SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Coracten XL 30 mg

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains 30mg Nifedipine.

Excipients with known effect: lactose monohydrate.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Prolonged release capsule, hard

Opaque caramel cap and body, printed with “COR 30 mg” using black ink, containing four off-white minitablets.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

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

4.2 Posology and method of administration

Posology

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.

Co-administration with CYP 3A4 inhibitors or CYP 3A4 inducers may result in the recommendation to adapt the nifedipine dose or not to use nifedipine at all (see Section 4.5).

Duration of treatment

Treatment may be continued indefinitely.

Elderly (≥ 65 years)
The pharmacokinetics of nifedipine are altered in the elderly so that lower maintenance doses of nifedipine may be required.

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 (see section 5.2).

Paediatric population
The safety and efficacy of Coracten XL in children below 18 years has not been established. Currently available data for the use of nifedipine in hypertension are described in section 5.1

Method of administration
Oral use.

The capsules should be swallowed whole with a little fluid.

The capsules should be taken at approximately 24-hour intervals, i.e. at the same time each day, preferably during the morning.

Coracten XL should not be taken with grapefruit juice (see section 4.5).

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 also not be used in cases of known hypersensitivity to any of the excipients listed in section 4.4 and 6.1.

They should not be used in nursing mothers and women who are or who may become pregnant (see section 4.6).

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 should not be used in patients with Kock pouch (ileostomy after proctocolectomy).

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 4.5).

As Coracten XL is a long acting formulation, it should not be administered to patients with hepatic impairment (see section 4.5).

4.4 Special warnings and precautions for use

Nifedipine should be used with caution in patients who are hypotensive as there is a risk of further reduction in blood pressure and care must be exercised in patients with very low blood pressure (severe hypotension with systolic blood pressure less than 90 mm Hg).

The use of Nifedipine in diabetic patients may require adjustment of their diabetic therapy

In dialysis patients with malignant hypertension and irreversible renal failure with hypovolaemia, a significant drop in blood pressure may occur due to the vasodilator effects of nifedipine.

Nifedipine should be used with caution in patients whose cardiac reserve is poor; in patients with heart failure or significantly impaired left ventricular function. Deterioration of heart failure has occasionally been observed with nifedipine.
In patients with impaired liver function careful monitoring and, in severe cases, a dose reduction may be necessary.

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

Although a ‘steal’ effect has not been demonstrated, patients experiencing this effect should discontinue nifedipine therapy.

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.

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.

Nifedipine is metabolised via the cytochrome P450 3A4 system. Drugs that are known to either inhibit or to induce this enzyme system may therefore alter the first pass or the clearance of nifedipine (see section 4.5).

Drugs, which are inhibitors on the cytochrome P450 3A4 system and therefore may lead to increased plasma concentrations of nifedipine are, e.g.:
- macrolide antibiotics (e.g. erythromycin)
- anti-HIV protease inhibitors (e.g. ritonavir)
- azole antimycotics (e.g. ketoconazole)
- the antidepressants nefazodone and fluoxetine
- quinupristin/dalfopristin
- valproic acid
- cimetidine.

Upon co-administration with these drugs, the blood pressure should be monitored and if necessary, a reduction of the nifedipine dose should be considered (see section 4.5).

This medicinal product contains lactose monohydrate. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.

For use in special populations see section 4.2.

4.5 Interaction with other medicinal products and other forms of interaction

Drugs that affect nifedipine

Nifedipine is metabolised via the cytochrome P450 3A4 system, located both in the intestinal mucosa and in the liver. Drugs that are known to either inhibit or to induce this enzyme system may therefore alter the first pass (after oral administration) or the clearance of nifedipine (see section 4.4).

The extent as well as the duration of interactions should be taken into account when administering nifedipine together with the following drugs:

Rifampicin: Rifampicin strongly induces the cytochrome P450 3A4 system. Upon co-administration with rifampicin, the bioavailability of nifedipine is distinctly reduced and thus its efficacy weakened. The use of nifedipine in combination with rifampicin is therefore contraindicated (see section 4.3).

