1.3 Product Information

1.3.1 Summary of Product Characteristics

Summary of product characteristic is attached.

SUMMARY OF THE PRODUCT CHARACTERISTICS

1. Trade name of medicinal product

Dilcontin XL 90
(Controlled Release Tablets of Diltiazem Hydrochloride)

2. Qualitative and Quantitative Composition

Core

Ingredient	Quantity (mg / tablet)	Active / Non-active	Reference to standard	Reason for inclusion
Diltiazem Hydrochloride	90.00	Active	USP	Antianginal (Calcium channel blocker)
Hydroxyethyl Cellulose (Natrosol 250 HX)	67.50	Non - active	BP	Release retarding polymer
Cetostearyl Alcohol (Kolliwax CSA 50)	42.525	Non - active	BP	Retarding agent
Ethyl Cellulose 10 CPS	9.975	Non - active	USNF	Release retardant polymer
Purified Talc	8.025	Non - active	BP	Lubricant
Magnesium Stearate	8.025	Non - active	BP	Lubricant

Coating

Ingredient	Quantity mg / tablet	Active / Non-active	Reference to standard	Reason for inclusion
Opadry OY-58900 White	6.00	Non - active	IH	Coating agent
Purified Water	168.40*	Non - active	BP	Solvent

*Not present in final weight

3. Pharmaceutical form

Controlled Release Tablets (Oral dosage form)

4. Clinical Particulars

4.1 Therapeutic indications

Management of angina pectoris and hypertension.

4.2 Posology and Method of Administration

Dosage requirements may differ between patients with angina and patients with hypertension. In addition, individual patient's response may vary, necessitating careful titration of dosage. The range of tablet strengths facilitates titration to the optimal dose. In order to avoid confusion it is suggested that patients once titrated to an effective dose using Dilcontin XL Continus tablets, should remain on this treatment and should not be changed between different presentations. Maximum antihypertensive effect is usually observed by 14 days of therapy; therefore, dosage adjustments should be scheduled accordingly.

The tablets should be swallowed whole and not chewed.

Adults:
For patients new to diltiazem therapy, the usual starting dose is 120mg tablet daily. However, patients on polytherapy and those on other vasodilators like nitrate and hydralazine are usually started on a lower strength Dilcontin XL 90 Continus tablets.

Patients currently receiving a total daily dose of 120mg diltiazem (as 60mg sustained release b.i.d or 30mg normal release q.i.d.) or 180mg diltiazem (as 90mg sustained release b.i.d.) while transferring to Dilcontin XL Continus tablets, should be given the 120mg or 180mg tablet once-a-day respectively.

Elderly (over 65 years) and patients with renal or hepatic impairment:
Clinical studies of diltiazem did not include sufficient number of subjects aged 65 and above to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between elderly and younger patients. In general, dose selection for an elderly and patients with renal/hepatic impairment should be cautious, usually starting at the lower end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

Children:
Not recommended

4.3 Contraindications

Hypersensitivity, bradycardia (heart rate < 50 beats/min.),second or third degree heart block, sick sinus syndrome, decompensated cardiac failure, patients with left ventricular dysfunction following myocardial infarction, pregnant women or those of child-bearing potential. Concurrent use with dantrolene infusion is contraindicated because of the risk of ventricular fibrillation.

4.4 Special warnings and special precautions for use

The product should be used with caution in patients with reduced left ventricular function. Patients with mild bradycardia, first-degree atrioventricular block or prolonged PR interval should be observed closely. As with any drug given over prolonged periods, laboratory parameters of renal and hepatic function should be monitored at regular intervals. The drug should be used with caution in patients with impaired renal and hepatic function. Diltiazem is considered unsafe in patients with acute porphyria.

4.5 Interaction with other medicinal products and other forms of Interaction.

Diltiazem is both a substrate and an inhibitor of the cytochrome P450-3A4 (CYP 3A4) enzyme system. Other drugs that are specific substrates, inhibitors, or inducers of the enzyme system may have a significant impact on the efficacy and side effect profile of diltiazem. Patients taking other drugs that are substrates of CYP 3A4, especially patients with renal and/or hepatic impairment, may require dosage adjustment when starting or stopping concomitantly administered diltiazem in order to maintain optimum therapeutic blood levels.

Co-administration of rifampicin with diltiazem lowered the diltiazem plasma concentration to undetectable level. Co-administration of diltiazem with rifampicin or any known CYP 3A4 inducer should be avoided when possible, and alternative therapy considered.

