

Package leaflet: Information for the user
CORACTEN XL 30 mg and 60 mg Capsules
Nifedipine



Read all 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 Coracten XL is and what it is used for
2. What you need to know before you take Coracten XL
3. How to take Coracten XL
4. Possible side effects
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1. What Coracten XL is and what it is used for

Coracten XL contains nifedipine, which belongs to a group of medicines called calcium-channel blockers.

Used to treat:

- high blood pressure in adults

To prevent:

- chronic stable angina pectoris (heart/chest pain) in adults.

For high blood pressure: Coracten XL works by relaxing and expanding the blood vessels. This makes the blood flow more easily and lowers blood pressure. Lower blood pressure reduces the strain on your heart.

For angina: Coracten XL works by relaxing and expanding the arteries supplying the heart. This allows more blood and oxygen to reach the heart and decreases the strain on it. Your angina attacks will be less severe and less frequent if there is less strain on the heart.

PLEASE NOTE: These capsules are sustained-release capsules which release the active ingredient slowly over 24 hours. Do not use to treat attacks of angina or heart attacks when they happen. See your doctor if you are unsure why you have been prescribed these capsules.

2. What you need to know before you take Coracten XL

Do not take Coracten XL:

- if you are allergic to nifedipine or any of the other ingredients of this medicine (listed in section 6) or other dihydropyridines such as amlodipine, felodipine, isradipine or nisoldipine.
- if you have taken nifedipine before and found your heart pain got worse
- if you get a sudden angina attack. Coracten XL will not help relieve symptoms of angina quickly
- if you are pregnant, or likely to become pregnant and breast-feeding
- if you have Porphyria
- if you have narrowing (stenosis) of the aortic valve (one of the valves of the heart)
- if you have unstable angina (heart pain)
- if you have suffered a heart attack less than one month ago
- if you have collapse of the circulation (cardiogenic shock)
- if you have very high blood pressure (malignant hypertension)
- if you are taking rifampicin – a treatment for tuberculosis
- if you have a “Kock pouch” (a surgically constructed intestinal reservoir with an opening through the abdominal wall) in your gut.

This medicine is not recommended for use in children.

Warnings and precautions

Talk to your doctor or pharmacist before taking Coracten XL

- if you have heart problems other than chronic stable angina (heart failure)
- if you have low blood pressure
- if you have diabetes. The treatment for your diabetes may need to be adjusted
- if you are on kidney dialysis. If you have a very high blood pressure and a low blood volume, you might experience a sudden drop in blood pressure when you take Coracten XL
- if your liver is not working properly. Your doctor may need to do some blood tests. You may also be given a lower dose of Coracten XL.

Children

Coracten XL is not recommended for use in children and adolescents below 18 years of age, because there are only limited data on the safety and efficacy in this population.

Other medicines and Coracten XL

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

Tell your doctor if you are taking any of the following medicines:

- Other medicines to treat high blood pressure.
- Rifampicin (an antibiotic).
- Cimetidine (to treat stomach ulcers).
- Digoxin, diltiazem, quinidine or beta-blockers (to treat heart conditions).
- Quinupristin/dalfopristin (a combination antibiotic).
- Phenytoin, carbamazepine or valproic acid (to treat epilepsy).
- Cisapride (to treat reduced movements of the gullet and stomach).
- Magnesium sulphate injections during pregnancy (may cause a severe fall in blood pressure).
- Erythromycin (an antibiotic).
- Ketoconazole, itraconazole or fluconazole (anti-fungal medicines).
- Indinavir, nelfinavir, ritonavir, saquinavir or amprenavir (to treat HIV).
- Fluoxetine or nefazodone (to treat depression).
- Tacrolimus (to prevent the rejection of transplanted organs).
- Phenobarbital (usually used to treat insomnia or anxiety).
- St John's Wort (herbal medicine).

If you are unsure about your other medication, please talk to your doctor or pharmacist before taking Coracten XL. They may need to alter your treatment or give you some special advice.

Coracten XL with food, drink and alcohol

Coracten XL may be taken with or without food. As a safety precaution, do not take with alcohol.

Do not drink grapefruit juice or eat grapefruit while you are taking Coracten XL.

Do not start taking Coracten XL within 3 days of drinking grapefruit juice or eating grapefruit. Tell your doctor if you have had grapefruit or grapefruit juice in this time. Also, do not drink grapefruit juice or eat grapefruit whilst taking Coracten XL. Grapefruit juice is known to increase the blood levels of the active ingredient, nifedipine. This effect can last for at least 3 days.

Pregnancy, breast-feeding and fertility

Do not take Coracten XL if you are pregnant or breastfeeding. Medicines like Coracten XL Capsules have been shown in laboratory experiments to impair sperm function. If you are male and have been unsuccessful in fathering a child please consult your doctor.

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

Driving and using machines

Coracten XL may make you feel dizzy, faint, extremely tired or have visual disturbances. Do not drive or operate machinery if you are affected in this way. This may be more likely when you first start treatment, if you change medication, or if you have drunk alcohol.

Coracten XL contains lactose

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 Coracten XL

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 recommended dose is one 30 mg or one 60 mg capsule per day (every 24 hours). Doses of up to 90 mg per day may be prescribed by your doctor if considered necessary.

Coracten XL should be swallowed whole with a drink of water. Do not break or chew the capsules.

Do not take them with grapefruit juice.

Duration of treatment

Treatment for high blood pressure or angina is usually for life. Your doctor will monitor your treatment and check your blood pressure. Do not stop taking the capsules unless your doctor tells you to. **DO NOT EXCEED THE STATED DOSE**

Use in children and adolescents: Coracten XL is not recommended for use in children and adolescents below 18 years of age, because there are only limited data on the safety and efficacy in this population.