Upon co-administration of known inhibitors of the cytochrome P450 3A4 system, the blood pressure should be monitored and, if necessary, a reduction in the nifedipine dose considered (see sections 4.2 and 4.4). In the majority of

these cases, no formal studies to assess the potential for a drug interaction between nifedipine and the drug(s) listed have been undertaken, thus far.

Drugs increasing nifedipine exposure:
- *macrolide antibiotics (e.g., erythromycin)*
- *anti-HIV protease inhibitors (e.g., ritonavir)*
- *azole anti-mycotics (e.g., ketoconazole)*
- *fluoxetine*
- *nefazodone*
- *quinupristin/dalfopristin*
- *cisapride*
- *valproic acid*
- *H_2-receptor antagonists (specifically cimetidine)*
- *other calcium channel blockers (specifically diltiazem)*

Upon co-administration of inducers of the cytochrome P450 3A4 system, the clinical response to nifedipine should be monitored and, if necessary, an increase in the nifedipine dose considered. If the dose of nifedipine is increased during co-administration of both drugs, a reduction of the nifedipine dose should be considered when the treatment is discontinued.

Increased plasma levels of nifedipine have been reported during concomitant use of alcohol, cyclosporin, gingko biloba and ginseng.

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.

Drugs decreasing nifedipine exposure:
- *rifampicin (see above)*
- *phenytoin*
- *carbamazepine*
- *phenobarbital*

Decreased plasma levels of nifedipine have been reported during concomitant use of St John's Wort.

Effects of nifedipine on other drugs

Nifedipine may increase the blood pressure lowering effect of concomitant applied antihypertensives.

When nifedipine is administered simultaneously with ß-receptor blockers the patient should be carefully monitored, since deterioration of heart failure is also known to develop in isolated cases.

Digoxin: The simultaneous administration of nifedipine and digoxin may lead to reduced digoxin clearance and, hence, an increase in the plasma digoxin

level. The patient should therefore be subjected to precautionary checks for symptoms of digoxin overdosage and, if necessary, the glycoside dose should be reduced.

Quinidine: Co-administration of nifedipine with quinidine may lower plasma quinidine levels, and after discontinuation of nifedipine, a distinct increase in plasma quinidine levels may be observed in individual cases. Consequently, when nifedipine is either additionally administered or discontinued, monitoring of the quinidine plasma concentration, and if necessary, adjustment of the quinidine dose are recommended. Blood pressure should be carefully monitored and, if necessary, the dose of nifedipine should be decreased.

Tacrolimus: Tacrolimus is metabolised via the cytochrome P450 3A4 system. Published data indicate that the dose of tacrolimus administered simultaneously with nifedipine may be reduced in individual cases. Upon co-administration of both drugs, the tacrolimus plasma concentrations should be monitored and, if necessary, a reduction in the tacrolimus dose considered.

The plasma concentrations of phenytoin, theophylline, non-depolarising muscle relaxants (e.g. tubocurarine) are increased when used in combination with nifedipine.

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

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

Nifedipine may increase the neuromuscular blocking effects of vecuronium.

Drug food interactions

Grapefruit juice inhibits the cytochrome P450 3A4 system. Administration of nifedipine together with grapefruit juice thus results in elevated plasma concentrations and prolonged action of nifedipine due to a decreased first pass metabolism or reduced clearance. As a consequence, the blood pressure lowering effect of nifedipine may be increased. After regular intake of grapefruit juice, this effect may last for at least three days after the last ingestion of grapefruit juice. Ingestion of grapefruit/grapefruit juice is therefore to be avoided while taking nifedipine (see section 4.2).

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

4.6 Fertility, Pregnancy and lactation

Pregnancy

Because animal studies show embryotoxicity and teratogenicity, nifedipine is contraindicated during pregnancy (see section 4.3). 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. There are no adequate well controlled studies in pregnant women.