Due consideration should be given to the possibility of an additive effect when diltiazem is prescribed with antiarrhythmic drugs or drugs which may induce bradycardia.

Diltiazem hydrochloride has been used safely in combination with beta-blockers, diuretics, ACE-inhibitors and other anti-hypertensive agents. It is recommended that patients receiving these combinations should be regularly monitored. Concomitant use with alpha-blockers such as prazosin should be strictly monitored because of the possible synergistic hypotensive effect of this combination.

Patients with pre-existing conduction defects should not receive the combination of diltiazem and beta-blockers.

In a ten-subject study, co administration of diltiazem (120mg bid) with lovastatin resulted in a 3-4 times increase in mean lovastatin AUC and Cmax vs. lovastatin alone; no change in pravastatin AUC and Cmax was observed during diltiazem coadministration. Diltiazem plasma levels were not significantly affected by lovastatin or pravastatin.

Case reports have suggested that blood levels of carbamazepine, cyclosporin and theophylline may be increased when given concurrently with diltiazem hydrochloride. Care should be exercised in patients taking these drugs. In common with other calcium antagonists, diltiazem hydrochloride may cause small increase in plasma levels of digoxin.

Concurrent use with H_2-antagonists may increase serum levels of diltiazem.

Studies showed that diltiazem increased the AUC of midazolam and triazolam by 3-4 fold and the Cmax by 2-fold, compared to placebo. The elimination half-life of midazolam and triazolam increased (1.5-2.5 fold) during coadministration with diltiazem. These pharmacokinetic effects seen during diltiazem co-administration can result in increased clinical effects (e.g., prolonged sedation) of both midazolam and triazolam.

Treatment with diltiazem has been continued without problem during anaesthesia, but the anaesthetist should be made aware of the treatment regimen.

4.6 Pregnancy and lactation

Dilcontin XL Continus is contraindicated in pregnant woman or woman of child bearing potential, and is not recommended in nursing mothers.

Children :
Safety and efficacy in children have not been established.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Diltiazem is generally well tolerated. Occasional undesirable effects are nausea, headache, oedema of the legs, facial flushing, gingival hyperplasia, gastrointestinal disturbance and fatigue, which disappear on cessation of the treatment. Serious skin reactions such as exfoliative dermatitis, and allergic skin reactions such as angioneurotic oedema, erythema multiforme and vasculitis have been reported. Diltiazem may cause depression of atrioventricular nodal conduction as well as hypotension and bradycardia. Isolated cases of moderate and transient increased liver transaminases have been observed at the start of treatment. Isolated cases of clinical hepatitis have been reported, which resolved when diltiazem was withdrawn.

4.9 Overdose

The clinical symptoms of acute intoxication may include pronounced hypotension or even collapse and sinus bradycardia with or without atrioventricular conduction defects. The patient should be closely monitored in hospital to exclude arrhythmias or atrioventricular conduction defects. Gastric lavage and osmotic diuresis should be undertaken when considered appropriate. Symptomatic bradycardia and high grade atrioventricular block may respond to atropine, isoprenaline or occasionally temporary cardiac pacing.

Hypotension may require correction with plasma volume expanders, intravenous calcium gluconate and positive inotropic agents. The Dilcontin XL Continus tablet formulations employ a controlled release system, which continues to release diltiazem for some hours.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Diltiazem is a calcium antagonist. It restricts the slow channel entry of calcium ions into the cell and so reduces the liberation of calcium from stores in the sarcoplasmic reticulum. This results in a reduction in the amount of available intracellular calcium and consequently a reduction of myocardial oxygen consumption, dilation of small and large coronary arteries, mild peripheral vasodilation, negative dromotropic effects, and a slight reduction or change in heart rate due to the negative chronotropic effects, counteracting the reflex increase in heart rate that occurs as a result of peripheral vasodilation. The antihypertensive effect is due to the reduction in peripheral vascular resistance. The antianginal effect is due to reduction in the peripheral vascular resistance, thereby decreasing the after load, whilst a reduction in the vasomotor tone of the coronary vessels maintain the coronary blood flow. Cardiac contractility and ventricular ejection fraction are unchanged. Diltiazem increases exercise capacity and improves indices of myocardial ischaemia in angina patient. Diltiazem relieves the spasm of vasospastic (Prinzmetal's) angina.

