



Medicinal products in ATC group C08, Calcium channel blockers

Reading instructions for the table below

Approved indication: The specified indication(s) of an active substance and pharmaceutical form, if stated, relate(s) to the medicinal product that has been licensed for the longest period of time.

Reimbursement status: The current reimbursement status of the medicinal product.

Treatment price per day: The listed prices per day are based on the medicinal products' reimbursement prices calculated in accordance with the Danish Medicines Agency's guidelines for evaluation and comparison of medicinal products in reassessments of reimbursement status dated 4 July 2006, cf. Appendices C4 and D.

Consumption: The number of persons in treatment is based on the Danish Medicines Agency's Register of Medicinal Product Statistics, cf. www.medstat.dk.

Single substance medicinal products for oral use

C08CA01	Amlodipine
Pharmaceutical forms	Tablets
Traded names	Amlodipin "1A Farma, Amlodipin "Alpharma", Amlodipin "Alternova", Amlodipin "Copyfarm", Amlodipin "GEA", Amlodipin "Hexal", Amlodipin "KRKA", Amlodipin "Orion", Amlodipin "PCD", Amlodipin "Ranbaxy", Amlodipin "ratiopharm", Amlodipin "Sandoz", Amlovis, Norvasc
Approved indication	"Prevention of angina pectoris. Arterial hypertension."
Dispensing terms	B
Reimbursement status	General reimbursement
Price per day	5 - 10 mg tablets: DKK 0.90 – 0.48
Consumption	174,747 persons in treatment in 2006 192,629 persons in treatment in the first 10 months of 2007
Discussion	Together with felodipine, amlodipine is one of the cheapest calcium antagonists. Amlodipine is used for the large majority of patients treated with calcium antagonists, which, in the opinion of the Committee, is a rational consumption.
Assessment	The Committee assesses that there are <u>no</u> grounds to open a case to change the reimbursement status for oral medicinal products in ATC group C08CA01

C08CA02	Felodipine
Pharmaceutical forms	Prolonged-release tablets
Traded names	Felodin, Felodipin "Actavis", Felodipin "Hexal", Felodipin "ratiopharm", Felodipin "Sandoz", Felodipin Retard "1A Farma", Hydac, Plendil, Plendur
Approved indication	"Arteriel hypertension"
Dispensing terms	B
Reimbursement status	General reimbursement
Price per day	5 - 10 mg prolonged-release tablets: DK 1.16 – 1.27
Consumption	33,796 persons in treatment in 2006 32,820 persons in treatment in the first 10 months of 2007

Discussion	Felodipine is more expensive than amlodipine, but is, however, together with this substance, one of the cheapest calcium antagonists and is used for many of the patients treated with calcium antagonists, which, in the opinion of the Committee, is appropriate.
Assessment	The Committee assesses that there are <u>no</u> grounds to open a case to change the reimbursement status for oral medicinal products in ATC group C08CA02

C08CA03	Isradipine
Pharmaceutical forms	Prolonged-release capsules
Traded names	Lomir Retard
Approved indication	"Arterial hypertension"
Dispensing terms	B
Reimbursement status	General reimbursement
Price per day	5 - 10 mg prolonged-release capsules: DK 4.76 – 7.52
Consumption	2,181 persons in treatment in 2006 2,061 persons in treatment in the first 10 months of 2007
Discussion	The consumption of isradipine is very modest. It is the opinion of the Reimbursement Committee that isradipine is used for a small number of patients who, as a result of adverse reactions or interactions, cannot use the cheaper calcium antagonists. The price is at the high end for calcium antagonists, and the Committee proposes that the consumption be monitored.
Assessment	The Committee assesses that there are <u>no</u> grounds to open a case to change the reimbursement status for oral medicinal products in ATC group C08CA03

C08CA05	Nifedipine
Pharmaceutical forms	Tablets, capsules, prolonged-release tablets
Traded names	Adalat, Adalat Oros, Hexadilat, Nifecodan, Nifedipin "Alternova", Nifedipin "NM", Nifedipin 10 "Stada"
Approved indication	"Chronic, stable angina pectoris. Arterial hypertension. Raynaud's phenomenon."
Dispensing terms	B
Reimbursement status	General reimbursement
Price per day	30 - 120 mg prolonged-release tablets: DKK 3.24 – 8.90 30 mg tablets, capsules: DKK 2.85
Consumption	11,330 persons in treatment in 2006 10,385 persons in treatment in the first 10 months of 2007
Discussion	It is the opinion of the Reimbursement Committee that nifedipine is used for patients who cannot use the cheaper calcium antagonists. In addition, nifedipine is used for patients with Raynaud's phenomenon. Nifedipine is recommended in prolonged-release form only as the rapid forms have shown to increase the mortality in patients with ischaemic heart disease. It is the opinion of the Committee that the 6:1 ratio in the sale of DDD between the prolonged-release form and the tablet form is an appropriate distribution.
Assessment	The Committee assesses that there are <u>no</u> grounds to open a case to change the reimbursement status for oral medicinal products in ATC group C08CA05.

