)
- essential hypertension (high blood pressure of unknown cause).

2. Before you take Corinfar retard 20 mg prolonged-release tablets
Do not take Corinfar retard 20 mg prolonged-release tablets
- if you are hypersensitive to the active substance nifedipine or any of the other ingredients of Corinfar retard 20 mg prolonged-release tablets
- if you have suffered shock
- if you have a narrowing of the heart valve (aortic stenosis)
- if you have symptoms of angina at rest (e.g. pain or tightness in the chest area, caused by poor oxygen supply to the heart muscle)
- if you have had an acute heart attack within the last 4 weeks
- if you are also taking medicines containing the active substance rifampicin (medicines used to treat tuberculosis)
- if you are pregnant or breast-feeding.
Take special care with Corinfar retard 20 mg prolonged-release tablets
Treatment with Corinfar retard 20 mg prolonged-release tablets requires regular medical surveillance
- if you have low blood pressure (systolic less than 90 mmHg)
- if you have a weak heart not receiving adequate treatment (congestive heart failure)
- if you are a patient on dialysis with severe high blood pressure and a low circulating blood volume, as you may experience a marked drop in blood pressure.

Taking other medicines
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.
If used at the same time, treatment with Corinfar retard 20 mg prolonged-release tablets can interfere with the effect of the following active substances or groups of medicines.

**High blood pressure medications, tricyclic antidepressants (used to treat depression), vasodilators (used to widen the blood vessels)**

Increase in the blood pressure-lowering effect.

**Beta-receptor blockers**
Marked reduction in blood pressure and occasionally onset of heart failure.

**Diltiazem (used to treat high blood pressure and coronary heart disease)**
Diltiazem reduces the breakdown of nifedipine. In combined treatment, the patient should be carefully monitored and the nifedipine dose should be reduced as appropriate.

**Quinidine (used to treat heart rhythm disorders)**
Reduced quinidine concentration in the blood or, after stopping nifedipine, increased quinidine concentration in the blood. Monitoring of quinidine blood levels is recommended.

**Digoxin (used to increase cardiac strength), theophylline (used to widen the bronchial tubes)**
The concentration of these medicines in the blood may rise. Vigilance is required for signs of a digoxin overdose and, if necessary, the digoxin dose should be reduced by the doctor (possibly after measuring digoxin concentrations in the blood).

**Quinupristin (antibiotics), dalfopristin (antibiotics), cimetidine (used to treat stomach and duodenal ulcers)**
Increased nifedipine levels in the blood and hence a marked reduction in blood pressure.

**Rifampicin (used to treat tuberculosis)**
Rifampicin speeds up the breakdown of nifedipine. It must not be used at the same time as nifedipine, as no effective blood levels of nifedipine will be reached.

**Vincristine (used to treat tumours)**
Excretion of vincristine is reduced, which may result in increased side effects of vincristine.

**Cephalosporins (used to treat infections)**
Increased cephalosporin concentrations in the blood.

**Phenytoin (used to treat epileptic fits)**
Weaken the effect of Corinfar retard 20 mg prolonged-release tablets.

**Tacrolimus (used to prevent transplant rejection after a liver or kidney transplant)**
Increased tacrolimus concentrations in the blood.

**Active substances used to treat infections (macrolides, e.g. erythromycin), fluoxetine, nefazodone (antidepressants), protease inhibitors (used to treat HIV, e.g. amprenavir, indinavir, nelfinavir, ritonavir or saquinavir), fungistatic agents (used to treat fungal disease, e.g. ketoconazole, itraconazole and fluconazole)**
Increased nifedipine concentrations in the blood.

Based on experience with nimodipine, an active substance belonging to the same substance class as Corinfar retard 20 mg prolonged-release tablets, the following interactions cannot be ruled out: **Carbamazepine, phenobarbital (used to treat epileptic fits)**
These weaken the effect of Corinfar retard 20 mg prolonged-release tablets.

**Valproic acid (used to treat epileptic fits)**
Enhances the effect of Corinfar retard 20 mg prolonged-release tablets.

**Taking Corinfar retard 20 mg prolonged-release tablets with food and drink**
Do not take Corinfar retard 20 mg prolonged-release tablets with grapefruit juice, as this slows the breakdown of nifedipine in the body, thereby enhancing the effect of Corinfar retard 20 mg prolonged-release tablets.