5.2 Pharmacokinetic properties

An oral dose of diltiazem is completely absorbed. Despite this diltiazem has a low bioavailability owing to extensive first pass metabolism. This process is saturable at higher doses of the drug resulting in non-linear accumulation and higher blood concentrations at steady state than would be anticipated from those following a single dose.

The primary metobolites, n-demethyl diltiazem and desacetyl diltiazem, exert less pharmacological activity than diltiazem. Plasma protein binding is 80% and only 1- 3% of the dose is excreted in the urine as unchanged diltiazem.

6. Pharmaceutical Particulars

6.1 List of Excipients

S. No.	Name of the Excipient
1.	Hydroxyethyl cellulose (Natrosol 250 HX)
2.	Kolliwax CSA 50 (Cetostearyl Alcohol)
3.	Ethyl Cellulose 10cps
4.	Purified Talc
5.	Magnesium Stearate
6.	Opadry white OY-58900
7.	Purified Water

6.2 Incompatibilities

None of the incompatibilities has been reported.

6.3 Shelf life

24 months

6.4 Special precautions for storage

Store at or below 30^{o} C, in a dry place, protected from light.

6.5 Nature and content of container

Primary Packaging:

Dilcontin XL 90 is packed in aluminum strip of printed aluminium foil (width 168 mm, thickness 0.03 mm) & plain aluminium foil (width 168 mm, thickness 0.03 mm).

Secondary Packaging:

Such ten aluminium strips are placed in a carton along with a package insert.

Pack Size: Box of 100 tablets (10X10`s)

6.6 Instructions for use/handling

Keep out of reach of children,

The tablets should be swallowed whole and not chewed.

7. Marketing authorization holder

Modi-Mundipharma Private Limited
1400, Modi Tower, 98 Nehru Place,
New Delhi – 110019, India
Phone: +91-11-42504696
Fax: +91-11-26451659
E-mail: mithu.sen@winmedicare.com

8. Marketing authorization number

A4-5844

9. Date of first authorization/renewal of the authorization

Second Authorization date: 31st October 2017

Renewal date: 30th October 2022

10. Date of revision of the text

20/03/2022

1.3.2 Labelling (outer & inner labels)

Please find the enclosed mock ups of Dilcontin XL 90 attached.

℞

100 Tablets

90 mg

DILCONTIN™ XL 90

CONTINUS™ controlled release system

Controlled Release Tablets of
Diltiazem Hydrochloride

℞

DILCONTIN™ XL 90

CONTINUS™ controlled release system

Controlled Release Tablets of
Diltiazem Hydrochloride

Each film-coated tablet contains :
Diltiazem Hydrochloride USP : 90 mg
(in a controlled release system)
Colour : Titanium Dioxide
Dosage : As directed by the physician.

Warning : To be sold by retail on the Prescription of a Registered Medical Practitioner only.

These tablets should be swallowed whole and not chewed.

For full prescribing information, please consult the package insert.

Store at or below 30°C, in a dry place, protected from light.

Keep out of reach of children.

TM : Trade Mark

℞

100 Tablets

90 mg

DILCONTIN™ XL 90

CONTINUS™ controlled release system

Controlled Release Tablets of
Diltiazem Hydrochloride

℞

DILCONTIN™ XL 90

CONTINUS™ controlled release system

Controlled Release Tablets of
Diltiazem Hydrochloride

Manufactured by :
MODI-MUNDIPHARMA PVT. LTD.
Mfd. at : Modipuram - 250 110, U.P., India.
Office : 1400, Modi Tower,
98, Nehru Place, New Delhi - 110 019, India.

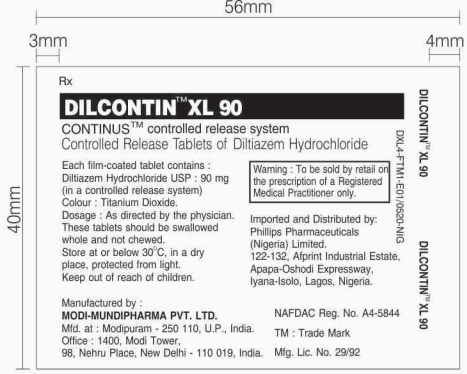
8 901814 002209

NAFDAC Reg. No. A4-5844
Mfg. Lic. No. : 29/92

Imported and Distributed by:
Phillips Pharmaceuticals (Nigeria) Limited.
122-132, Afprint Industrial Estate,
Apapa-Oshodi Expressway,
Iyana-Isolo, Lagos, Nigeria.

