Name of Trust / logo

Memo (for local adaptation) - shortage of supply

To:
From:
Date:

Re: Adalat (nifedipine) products

Description of products affected

Nifedipine capsule 5mg is licensed for the prophylaxis of chronic stable angina pectoris, the treatment of Raynaud's phenomenon and essential hypertension. The recommended starting dose is 5 mg every eight hours with subsequent titration of dose according to response permitting an increase to a maximum of 20 mg every eight hours.[1]

The long acting and slow release formulations of Adalat are licensed for the treatment of hypertension and prophylaxis of angina.[2]

Background

There will be some out of stock periods for some preparations and long-term discontinuations:

Adalat 5mg immediate release capsules* –discontinued from February 2019.
Adalat 10mg immediate release capsules* – discontinued after March 2019
Adalat Retard 10mg modified release tablets – discontinued after November 2018
Adalat Retard 20mg modified release tablets – discontinued August 2018
Adalat LA 20mg*, 30mg and 60mg prolonged release – out of stock until 2021.

*Bayer is the sole supplier of these 3 formulations

Supplies of other nifedipine capsules and tablets remain available currently, including: Adipine (Chiesi), Coracten (UCB), Nifedipress (Dexcel) and Tensipine (Genus).

Alternative agents and management options

Immediate release capsules (5mg and 10mg)

Nifedipine is a dihydropyridine calcium-channel blocker (CCB). In practice, the immediate release capsules should only have been used for treating patients with essential hypertension or chronic stable angina pectoris if no other treatment is appropriate because of a risk of a dose dependent increase in the risk of cardiovascular complications (e.g. myocardial infarction) and mortality which may occur with use of fast release nifedipine capsules.[1,3] In addition, use of the immediate release capsules can be associated with precipitate and uncontrolled reduction in blood pressure. It would therefore not be the initial treatment of choice for patients with hypertension and angina.

Nifedipine is also formulated as slow release tablets[3], but they are not licensed for the treatment of Raynaud's phenomenon, which is an indication for the immediate-release formulation. No other dihydropyridines are licensed for the treatment of Raynaud's phenomenon. There is clinical experience suggesting that long-acting nifedipine is effective for the treatment of Raynaud's and has fewer adverse reactions than rapid-acting preparations, therefore patients could be switched to a similar dose of a modified

release preparation.[4]

Dihydropyridines vary in their licenses for the treatment of angina and hypertension, but amlodipine and felodipine are licensed for both indications.[5,6]

There are no guidance or data on dose conversion between immediate and modified release nifedipine preparations so if a patient needs to be switched, the nearest equivalent dose should be prescribed and patient's blood pressure and / or frequency of angina attacks (if applicable) monitored in the initial stages of the switch, in addition to monitoring for adverse effects such as headaches, dizziness and oedema. Immediate-release nifedipine capsules are administered three times a day.[1] Modified release nifedipine preparations are dosed once or twice daily depending on brand selected. Patients will need to be counselled on the change in frequency of dosing to avoid potential errors. Likewise they should be advised to report any adverse effects. There is also a lack of data on switching to an alternative CCB such as amlodipine (dose range 5 to 10mg once a day) or felodipine (2.5 to 10mg once a day) so dosing should be based on where nifedipine fell in the licensed dose range (5 to 20mg three times a day).

Autonomic dysreflexia

Individuals with spinal cord injury (SCI) at or above T6 level are at risk of autonomic dysreflexia (AD), an acute and potentially life threatening condition resulting from an excessive autonomic response to stimuli below the level of the SCI.[7] This can cause severe, sudden hypertension which requires immediate treatment with nifedipine capsules administered sublingually (5 or 10 mg).[7,8] Patients at risk of experiencing AD are advised to have a small quantity of the drug close at hand.[8] Glyceryl trintrate (GTN) spray is a second line treatment option[8] but it causes headaches which can mask further episodes of AD or cardiovascular complications.[9]

Imports of 5mg immediate release capsules

The Department of Health have been working with potential alternative manufacturers and are working to get another licensed supply to the UK market; it is currently estimated that supplies could be available April to May 2019. In the interim, imports of unlicensed product are available.

Long acting/ slow release formulations

The long acting preparations are administered once daily and the slow release preparations twice daily. There are generic versions of all Adalat modified release preparations apart from Adalat LA 20mg.[10] When switching between brands, closer monitoring of BP may be required in the initial stages and patients reassured that they are receiving the same drug and dose but to report any adverse effects. For patients on Adalat LA 20mg, options are to switch to slow release preparation of 10mg strength which is administered twice a day or depending on current BP, trial next strength up (30mg) of a once daily preparation .Other long acting CCBs are available and licensed indications should be checked as they may not all share the same ones as the Adalat range.

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