An increase in perinatal asphyxia, caesarean delivery as well as prematurity and intrauterine growth retardation has been reported, however it is unclear whether these reports are due to the underlying hypertension, its treatment or to a specific drug effect.

Acute pulmonary oedema has been observed when calcium channel blockers, among others nifedipine, have been used as a tocolytic agent during pregnancy (see section 4.8), especially in cases of multiple pregnancy (twins or more), with the intravenous route and/or concomitant use of beta-2 agonists.

Breast-feeding
Nifedipine is excreted in breast milk, therefore, Coracten XL capsules are not recommended during lactation (see section 4.3).

Fertility
In single cases of *in-vitro* fertilization calcium-antagonists like nifedipine have been associated with reversible biochemical change in the spermatozoa's head section that may results in impaired sperm function. Nifedipine should be considered as a possible cause if there is no other explanation for unsuccessful fathering.

4.7 Effects on ability to drive and use machines

Reactions to the drug, which vary in intensity from individual to individual, may impair the ability to drive or to operate machinery (see section 4.8). This applies particularly at the start of treatment, on changing the medication and in combination with alcohol.

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

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

4.8 Undesirable effects

Adverse drug reactions (ADRs) based on placebo-controlled studies with nifedipine sorted by CIOMS III categories of frequency (clinical trial data base: nifedipine n = 2,661; placebo n = 1,486; status: 22 Feb 2006 and the ACTION study: nifedipine n = 3,825; placebo n = 3,840) are listed below:

ADRs listed under “common” were observed with a frequency below 3% with the exception of oedema (9.9%) and headache (3.9%). Most side-effects are consequences of the vasodilatory effects of nifedipine.

The frequencies of ADRs reported with nifedipine containing products are summarised in the table below. Within each frequency grouping, undesirable effects are presented in order of decreasing seriousness. Frequencies are defined as common (≥ 1/100 to < 1/10), uncommon (≥ 1/1,000 to < 1/100) and rare (≥ 1/10,000 to < 1/1,000). The ADRs identified only during the ongoing postmarketing surveillance and for which a frequency could not be estimated, are listed under “Not known”.

System Organ Class (MedDRA)	Common	Uncommon	Rare	Not known
Blood and lymphatic system disorders				Agranulocytosis Leukopenia
Immune system disorders		Allergic reaction Allergic oedema / angioedema (incl. larynx oedema [1])	Pruritus Urticaria Rash	Anaphylactic/ anaphylactoid reaction Systemic allergic reactions
Psychiatric disorders		Anxiety reactions Sleep disorders	Mood changes	Depression
Metabolism and nutrition disorders				Hyperglycaemia
Nervous system disorders	Headache	Vertigo Migraine Dizziness Tremor	Par-/ Dysaesthesia	Hypoaesthesia Somnolence Lethargy Cerebral ischemia (due to excessive fall in blood pressure)
Eye disorders		Visual disturbances		Eye pain Transient blindness (due to excessive fall in blood pressure)
Cardiac disorders		Tachycardia Palpitations		Chest pain (Angina Pectoris) Myocardial infarction[2] Myocardial ischemia (due to excessive fall in blood pressure)
Vascular disorders	Oedema (incl.	Hypotension		Flushing

System Organ Class (MedDRA)	Common	Uncommon	Rare	Not known
	peripheral oedema) Vasodilatation	Syncope		
Respiratory, thoracic, and mediastinal disorders		Nosebleed Nasal congestion		Dyspnea Pulmonary oedema*
Gastrointestinal disorders	Constipation	Gastrointestinal and abdominal pain Nausea Dyspepsia Flatulence Dry mouth	Gingival hyperplasia	Vomiting Gastrooesophageal sphincter insufficiency Diarrhoea Dysphagia Intestinal Ulcer
Hepatobiliary disorders		Transient increase in liver enzymes		Jaundice Intra-hepatic cholestasis
Skin and subcutaneous tissue disorders		Erythema		Toxic Epidermal Necrolysis Photosensitivity allergic reaction Palpable purpura Telangiectasia Erythema multiforme Pemphigoid reaction Exfoliative dermatitis Purpura
Musculoskeletal and connective tissue disorders		Muscle cramps Joint swelling		Arthralgia Myalgia Worsening of myasthenia gravis
Renal and urinary disorders		Polyuria Dysuria		Increased frequency of micturition
Reproductive system and breast disorders		Erectile dysfunction		Gynaecomastia (long-term therapy)
General disorders and administration site conditions	Feeling unwell	Unspecific pain Chills		Fever