DXL4-CTM1-E01/0520-NIG

Artwork of Dilcontin XL 90 Sale Pack
Actual Size : 133 x 50 x 60mm Same Size Print Out
25.05.2020, Dynamic Design (ND0917)
Nigeria



Artwork of **DilcontinXL 90 Foil (Nigeria)**
Foil width : 168mm, Strip Size - 56 x 50 mm,
Repeat 40 mm, S/S Print
8.9.2017, Dynamic Design (ND0917)

Rx

DILCONTIN™ XL 90

CONTINUS™ controlled release system

Controlled Release Tablets of Diltiazem Hydrochloride

Each film-coated tablet contains :
Diltiazem Hydrochloride USP : 90 mg
(in a controlled release system)
Colour : Titanium Dioxide.
Dosage : As directed by the physician.
These tablets should be swallowed
whole and not chewed.
Store at or below 30°C, in a dry
place, protected from light.
Keep out of reach of children.

Warning : To be sold by retail on the prescription of a Registered Medical Practitioner only.

Imported and Distributed by:
Phillips Pharmaceuticals
(Nigeria) Limited.
122-132, Afprint Industrial Estate,
Apapa-Oshodi Expressway,
Iyana-Isolo, Lagos, Nigeria.

Manufactured by :
MODI-MUNDIPHARMA PVT. LTD.
Mfd. at : Modipuram - 250 110, U.P., India.
Office : 1400, Modi Tower,
98, Nehru Place, New Delhi - 110 019, India.

NAFDAC Reg. No. A4-5844

TM : Trade Mark

Mfg. Lic. No. 29/92

DXL4-FTM1-E01/0520-NIG

DILCONTIN™ XL 90

DILCONTIN™ XL 90

200%

1.3.3 Packaging Insert (also known as patient information PIL)

Pack insert of Dilcontin XL 90 mg is enclosed.

the treatment. Serious skin reactions such as exfoliative dermatitis, and allergic skin reactions such as angioneurotic oedema, erythema multiforme and vasculitis have been reported. Diltiazem may cause depression of atrioventricular nodal conduction as well as hypotension and bradycardia. Isolated cases of moderate and transient increased liver transaminases have been observed at the start of treatment. Isolated cases of clinical hepatitis have been reported, which resolved when diltiazem was withdrawn.

Overdose & Its Treatment

The clinical symptoms of acute intoxication may include pronounced hypotension or even collapse and sinus bradycardia with or without atrioventricular conduction defects. The patient should be closely monitored in hospital to exclude arrhythmias or atrioventricular conduction defects. Gastric lavage and osmotic diuresis should be undertaken when considered appropriate. Symptomatic bradycardia and high grade atrioventricular block may respond to atropine, isoprenaline or occasionally temporary cardiac pacing. Hypotension may require correction with plasma volume expanders, intravenous calcium gluconate and positive inotropic agents.

The DILCONTIN™ XL CONTINUS™ tablet formulations employ a controlled release system, which continues to release diltiazem for some hours.

Further Information

An oral dose of normal release diltiazem is almost completely absorbed. Despite this, diltiazem has a low bioavailability owing to extensive first pass metabolism. This process is saturable at higher doses of the drug, resulting in a non-linear accumulation and higher blood concentrations at steady state than would be anticipated from those following a single dose of normal release diltiazem.

DILCONTIN™ XL CONTINUS™ tablets reduce the degree of saturation by presenting diltiazem in a controlled rate, therefore eliminating the high peak concentrations of the absorption phase. This allows the tablet to be administered once daily.

Pharmaceutical Particulars

Incompatibilities : None reported

Shelf Life : 24 months

Storage Precautions : Store at or below 30°C, in a dry place, protected from light.

Keep out of reach of children.

Presentation :

Box of 100 tablets (10x10's Aluminum strip)

Imported and Distributed by:
Phillips Pharmaceuticals (Nigeria) Limited.
122-132, Afprint Industrial Estate,
Apapa-Oshodi Expressway,
Iyana-Isolo, Lagos, Nigeria.