**Pregnancy and breast-feeding**
Ask your doctor or pharmacist for advice before taking any medicine.

There is insufficient experience regarding the safety of using Corinfar retard 20 mg prolonged-release tablets, particularly in the first three months of pregnancy. As experimental studies have shown evidence of damage to the embryo/fetus, you must not take Corinfar retard 20 mg prolonged-release tablets during pregnancy unless your treating doctor considers this absolutely necessary (strict indication for use, no other therapeutic option available). If you require treatment with Corinfar retard 20 mg prolonged-release tablets during pregnancy, you and your unborn child should be carefully monitored.
monitored. If you have been taking Corinfar retard 20 mg prolonged-release tablets during the first three months of pregnancy, you should be offered a detailed ultrasound scan.

For this reason, please contact your doctor immediately if you are pregnant or planning a pregnancy, so that he/she can decide whether you should continue/discontinue treatment with Corinfar retard 20 mg prolonged-release tablets.

You must not take Corinfar retard 20 mg prolonged-release tablets during breast-feeding, as the active substance in Corinfar retard 20 mg prolonged-release tablets passes into breast milk and only limited experience is available with their use during the breast-feeding period. You must stop breast-feeding if your treating doctor considers treatment with Corinfar retard 20 mg prolonged-release tablets absolutely necessary during the breast-feeding period.

Driving and using machines

Treatment with this medicine requires regular medical surveillance. Reactions that occur can vary depending on the individual and may alter responsiveness to such an extent that the ability to drive, use machines or perform dangerous tasks is impaired. This particularly applies at the start of treatment, when increasing the dose or switching from another product and in interaction with alcohol.

Important information about some of the ingredients of Corinfar retard 20 mg prolonged-release tablets

This medicine contains lactose. For this reason, if you have been told that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE CORINFAR RETARD 20 MG PROLONGED-RELEASE TABLETS

Always take Corinfar retard 20 mg prolonged-release tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The usual dose is:

Coronary heart disease
1 Corinfar retard 20 mg prolonged-release tablet twice daily (equivalent to 40 mg nifedipine a day).
If required, the dose can be increased to 40 mg nifedipine twice daily.

High blood pressure
1 Corinfar retard 20 mg prolonged-release tablet twice daily (equivalent to 40 mg nifedipine a day).
If required, the dose can be increased to 40 mg nifedipine twice daily.

Wherever possible, treatment should be individualised according to the severity of the disease and patient response.

Depending on the symptoms in each case, the target dose should be reached gradually.

Patients with poor liver function should be carefully monitored; in some cases, the dose may have to be reduced.

Patients with severely restricted blood flow through the brain (cerebrovascular disease) should be treated with a lower dose.

Corinfar retard 20 mg prolonged-release tablets are taken whole (not chewed) after a meal with sufficient liquid (e.g. a glass of water, no grapefruit juice). They are best taken in the morning and evening; always at the same time of day wherever possible.

As the active substance nifedipine is sensitive to light, the prolonged-release tablets must not be divided. Otherwise, the protection against light provided by the coating will no longer be assured.

Please talk to your doctor or pharmacist if you have the impression that the effect of Corinfar retard 20 mg prolonged-release tablets is too strong or too weak.

If you take more Corinfar retard 20 mg prolonged-release tablets than you should

An overdose with Corinfar retard 20 mg prolonged-release tablets can lead to a severe drop in blood pressure, a slower or faster heart rate, reduced level of consciousness and even deep coma, increased blood sugar levels (hyperglycaemia), reduced blood flow through major organs and shock triggered by heart failure, with fluid accumulation in the lungs (lung oedema).

If you suspect an overdose, inform a doctor/emergency doctor immediately, so that he/she can decide what to do next.

If you forget to take Corinfar retard 20 mg prolonged-release tablets
If you have forgotten to take a dose of Corinfar retard 20 mg prolonged-release tablets, do not take a double dose at the next scheduled time. Continue your treatment as described in the dosage instructions or as prescribed by the doctor.

**If you stop taking Corinfar retard 20 mg prolonged-release tablets**
Please do not interrupt or stop your treatment with Corinfar retard 20 mg prolonged-release tablets without talking to your doctor first.
Especially at high doses, treatment with Corinfar retard 20 mg prolonged-release tablets should be phased out gradually.

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

**4. POSSIBLE SIDE EFFECTS**
Like all medicines, Corinfar retard 20 mg prolonged-release tablets can cause side effects, although not everybody gets them.
The following categories are used for stating the frequency of side effects:
- Very common: more than 1 in 10 patients treated
- Common: 1 to 10 out of 100 patients treated
- Uncommon: 1 to 10 out of 1,000 patients treated
- Rare: 1 to 10 out of 10,000 patients treated
- Very rare: less than 1 in 10,000 patients treated
- Not known: cannot be estimated from the available data

**Possible side effects**

*Blood and lymphatic system*
- Rare: changes in the blood count, e.g. reduction in red or white blood cells or platelets (anaemia, leukopenia, thrombopenia), bleeding of the skin and mucous membranes in the presence of a low platelet count (thrombocytopenic purpura).