C08CA06	Nimodipine
Pharmaceutical forms	Tablets
Traded names	Nimotop
Approved indication	“Prevention and treatment of spasms in subarachnoidal haemorrhage caused by a burst aneurysm.”
Dispensing terms	B
Reimbursement status	No general reimbursement
Price per day	300 mg tablets: DKK 65.90
Consumption	45 persons in treatment in 2006 23 persons in treatment in the first 10 months of 2007
Discussion	The indication for nimodipine is totally different from that of the other calcium antagonists. The treatment with nimodipine is initiated from the hospital, and there is no alternative treatment. Nimodipine is not granted general reimbursement, but over the years single reimbursement has been granted following applications from doctors. It is the opinion of the Committee that nimodipine has a valuable therapeutic effect with a specific place in the therapy.
Assessment	The Committee assesses that <u>there are grounds</u> to open a case to change the reimbursement status for oral medicinal products in ATC group C08CA06 such that the medicinal products be eligible for general unlimited reimbursement.

*Based on the lowest actual prices.

⁰The figures also include patients treated with the medicinal product for injection.

C08CA08	Nitrendipine
Pharmaceutical forms	Tablets
Traded names	Baypress
Approved indication	”Arterial hypertension.”
Dispensing terms	B
Reimbursement status	General reimbursement
Price per day	10 - 20 mg tablets: DKK 3.38 – 4.71
Consumption	740 persons in treatment in 2006 673 persons in treatment in the first 10 months of 2007
Discussion	Nitrendipine is used for a very limited number of patients. It is the opinion of the Reimbursement Committee that nitrendipine has its place in the therapy as a substance used for patients who cannot use the cheaper calcium antagonists.
Assessment	The Committee assesses that there are <u>no</u> grounds to open a case to change the reimbursement status for oral medicinal products in ATC group C08CA08.

C08CA09	Lacidipine
Pharmaceutical forms	Tablets
Traded names	Midotens, Motens
Approved indication	“For the treatment of hypertension either as monotherapy or in combination with other antihypertensive drugs, including β -receptor blocking agents, diu-

	retics or ACE inhibitors.”
Dispensing terms	B
Reimbursement status	General reimbursement
Price per day	2 - 4 mg tablets: DKK 5.38 – 5.47
Consumption	1,988 persons in treatment in 2006 1,931 persons in treatment in the first 10 months of 2007
Discussion	It is the opinion of the Reimbursement Committee that the modest use of lacidipine is for patients who cannot use the cheaper calcium antagonists and that the low consumption indicates that the consumption has found its place.
Assessment	The Committee assesses that there are <u>no</u> grounds to open a case to change the reimbursement status for oral medicinal products in ATC group C08CA09.

C08CA13	Lercanidipine
Pharmaceutical forms	Tablets
Traded names	Zanidip
Approved indication	“For the treatment of mild to moderate essential hypertension.”
Dispensing terms	B
Reimbursement status	General reimbursement
Price per day	10 - 20 mg tablets: DKK 3.52 – 7.01
Consumption	7,850 persons in treatment in 2006 9,621 persons in treatment in the first 10 months of 2007
Discussion	It is the opinion of the Reimbursement Committee that lercanidipine is used for patients who cannot use the cheaper calcium antagonists.
Assessment	The Committee assesses that there are <u>no</u> grounds to open a case to change the reimbursement status for oral medicinal products in ATC group C08CA13.

C08DA01	Verapamil
Pharmaceutical forms	Tablets, prolonged release tablets, prolonged release capsules
Traded names	Geangin, Geangin Retard, Hexasoptin, Hexasoptin Retard, Isoptin, Isoptin Retard, , Veraloc, Veraloc Retard, Verapamil ”1A Farma”, Verapamil ”Hexal”, Verapamil ”Merck NM”
Approved indication	“Prevention of angina pectoris. Prevention and treatment of supraventricular tachycardia, including atrial fibrillation and atrial flutter. Arterial hypertension. Prophylaxis following acute myocardial infarction.”
Dispensing terms	B
Reimbursement status	General reimbursement
Price per day	240 - 480 mg tablets: DKK 1.95 – 2.84. 240 - 480 mg prolonged release tablets and capsules: DKK 3.10 – 5.52
Consumption	29,985 persons in treatment in 2006 27,057 persons in treatment in the first 10 months of 2007
Discussion	The indications for verapamil differ from and are wider than for the dihydropyridines. The consumption has seen a stationary to slight decreasing tendency during recent years, and it is the opinion of the Reimbursement Committee that it is rational, in particular for the treatment of tachyarrhythmias, for the prevention of angina pectoris and as prophylaxis following AMI when a

	relevant beta blocker cannot be tolerated. The prolonged-release tablets are a little more expensive than the film-coated tablets, but should only be given twice a day as compared to six times a day for the tablets and are expected to improve compliance.
Assessment	The Committee assesses that there are <u>no</u> grounds to open a case to change the reimbursement status for oral medicinal products in ATC group C08DA01.