[1] = may result in life-threatening outcome.

[2] = 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.
*cases have been reported when used as tocolytic during pregnancy (see section 4.6)

In dialysis patients with malignant hypertension and hypovolaemia a distinct fall in blood pressure can occur as a result of vasodilation.

Reporting of Suspected Adverse Reactions
Reporting suspected adverse after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

4.9 Overdose

Symptoms
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.

The benefit of gastric decontamination is uncertain.

1. Consider activated charcoal (50 g for adults, 1 g/kg for children) if the patient presents within 1 hour of ingestion of a potentially toxic amount.

Although it may seem reasonable to assume that late administration of activated charcoal may be beneficial for sustained release (SR, MR) preparations there is no evidence to support this.

2. Alternatively consider gastric lavage in adults within 1 hour of a potentially life-threatening overdose.

3. Consider further doses of activated charcoal every 4 hours if a clinically significant amount of a sustained release preparation has been ingested with a single dose of an osmotic laxative (e.g. sorbitol, lactulose or magnesium sulphate).

4. Asymptomatic patients should be observed for at least 4 hours after ingestion and for 12 hours if a sustained release preparation has been taken.

Haemodialysis serves no purpose, as nifedipine is not dialysable, but as plasmapheresis is advisable (high plasma protein binding, relatively low volume of distribution).

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

Pharmacotherapeutic group: selective calcium channel blockers with mainly vascular effect, dihydropyridine derivatives, ATC code: C08 CA05

Nifedipine is a calcium antagonist of the 1,4-dihydropyridine type. Calcium antagonists reduce the transmembranal influx of calcium ions through the slow calcium channel into the cell. As a specific and potent calcium antagonist, nifedipine acts particularly on the cells of the myocardium and the smooth muscle cells of the coronary arteries and the peripheral resistance vessels. The main action of nifedipine is to relax arterial smooth muscle, both in the coronary and peripheral circulation. The Coracten XL capsules is formulated to achieve controlled delivery of nifedipine in a

release profile sufficient to enable once-daily administration to be effective in clinical use.

In hypertension, the main action of nifedipine is to cause peripheral vasodilatation and thus reduce peripheral resistance. Nifedipine administered once-daily provides 24-hour control of raised blood pressure. Nifedipine causes reduction in blood pressure such that the percentage lowering is proportional to its initial level. In normotensive individuals, nifedipine has little or no effect on blood pressure.

In angina, nifedipine reduces peripheral and coronary vascular resistance, leading to an increase in coronary blood flow, cardiac output and stroke volume, whilst decreasing after-load. Additionally, nifedipine dilates submaximally both clear and atherosclerotic coronary arteries, thus protecting the heart against coronary artery spasm and improving perfusion to the ischaemic myocardium. Nifedipine reduces the frequency of painful attacks and the ischaemic ECG changes irrespective of the relative contribution from coronary artery spasm or atherosclerosis.

In a multi-national, randomised, double-blind, prospective study involving 6321 hypertensive patients with at least one additional risk factor followed over 3 to 4.8 years, nifedipine 30 and 60 (nifedipine GITS) were shown to reduce blood pressure to a comparable degree as a standard diuretic combination.