If you take more Coracten XL than you should

If you take too many go straight to your casualty department. Take the capsules, box and this leaflet with you.

Taking too many capsules may cause your blood pressure to become too low and your heartbeats to speed up or slow down. It may also lead to an increase in your blood sugar level or an increase in the acidity of your blood, swelling in the lungs, low blood oxygen levels and disturbances in consciousness, possibly leading to unconsciousness.

If you forget to take Coracten XL

Do not worry. Take the missed dose as soon as you remember and take the next dose 24 hours later. Do not take more than your prescribed dose in 24 hours. Tell



your doctor at your next visit if you have missed a few doses.
Do not take a double dose to make up for a forgotten dose.

4. Possible side effects

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

It is important that you are aware of what these side effects may be. They are usually mild and disappear after a short time.

Stop taking Coracten XL and seek urgent medical help immediately if you suffer from:

- An increase in chest pain at the start of treatment
- An allergic reaction and experience difficulty breathing, with or without swelling of the face, lips, tongue, and/or throat which may cause difficulty in swallowing.

Also stop taking Coracten XL and talk to your doctor immediately if you:

- Start shaking or experience a loss of eyesight caused by a sudden drop in blood pressure
- Notice a yellowing of the skin and eyes caused by liver problems such as allergic hepatitis, intra-hepatic cholestasis
- Notice flaking or purple blotching of the skin caused by exfoliative dermatitis, erythema multiform or pemphigoid reactions.

Other side effects

If any of the following side-effects become troublesome, continue taking Coracten but talk to your doctor immediately:

Common Side Effects: may affect up to 1 in 10 people

- headache
- general feeling of being unwell
- constipation
- swelling, particularly of the ankles and legs

Uncommon Side Effects: may affect up to 1 in 100 people

- stomach pain
- unspecific pain
- low blood pressure when standing up (symptoms include fainting, dizziness, light headedness, occasional palpitations, blurred vision and sometimes confusion)
- fainting
- faster or irregular heartbeat (palpitations)
- dry mouth
- indigestion or upset stomach, wind (flatulence)
- feeling sick (nausea)
- muscle cramps
- joint swelling
- sleep disorders
- anxiety or nervousness
- reddening of the skin
- nosebleeds
- nasal congestion
- a feeling of dizziness or "spinning" (vertigo)
- migraine
- trembling
- increase in the need to pass water (urinate)
- painful or difficult urination
- inability to achieve or maintain an erection (impotence)
- blurred vision
- temporary increase in certain liver enzymes
- chills

Rare side effects: may affect up to 1 in 1,000 people

- pins and needles
- itchy skin
- rash, hives
- changes in mood
- inflammation of the gums
- tender or swollen gums
- bleeding gums

Not known: frequency cannot be estimated from the available data

- a reduction in the number of white blood cells (leucopenia)
- a more severe decrease in the number of white blood cells (agranulocytosis)
- depression
- increased blood sugar (hyperglycaemia)
- decreased skin sensitivity (hypoesthesia)
- sleepiness
- lethargy
- insufficient blood flow to the brain
- eye pain

- chest pain (angina pectoris)
- decreased blood flow to your heart
- shortness of breath (dyspnea)
- flushing
- vomiting
- heartburn or indigestion (gastroesophageal sphincter insufficiency)
- diarrhoea
- sensitivity to light (photosensitivity allergic reaction)
- small raised areas of bleeding in the skin (palpable purpura)
- spider veins
- joint pain
- muscle pain
- muscle weakness
- fever
- worsening of myasthenia gravis
- development of breast tissue in older men on long term therapy has been reported

Because of the nature of coronary heart disease, heart attacks have occurred in patients treated with the active ingredient, nifedipine. It has not been shown that these heart attacks were due to treatment with nifedipine.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at:

www.mhra.gov.uk/yellowcard By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Coracten XL

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 the blister foil after EXP. The expiry date refers to the last day of that month. Store in the original package.

Do not store above 25°C.

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 Coracten XL contains

The active substance is nifedipine. Each capsule contains either 30 mg or 60 mg Nifedipine, in sustained release form.

The other ingredients are: lactose monohydrate; microcrystalline cellulose; hydroxypropyl methylcellulose K100; povidone K30; magnesium stearate; hydroxypropylcellulose; ammonio methacrylate copolymer type B; polyethylene glycol 6000; dibutylphthalate; titanium dioxide E171; talc.

The capsule shells for Coracten XL 30 mg contain: yellow iron oxide E172; red iron oxide E172; titanium dioxide E171; gelatin. The capsule shells for Coracten XL 60 mg contain: red iron oxide E172; titanium dioxide E171; gelatin; black printing ink.

What Coracten XL looks like and contents of the pack

The 30 mg capsules have an opaque caramel cap and body overprinted in black with 'COR 30'. The 60 mg capsules have an opaque orange cap and body overprinted in black with 'COR 60'.

Coracten XL is available in PVC/PVdC/aluminium blister strips packed in cartons containing 10, 15, 30, 56, 60, 100, 150, 250, 500 and 600. Not all pack sizes may be marketed.

This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist, who will have access to further information.

High blood pressure and heart disease are very common. It is important to help yourself by losing weight if you need to and taking regular exercise.

Your doctor can put you in touch with organisations that offer information and advice to people in your situation. One such organisation is The British Heart Foundation.

Marketing Authorisation Holder and Manufacturer MA Holder:

Marketing Authorisation Holder:

Teofarma S.r.l.
Via F.lli Cervi, 8 - 27010 Valle Salimbene (PV) - Italy

Manufacturer:

Teofarma S.r.l.
Viale Certosa, 8/A - 27100 Pavia - Italy

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