Manufactured by
MODI-MUNDIPHARMA PVT. LTD.
Mfd. at : Modipuram - 250 110, U.P., India
Office : 1400, Modi Tower,
98, Nehru Place, New Delhi - 110 019, India

NAFDAC Reg. No.
Dilcontin XL 90 : A4-5844
Dilcontin XL 120: A4-8231

TM: Trade Mark

DXL4-PTM1-E01/0520-NIG

For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory.

Rx

DILCONTIN™ XL 90/120

CONTINUS™ controlled release system

Controlled Release Tablets of
Diltiazem Hydrochloride

Description

DILCONTIN™ XL 90/120 CONTINUS™ a white/grey film-coated round tablet marked with 'DXL' on one side and '90/120' on the other side, contains 90mg/120mg of diltiazem hydrochloride USP in a controlled release system.

Indications

DILCONTIN™ XL is indicated for the treatment of hypertension. It may be used alone or in combination with other antihypertensive medications.

DILCONTIN™ XL is indicated for the management of chronic stable angina.

Clinical Pharmacology

Diltiazem is a calcium antagonist. It restricts the slow channel entry of calcium ions into the cell and so reduces the liberation of calcium from stores in the sarcoplasmic reticulum. This results in a reduction in the amount of available intracellular calcium and consequently a reduction of myocardial oxygen consumption, dilation of small and large coronary arteries, mild peripheral vasodilation, negative dromotropic effects, and a slight reduction or change in heart rate due to the negative chronotropic effects, counteracting the reflex increase in heart rate that occurs as a result of peripheral vasodilation. The antihypertensive effect is due to the reduction in peripheral vascular resistance. The antianginal effect is due to reduction in the peripheral vascular resistance, thereby decreasing the after load, whilst a reduction in the vasomotor tone of the coronary vessels maintain the coronary blood flow. Cardiac contractility and ventricular ejection fraction are unchanged. Diltiazem increases exercise capacity and improves indices of myocardial ischaemia in angina patient. Diltiazem relieves the spasm of vasospastic (Prinzmetal's) angina.

An oral dose of diltiazem is completely absorbed. Despite this diltiazem has a low bioavailability owing to extensive first pass metabolism. This process is saturable at higher doses of the drug resulting in non-linear accumulation and higher blood concentrations at steady state than would be anticipated from those following a single dose.

The primary metobolites, n-demethyl diltiazem and desacetyl diltiazem, exert less pharmacological activity than diltiazem. Plasma protein binding is 80% and only 1-3% of the dose is excreted in the urine as unchanged diltiazem.

Dosage & Administration

DILCONTIN™ XL CONTINUS™ Tablets are Controlled release formulation intended for once-a-day administration.

Patients controlled on diltiazem alone or in combination with other medications may be switched to DILCONTIN™ XL CONTINUS™ Tablets once a day at the nearest equivalent total daily dose. Higher doses of DILCONTIN™ XL CONTINUS™ Tablets once daily dosage may be needed in some patients. Patients should be closely monitored. Subsequent titration to higher or

Artwork of **Dilcontin XL 90/120 Pack Insert (Nigeria)**
A/w Size : 70 x 210 mm, Same Size Print
25.05.2020, **Dynamic Design** (OD0520)

lower doses may be necessary and should be initiated as clinically warranted. There is limited general clinical experience with doses above 360mg, but the safety and efficacy of doses as high as 540mg have been studied in clinical trials. The incidence of side effects increases as the dose increases with first degree AV block, dizziness, and sinus bradycardia bearing the strongest relationship to dose.

The tablet should be swallowed whole and not chewed or crushed.

Hypertension

Dosage needs to be adjusted by titration to individual patient needs. When used as monotherapy, reasonable starting doses are 180 to 240mg once daily, although some patients may respond to lower doses. Maximum antihypertensive effect is usually observed by 14 days of chronic therapy; therefore, dosage adjustments should be scheduled accordingly. The dosage range studied in clinical trials was 120 to 540 mg once daily. The dosage may be titrated to a maximum of 540 mg daily.

DILCONTIN™ XL CONTINUS™ Tablets should be taken about the same time once each day either in the morning or at bed time. The time of time of dosing should be considered when making the dose adjustments based on trough effects.

Angina

Dosage for the treatment of angina should be individualized based on response. The initial dose of 180mg once daily may be increased at intervals of 7 to 14 days if adequate response is not obtained . DILCONTIN™ XL doses above 360 mg appear to confer no additional benefit.

DILCONTIN™ XL CONTINUS™ Tablets can be given once daily, either in evening or in the morning.

