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Summary of Product Characteristics last updated on the eMC: 20/04/2009

Coracten XL Joint SPC 30mg, 60mg

1. NAME OF THE MEDICINAL PRODUCT

Coracten XL 30mg.

Coracten XL 60mg.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains 30mg Nifedipine Ph.Eur in sustained release form.

Each capsule contains 60mg Nifedipine Ph.Eur in sustained release form.

For excipients, see 6.1

3. PHARMACEUTICAL FORM

Prolonged release capsule, hard

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Coracten XL capsules are indicated for the treatment of hypertension and the prophylaxis of chronic stable angina pectoris.

4.2 Posology and method of administration

The capsules are for oral administration and should be swallowed whole with a little fluid.

Dosage - Angina Pectoris and Hypertension

Adults only: Normally treatment is initiated with one 30mg Coracten XL capsule every 24 hours. Dosage may be titrated to a higher level as clinically warranted. The dose may be adjusted to 90mg every 24 hours.

Children: Coracten XL capsules are not recommended for use in children.

Elderly: The pharmacokinetics of nifedipine are altered in the elderly so that lower maintenance doses of nifedipine may be required compared to younger patients.

Hepatic impairment: As Coracten XL is a long acting formulation, it should not be administered to patients with hepatic impairment.

Renal impairment: Dosage adjustments are not usually required in patients with renal impairment.

4.3 Contraindications

Coracten XL capsules are contra-indicated in patients with known hypersensitivity to nifedipine or other dihydropyridines because of the theoretical risk of cross reactivity. They should not be used in nursing mothers and women who are or who may become pregnant (see section 4.6. Pregnancy and Lactation).

Coracten XL capsules should not be used in clinically significant aortic stenosis, unstable angina, or during or within one month of a myocardial infarction. They should not be used in patients in cardiogenic shock.

Coracten XL capsules should not be used for the treatment of acute attacks of angina, or in patients who have had ischaemic pain following its administration previously.

The safety of Coracten XL capsules in malignant hypertension has not been established.

Coracten XL capsules should not be used for secondary prevention of myocardial infarction.

Coracten XL capsules are contra-indicated in patients with acute porphyria.

Coracten XL capsules should not be administered concomitantly with rifampicin since effective plasma levels of nifedipine may not be achieved owing to enzyme induction.

As Coracten XL is a long acting formulation, it should not be administered to patients with hepatic impairment.

4.4 Special warnings and precautions for use

The dose of nifedipine should be reduced in patients with hepatic impairment (***see section 4.2. Posology and Method of Administration***). Nifedipine should be used with caution in patients who are hypotensive; in patients with poor cardiac reserve; in patients with heart failure or significantly impaired left ventricular function as their condition may deteriorate; in diabetic patients as they may require adjustment of their diabetic therapy; and in dialysis patients with malignant hypertension and irreversible renal failure with hypovolaemia, since a significant drop in blood pressure may occur due to the vasodilator effects of nifedipine.

Excessive falls in blood pressure may result in transient blindness. If affected do not attempt to drive or use machinery (see also section 4.8. Undesirable Effects).

Since nifedipine has no beta-blocking activity, it gives no protection against the dangers of abrupt withdrawal of beta-blocking drugs. Withdrawal of any previously prescribed beta-

blockers should be gradual, preferably over 8 to 10 days.

The dose of nifedipine should be reduced in patients with hepatic impairment (see section 4.2.Posology and Method of Administration).

Nifedipine may be used in combination with beta-blocking drugs and other antihypertensive agents, but the possibility of an additive effect resulting in postural hypotension should be borne in mind. Nifedipine will not prevent possible rebound effects after cessation of other anti-hypertensive therapy.

4.5 Interaction with other medicinal products and other forms of interaction

As with other dihydropyridines, nifedipine should not be taken with grapefruit juice because bioavailability is increased.

The simultaneous administration of nifedipine and digoxin may lead to reduced digoxin clearance and hence an increase in the plasma digoxin. Digoxin levels should be monitored and, if necessary, the digoxin dose reduced.

Nifedipine may increase the spectrophotometric values of urinary vanillylmandelic acid falsely. However, HPLC measurements are unaffected.

Coracten XL capsules should not be administered concomitantly with rifampicin since effective plasma levels of nifedipine may not be achieved owing to enzyme induction (see section 4.3. Contra-indications).