Paediatric population:
Limited information on comparison of nifedipine with other antihypertensives is available for both acute hypertension and long-term hypertension with different formulations in different dosages. Antihypertensive effects of nifedipine have been demonstrated but dose recommendations, long term safety and effect on cardiovascular outcome remain unestablished. Pediatric dosing forms are lacking.

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

Preclinical data reveal no special hazards for humans based on conventional studies of single and repeated dose toxicity, genotoxicity and carcinogenic potential.

Following acute oral and intravenous administration of nifedipine in various animal species, the following LD_{50} (mg/kg) values were obtained:

Mouse:	Oral: 494 (421-572)*;	i.v.: 4.2 (3.8-4.6)*.
Rat:	Oral: 1022 (950-	i.v.: 15.5 (13.7-

	1087)*;	17.5)*.
Rabbit	Oral: 250-500;	i.v.: 2-3.
Cat:	Oral: ~ 100;	i.v.: 0.5-8.
Dog:	Oral: > 250;	i.v.: 2-3.
* 95% confidence interval.		

In subacute and subchronic toxicity studies in rats and dogs, nifedipine was tolerated without damage at doses of up to 50 mg/kg (rats) and 100 mg/kg (dogs) p.o. over periods of thirteen and four weeks, respectively. Following intravenous administration, dogs tolerated up to 0.1 mg/kg nifedipine for six days without damage. Rats tolerated daily intravenous administration of 2.5 mg/kg nifedipine over a period of three weeks without damage.

In chronic toxicity studies in dogs with treatment lasting up to one year, nifedipine was tolerated without damage at doses up to and including 100 mg/kg p.o. In rats, toxic effects occurred at concentrations above 100 ppm in the feed (approximately 5-7 mg/kg bodyweight).

In a carcinogenicity study in rats (two years), there was no evidence of a carcinogenic effect of nifedipine.

Nifedipine has been shown to produce teratogenic findings in rats, mice and rabbits, including digital anomalies, malformation of the extremities, cleft palates, cleft sternum and malformation of the ribs.

Digital anomalies and malformation of the extremities are possibly a result of compromised uterine blood flow, but have also been observed in animals treated with nifedipine solely after the end of the organogenesis period.

Nifedipine administration was associated with a variety of embryotoxic, placentotoxic and foetotoxic effects, including stunted foetuses (rats, mice, rabbits), small placentas and underdeveloped chorionic villi (monkeys), embryonic and foetal deaths (rats, mice, rabbits) and prolonged pregnancy/decreased neonatal survival (rats; not evaluated in other species). The risk to humans cannot be ruled out if a sufficiently high systemic exposure is achieved, however, all of the doses associated with the teratogenic, embryotoxic or foetotoxic effects in animals were maternally toxic and were several times the recommended maximum dose for humans.

In *in vitro* and *in vivo* tests, nifedipine has not been associated with mutagenic properties.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Capsule contents*:*
Lactose monohydrate
Microcrystalline Cellulose
Hydroxylpropyl methylcellulose K100
Povidone K30
Magnesium Stearate
Hydroxypropyl cellulose
Ammonio methacrylate copolymer type B
Polyethylene Glycol 6000
Dibutylphthalate
Titanium dioxide E171
Talc

Capsule shells (size 3)*:*
Yellow iron oxide E172
Red iron oxide E172
Titanium dioxide E171
Gelatin

The printing ink is made of shellac, purified water, black iron oxide (E172), dehydrated alcohol, isopropyl alcohol, butyl alcohol, propylene glycol, strong ammonia solution and potassium hydroxide or shellac, purified water, black iron oxide (E172), n-butyl alcohol, propylene glycol, dehydrated ethanol, isopropyl alcohol and ammonium hydroxide 28%.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

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.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Teofarma S.r.l.
Via Fratelli Cervi 8
Valle Salimbene
PV
27010
Italy

8 MARKETING AUTHORISATION NUMBER(S)

PL 16250/0012

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

7 October 1998

10 DATE OF REVISION OF THE TEXT

22/08/2023