Elderly (over 65 years) and patients with renal or hepatic impairment

Clinical studies of diltiazem did not include sufficient number of subjects aged 65years and above to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between elderly and younger patients. In general, dose selection for an elderly and patients with renal /hepatic impairment should be cautious, usually starting at the lower end of the dosing range, reflecting the greater frequency of decreased hepatic, renal or cardiac function, and of concomitant disease or other drug therapy.

Contraindications

Hypersensitivity, bradycardia (heart rate < 50 beats/min.), second or third degree heart block, sick sinus syndrome, decompensated cardiac failure, patients with left ventricular dysfunction following myocardial infarction, pregnant women or those of child-bearing potential. Concurrent use with dantrolene infusion is contraindicated because of the risk of ventricular fibrillation.

Warnings & Precautions

The product should be used with caution in patients with reduced left ventricular function. Patients with mild bradycardia, first degree atrioventricular block or prolonged PR interval should be observed closely. As with any drug given over prolonged periods, laboratory parameters of renal and hepatic function should be monitored at regular intervals. The drug should be used with caution in patients with impaired renal and hepatic function. Diltiazem is considered unsafe in patients with acute porphyria.

Pregnancy & Lactation :

DILCONTIN™ XL CONTINUS™ is contraindicated in pregnant woman or woman of child bearing potential, and is not recommended in nursing mothers.

Children :

Safety and efficacy in children have not been established.

Drug Interactions

Diltiazem is both a substrate and an inhibitor of the cytochrome P450-3A4 (CYP 3A4) enzyme system. Other drugs that are specific substrates, inhibitors, or inducers of the enzyme system may have a significant impact on the efficacy and side effect profile of diltiazem. Patients taking other drugs that are substrates of CYP 3A4, especially patients with renal and/or hepatic impairment, may require dosage adjustment when starting or stopping concomitantly administered diltiazem in order to maintain optimum therapeutic blood levels.

Co-administration of rifampicin with diltiazem lowered the diltiazem plasma concentration to undetectable level. Co-administration of diltiazem with rifampicin or any known CYP 3A4 inducer should be avoided when possible, and alternative therapy considered.

Due consideration should be given to the possibility of an additive effect when diltiazem is prescribed with antiarrhythmic drugs or drugs which may induce bradycardia.

Diltiazem hydrochloride has been used safely in combination with beta-blockers, diuretics, ACE-inhibitors and other anti-hypertensive agents. It is recommended that patients receiving these combinations should be regularly monitored. Concomitant use with alpha-blockers such as prazosin should be strictly monitored because of the possible synergistic hypotensive effect of this combination. Patients with pre-existing conduction defects should not receive the combination of diltiazem and beta-blockers.

In a ten-subject study, coadministration of diltiazem (120mg bid) with lovastatin resulted in a 3-4 times increase in mean lovastatin AUC and C_{max} vs. lovastatin alone; no change in pravastatin AUC and C_{max} was observed during diltiazem coadministration. Diltiazem plasma levels were not significantly affected by lovastatin or pravastatin.

Case reports have suggested that blood levels of carbamazepine, cyclosporin and theophylline may be increased when given concurrently with diltiazem hydrochloride. Care should be exercised in patients taking these drugs. In common with other calcium antagonists, diltiazem hydrochloride may cause small increase in plasma levels of digoxin.

Concurrent use with H_2-antagonists may increase serum levels of diltiazem.

Studies showed that diltiazem increased the AUC of midazolam and triazolam by 3-4 fold and the C_{max} by 2-fold, compared to placebo. The elimination half-life of midazolam and triazolam increased (1.5-2.5 fold) during co-administration with diltiazem. These pharmacokinetic effects seen during diltiazem co-administration can result in increased clinical effects (e.g., prolonged sedation) of both midazolam and triazolam.

Treatment with diltiazem has been continued without problem during anaesthesia, but the anaesthetist should be made aware of the treatment regimen.

Side Effects

Diltiazem is generally well tolerated. Occasional undesirable effects are nausea, headache, oedema of the legs, facial flushing, gingival hyperplasia, gastrointestinal disturbance and fatigue, which disappear on cessation of

Artwork of **Dilcontin XL 90/120 Pack Insert (Nigeria)**
A/w Size : 70 x 210 mm, Same Size Print
25.05.2020, **Dynamic Design** (OD0520)