Increased plasma levels of nifedipine have been reported during concomitant use of H_2-receptor antagonists (specifically cimetidine), other calcium channel blockers (specifically diltiazem), alcohol, cyclosporin, macrolide antibiotics, gingko biloba and ginseng. Azole antifungals may increase serum concentrations of nifedipine.

Decreased plasma levels of nifedipine have been reported during concomitant use of antibacterials (specifically rifampicin), and probably also antiepileptics and St John's Wort.

When used in combination with nifedipine, plasma concentrations of quinidine have been shown to be suppressed regardless of quinidine dosage. The plasma concentrations of phenytoin, theophylline, non-depolarising muscle relaxants (e.g. tubocurarine) and possibly digoxin are increased when used in combination with nifedipine. Tacrolimus concentrations may be increased by nifedipine.

Enhanced hypotensive effect of nifedipine may occur with: aldesleukin, alprostadil, anaesthetics, antipsychotics, diuretics, phenothiazides, prazosin and intravenous ionic X-ray contrast medium. Profound hypotension has been reported with nifedipine and intravenous magnesium sulphate in the treatment of pre-eclampsia.

Ritonavir and quinupristin/dalfopristin may result in increased plasma concentrations of nifedipine.

Effective plasma levels of nifedipine may not be achieved due to enzyme induction with concurrent administration of erythromycin, carbamazepine and phenobarbitone.

There is an increased risk of excessive hypotension, bradycardia and heart failure with β-blockers.

An increased rate of absorption of nifedipine from sustained release preparation may occur if given concurrently with cisapride.

Nifedipine may result in increased levels of mizolastine due to inhibition of cytochrome CYP3A4.

Nifedipine may increase the neuromuscular blocking effects of vecuronium.

4.6 Pregnancy and lactation

Pregnancy

Because animal studies show embryotoxicity and teratogenicity, nifedipine is contraindicated during pregnancy (see also section 4.3. Contra-indications). Embryotoxicity was noted at 6 to 20 times the maximum recommended dose for nifedipine given to rats, mice and rabbits, and teratogenicity was noted in rabbits given 20 times the maximum recommended dose for nifedipine.

Lactation

Nifedipine is secreted in breast milk, therefore, Coracten XL capsules are not recommended during lactation.

4.7 Effects on ability to drive and use machines

Dizziness and lethargy are potential undesirable effects. If affected do not attempt to drive or use machinery (see also section 4.8. Undesirable Effects).

Excessive falls in blood pressure may result in transient blindness. If affected do not attempt to drive or use machinery (see also section 4.8. Undesirable Effects).

4.8 Undesirable effects

Most side-effects are consequences of the vasodilatory effects of nifedipine.

Side-effects are generally transient and mild, and usually occur at the start of treatment only. They include headache, flushing and, usually at higher dosages, nausea, dyspepsia, heartburn, constipation, diarrhoea, dizziness, lethargy, skin reactions (rash, urticaria and pruritus), paraesthesia, hypotension, palpitation, tachycardia, dependent oedema, increased frequency of micturition, eye pain, depression, fever, gingival hyperplasia ,telangiectasia and erythema multiforme.

Other less frequently reported side-effects include myalgia, tremor, pemphigoid reaction and visual disturbances. Impotence may occur rarely. Mood changes may occur rarely.

Excessive falls in blood pressure may result in cerebral or myocardial ischaemia or transient blindness.

As with other sustained release dihydropyridines, exacerbation of angina pectoris may occur rarely at the start of treatment with sustained release formulations of nifedipine. The occurrence of myocardial infarction has been described

although it is not possible to distinguish such an event from the natural course of ischaemic heart disease. Ischaemic pain has been reported in a small proportion of patients following the introduction of nifedipine therapy. Although a 'steal' effect has not been demonstrated, patients experiencing this effect should discontinue nifedipine therapy.

There are reports in older men on long-term therapy of gynaecomastia which usually regresses upon withdrawal of therapy.

Side-effects which may occur in isolated cases are photosensitivity, exfoliative dermatitis, systemic allergic reactions, purpura and a worsening of myasthenia gravis. Usually, these regress after discontinuation of the drug.

Rare cases of hypersensitivity-type jaundice have been reported. In addition, disturbances of liver function such as intra-hepatic cholestasis may occur. These regress after discontinuation of therapy.