* The figures also include patients treated with the medicinal product for injection.

C08DB01	Diltiazem
Pharmaceutical forms	Tablets, prolonged release tablets, prolonged release capsules
Traded names	Cardil, Cardizem, Cardizem Retard, Cardizem Unotard, Dilcor, Dilcor Uno, Myonil, Myonil Retard, Myonil Uno, Tilker
Approved indication	“Prevention of angina pectoris. Arterial hypertension.”
Dispensing terms	B
Reimbursement status	General reimbursement
Price per day	180 - 360 mg tablets: DKK 4.50 – 9.00 180 - 360 mg prolonged release tablets and capsules: DKK 5.70 – 14.74
Consumption	16,029 persons in treatment in 2006 14,437 persons in treatment in the first 10 months of 2007
Discussion	The indications for diltiazem differ from and are wider than for the dihydropyridines. The consumption has seen a stationary to slight decreasing tendency during recent years, and it is the opinion of the Reimbursement Committee that it is rational, in particular for the treatment of tachyarrhythmias, for the prevention of angina pectoris and as prophylaxis following AMI when a relevant beta blocker cannot be tolerated. The prolonged-release tablets are a little more expensive than the film-coated tablets, but should only be given twice a day as compared to six times a day for the tablets and are expected to improve compliance.
Assessment	The Committee assesses that there are <u>no</u> grounds to open a case to change the reimbursement status for oral medicinal products in ATC group C08DB01

Combinations for oral use

C08DA51	Verapamil + trandolapril
Pharmaceutical forms	Tablets
Traded names	Tarka
Approved indication	“Essential hypertension in patients whose blood pressure has been normalised with the individual components in the same dose ratio.”
Dispensing terms	B
Reimbursement status	General reimbursement
Price per day	240 mg + 4 mg tablets: DKK 6.43
Consumption	767 persons in treatment in 2006 645 persons in treatment in the first 10 months of 2007
Discussion	The medicinal product is cheaper than the two substances separately, and the Committee emphasises the compliance benefit of using the combination product.

Assessment	The Committee assesses that there are <u>no</u> grounds to open a case to change the reimbursement status for oral medicinal products in ATC group C08DA51
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Parenteral medicinal products

C08CA06	Nimodipine
Pharmaceutical forms	Solution for infusion
Traded names	Nimotop
Approved indication	“Prevention and treatment of spasms in subarachnoidal haemorrhage caused by a burst aneurysm.”
Dispensing terms	B
Reimbursement status	No general reimbursement
Price per day	50 mg: DKK 1277,50
Consumption	-
Discussion	Nimodipine injection fluid is used in hospital treatment only, and general reimbursement is thus not relevant.
Assessment	The Committee assesses that there are <u>no</u> grounds to open a case to change the reimbursement status for parenteral medicinal products in ATC group C08CA06.

C08DA01	Verapamil
Pharmaceutical forms	Injection
Traded names	Veraloc
Approved indication	“Paroxysmic supraventricular tachycardia. Atrial fibrillation and atrial flutter with rapid ventricular response, except in WPW syndrome. Severe hypertension.”
Dispensing terms	B
Reimbursement status	No general reimbursement
Price per day	240 mg: DKK 455.04
Consumption	-
Discussion	Verpamil injection fluid is used in hospital treatment only, and general reimbursement is thus not relevant.
Assessment	The Committee assesses that there are <u>no</u> grounds to open a case to change the reimbursement status for parenteral medicinal products in ATC group C08DA01.