- Very rare: severe reduction in certain white blood cells (agranulocytosis).

*Metabolism and nutrition disorders*
- Rare: increase in blood sugar levels (hyperglycaemia).

*Nervous system*
- Very common: headache, particularly at the start of treatment.

- Common: dizziness, light-headedness, feeling weak.

- Uncommon: nervousness, sleep disorders or drowsiness, abnormal skin sensations (e.g. tingling, numbness), reduced sensitivity to touch (hypoesthesia), muscle tremor.

*Eyes*
- Uncommon: minor, temporary change in visual perception.

- Rare: weak-sightedness.

*Cardiovascular system*
- Very common: fluid accumulation, e.g. in the lower leg due to widening of the blood vessels (peripheral oedema), particularly at the start of treatment.

- Common: palpitations.

- Uncommon: increased heart rate (tachycardia), black-outs (syncope), drop in blood pressure (hypotensive circulatory reaction).

Angina attacks may occur especially at the start of treatment, or the frequency, duration and severity of attacks may increase in patients with existing angina.

- Very rare: heart attack.

*Lungs*
- Uncommon: shortness of breath (dyspnoea).

*Skin*
- Common: facial redness (flush), skin redness with sensations of heat (erythema), painful swelling and redness of the arms and legs (erythromelalgia), particularly at the start of treatment.

- Uncommon: hypersensitivity reactions of the skin, such as itching (pruritus), rash (exanthem), swelling of the skin and mucous membranes (angioedema, facial oedema), sweating.

- Rare: nettle rash (urticaria), pinpoint bleeding in the skin and mucous membranes (purpura), skin inflammation after exposure to sunlight and UV rays (photodermatitis). During
prolonged treatment with Corinfar retard 20 mg prolonged-release tablets, gum changes (gingival hyperplasia) may occur, which resolve completely upon discontinuation of therapy.

**Very rare:** flaking and inflamed skin (exfoliative dermatitis).

**Kidneys and lower urinary tract**

**Rare:** temporary worsening of kidney function in patients with kidney dysfunction. Increased urge to pass water and increased daily urine output.

**Liver**

**Uncommon:** liver dysfunction (intrahepatic cholestasis, rise in transaminase levels).

**Rare:** jaundice.

**Gastrointestinal tract**

**Common:** nausea.

**Uncommon:** gastrointestinal disorders such as upper abdominal complaints (dyspepsia), stomach ache, constipation, flatulence, vomiting, dry mouth.

**Rare:** feeling full, belching and loss of appetite.

**Musculoskeletal system**

**Uncommon:** muscle and joint pain (myalgia and arthralgia), muscle cramps.

**Reproductive system and breast**

**Rare:** male breast enlargement (gynaecomastia), which resolves after discontinuing Corinfar retard 20 mg prolonged-release tablets.

**General disorders**

**Uncommon:** tiredness, feeling unwell.

**Rare:** general allergic reactions, such as fever, swelling of the larynx (laryngeal oedema), constriction of the bronchial muscles and even life-threatening respiratory distress, which resolve after discontinuing Corinfar retard 20 mg prolonged-release tablets.

If you should notice any of the side effects listed above, inform your doctor, so that he/she can assess their severity and decide on any measures that may be required.

*If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.*

### 5. HOW TO STORE CORINFAR RETARD 20 MG PROLONGED-RELEASE TABLETS

Keep out of the reach and sight of children.

Do not use Corinfar retard 20 mg prolonged-release tablets after the expiry date which is stated on the blister strip/label and outer carton.

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

### 6. FURTHER INFORMATION

**What Corinfar retard 20 mg prolonged-release tablets contains**

The active substance is nifedipine.

1 prolonged-release tablet contains 20 mg nifedipine.

The other ingredients are:

- Lactose monohydrate, magnesium stearate (Ph.Eur.), macrogol 6000, macrogol 35000, talc, potato starch, hypromellose, povidone (K25), microcrystalline cellulose, colouring agents (quinoline yellow and titanium dioxide).

**What Corinfar retard 20 mg prolonged-release tablets looks like and contents of the pack**

Corinfar retard 20 mg prolonged-release tablets are yellow, biconvex, round with bevelled, intact edges and uniform in appearance.

Corinfar retard 20 mg prolonged-release tablets is available in packs of 30 (N1), 50 (N2) and 100 (N3) prolonged-release tablets.

**Marketing Authorisation Holder and Manufacturer**

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