4.9 Overdose

Clinical effects

Reports of nifedipine overdosage are limited and symptoms are not necessarily dose-related. Severe hypotension due to vasodilation, and tachycardia and bradycardia are the most likely manifestations of overdose.

Metabolic disturbances include hyperglycaemia, metabolic acidosis and hypo- or hyperkalaemia.

Cardiac effects may include heart block, AV dissociation and asystole, and cardiogenic shock with pulmonary oedema.

Other toxic effects include nausea, vomiting, drowsiness, dizziness, confusion, lethargy, flushing, hypoxia and unconsciousness to the point of coma.

Treatment

As far as treatment is concerned, elimination of nifedipine and the restoration of stable cardiovascular conditions have priority.

After oral ingestion, gastric lavage is indicated, if necessary in combination with irrigation of the small intestine. Ipecacuanha should be given to children.

Elimination must be as complete as possible, including the small intestine, to prevent the otherwise inevitable subsequent absorption of the active substance.

Activated charcoal should be given in 4-hourly doses of 25g for adults, 10g for children.

Blood pressure, ECG, central arterial pressure, pulmonary wedge pressure, urea and electrolytes should be monitored.

Hypotension as a result of cardiogenic shock and arterial vasodilation should be treated with elevation of the feet and plasma expanders. If these measures are ineffective, hypotension may be treated with 10% calcium gluconate 10-20 ml intravenously over 5-10 minutes. If the effects are

inadequate, the treatment can be continued, with ECG monitoring. In addition, beta-sympathomimetics may be given, e.g. isoprenaline 0.2 mg slowly i.v. or as a continuous infusion of 5µg/min. If an insufficient increase in blood pressure is achieved with calcium and isoprenaline, vasoconstricting sympathomimetics such as dopamine or noradrenaline should be administered. The dosage of these drugs should be determined by the patient's response.

Bradycardia may be treated with atropine, beta-sympathomimetics or a temporary cardiac pacemaker, as required.

Additional fluids should be administered with caution to avoid cardiac overload.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC Code: C08C A05

Nifedipine is a potent calcium-channel blocker which, by dilating peripheral arterial smooth muscle, decreases cardiac work and myocardial oxygen requirement. It also dilates coronary arteries, thereby improving myocardial perfusion and reducing coronary artery spasm. In hypertension, it reduces blood pressure but has little or no effect in normotensive subjects. It has no therapeutic antiarrhythmic effect.

5.2 Pharmacokinetic properties

Coracten XL capsules are a sustained release formulation of nifedipine designed to provide less fluctuation and more prolonged nifedipine blood concentrations than standard immediate release preparations.

Nifedipine is highly protein bound. It undergoes hepatic oxidation to inactive metabolites which are excreted in the urine (80%) and faeces (20%).

5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the Summary of Product Characteristics.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Capsule contents:

Lactose monohydrate

Microcrystalline Cellulose

Hydroxylpropyl methylcellulose K100

Povidone K30

Magnesium Stearate

Hydroxypropylcellulose

Ammonio methacrylate copolymer type B

Polyethylene Glycol 6000

Dibutylphthalate

Titanium dioxide E171

Talc

30 mg - Capsule shells (size 3):

Yellow iron oxide E172

Red iron oxide E172

Titanium dioxide E171

Gelatin

60 mg - Capsule shells (size 1)

Red iron oxide E172

Titanium dioxide E171

Gelatin

The printing ink is made of shellac, purified water, black iron oxide (E172) with 2 ‾ ethoxyethanol, soya lecithin, anitfoam and IMS or with ethyl alcohol, isopropyl alcohol, n ‾ butyl alcohol, propylene glycol, ammonium hydroxide and potassium hydroxide.

6.2 Incompatibilities

None known.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Do not store above 25°C. Store in the original package.

6.5 Nature and contents of container

Coracten XL capsules are available in blister strips packed in cartons containing 28, 30, 56 and 60 capsules. The blister strips are formed from PVC with a coating of PVdC backed with aluminium foil.

6.6 Special precautions for disposal and other handling

None.

7. MARKETING AUTHORISATION HOLDER

UCB Pharma Limited

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8. MARKETING AUTHORISATION NUMBER(S)

30 mg - PL 00039/0506

60 mg - PL 00039/0507

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

7 October 1998

10. DATE OF REVISION OF THE TEXT

April 2009

POM