Price survey of C08 - calcium channel blockers

Appendix C4
29 January 2008

Average lowest unit price for 6 price periods (period start from 22 october to 31 december 2007)

1. ATC	2. Medicinal product	3. Reimbursement status/dispensing terms	4. DDD (mg)	5. Daily Dose (mg) ¹	6. Pharmaceutical form	7. Strength (mg)	8. Average lowest unit price (DKK)	9. Price per day (DKK)	
C08CA	Dihydropyridine derivatives								
C08CA01	Amlodipine	•	B	5	5 - 10 ⁴⁵	Tablets	5 / 10	0.90 / 0.48	0.90 - 0.48
C08CA02	Felodipine	•	B	5	5 - 10 ⁴⁵	Prol.-release tab.	5 / 10	1.16 / 1.27	1.16 - 1.27
C08CA03	Isradipine	•	B	5	5 - 10 ⁴⁵	Prol.-release cap.	5	3.76	3.76 - 7.52
C08CA05	Nifedipine	•	B	30	30 - 120 ⁴⁵	Prol.-release tab.	30 / 60	3.24 / 4.45	3.24 - 8.90
		•	B	30	30 - 120 ³⁷	Capsules/tablets	10 / 20	0.95 / 2.22	2.85 - 11.40
C08CA06	Nimodipine	-	B	300	300 ³⁶⁸	Film-coated tab.	30	6.59	65.90
		-	B	50	50 ³⁶	Intravenous infusion	0.2 mg/ml	5.11 DKK./ml	1277.50
C08CA08	Nitrendipine	•	B	20	10 - 20 ⁴⁵	Tablets	10 / 20	3.38 / 4.71	3.38 - 4.71
C08CA09	Lacidipine	•	B	4	2 - 4 ⁴⁵	Tablets/film-coated t.	2 / 4	5.38 / 5.47	5.38 - 5.47
C08CA13	Lercanidipine	•	B	10	10 - 20 ⁴⁵	Film-coated tab.	10 / 20	3.52 / 7.01	3.52 - 7.01
C08DA	Phenylalkylamine derivatives								
C08DA01	Verapamil	•	B	240	240 - 480 ²⁴⁵	Prol.-release tab.	120 / 240	1.55 / 2.76	3.10 - 5.52
		•	B	240	240 - 480 ²⁴⁵	Prol.-release tab.	120 / 240	2.19 / 1.59	4.38 - 3.18
		•	B	240	240 - 480 ⁴⁵⁸	Tablets/film-coated t.	80 / 120	0.65 / 0.71	1.95 - 2.84
		-	B	240	240 ³	Injection	2.5 mg/ml	4.74 DKK./ml	455.04
C08DA51	Verapamil, combinations ¹⁰	•	B	-	240 - 360	Capsules	180 240	7.15 6.43	6.43 - 14.30
C08DB	Benzothiazepine derivatives								
C08DB01	Diltiazem	•	B	240	180 - 360 ²⁴⁵	Prol.-release cap.	90 / 180	2.85 / 5.72	5.70 - 11.44
		•	B	240	180 - 360 ²⁴⁵	Prol.-release cap.	120	3.56	10.68
		•	B	240	180 - 360 ²⁴⁵	Prol.-release tab.	60 / 180	1.93 / 7.37	5.79 - 14.74
		•	B		180 - 360 ⁴⁵⁸	Film-coated tab.	60	1.50	4.50 - 9.00

Notes and explanations:

1	Can be given once a day unless otherwise noted
2	Divided into 2 daily doses
3	DDD (Defined Daily Dose) by the WHO
4	Equieffective dose by the Institute for Rational Pharmacotherapy
5	Recommended by the Institute for Rational Pharmacotherapy
6	Not recommended by the Institute for Rational Pharmacotherapy
7	Divided into 3 daily doses
8	Divided into 6 daily doses
9	Recommended with certain limitations or in special cases by the Institute for Rational Pharmacotherapy
10	+ 2 mg trandolapril in the tablet containing 180 mg verapamil and 4 mg trandolapril in the tablet containing 240 mg verapamil

Symbols and abbreviations

Reimbursement status	
-	Not eligible for general reimbursement
●	General reimbursement for prescription-only medicinal products
■	Limited general reimbursement for over-the-counter medicinal products.
⊗	Limited general reimbursement for prescription-only medicinal products

Dispensing terms	
A	Only to be dispensed once on the same prescription, unless dispensed in smaller doses at a time.
AP4	Subject to the provisions of section 4 of the Executive Order on prescriptions.
AP4BG	Only to be dispensed to hospitals. Subject to the provisions of section 4 of the Executive Order on prescriptions.
AP4NB	Only to be dispensed to hospitals or following prescription by specific medical specialists. Subject to the provisions of section 4 of the Executive Order on prescriptions.
B	Only to be dispensed once on the same prescription, unless stated otherwise.
BEGR	Only to be dispensed to hospitals. Same terms apply as for dispensing group A.
HA	Over-the-counter drugs. Pharmacy-restricted medicinal product.
HF	Over-the-counter drugs. Non-pharmacy-restricted human medicinal product.
HX	Over-the-counter drugs. Non-pharmacy-restricted human medicinal product. Maximum 1 package/customer/day.
NBS	Only to be dispensed to hospitals or following prescription by specific medical specialists. Same terms apply as for dispensing group A.