Myprocam® extended-release
cyclobenzaprine hydrochloride capsule

Approved indication

Each Myprocam® extended-release capsule contains 15 mg or 30 mg cyclobenzaprine hydrochloride.1
Myprocam® is indicated as an adjunct to rest and physiotherapy for the relief of muscle spasms associated with acute, painful musculoskeletal conditions.1

Mode of action

Cyclobenzaprine hydrochloride, a skeletal muscle relaxant, primarily acts at the brain stem within the central nervous system (CNS), as opposed to the spinal cord. It influences both the gamma and alpha motor systems by reducing tonic somatic motor activity.2

A similarity has been demonstrated in pharmacological studies on animals between the effects of cyclobenzaprine and the structurally related tricyclic antidepressants (TCAs), including reserpine antagonism and noradrenaline potentiation, as well as potent peripheral and central anticholinergic effects and sedation.1

Dosage

The recommended adult dose is a Myprocam® 15 mg capsule, taken once daily. Some patients may require up to 30 mg per day, given as one Myprocam® 30 mg capsule, taken once daily, or as two Myprocam® 15 mg capsules, taken once daily.1

Myprocam® should be used only for short periods (up to 2-3 weeks) because adequate evidence of the effectiveness of more prolonged use is not available, and because muscle spasm associated with acute, painful musculoskeletal conditions is generally of short duration, and specific therapy for longer periods is seldom warranted.1

Dosage considerations for special patient populations

Myprocam® should not be used in the elderly or in patients with impaired hepatic function.1

Evidence of efficacy

Cyclobenzaprine has been shown to improve pain, muscle spasms, functional status and global evaluation better than diazepam.2 It has also demonstrated moderate effectiveness as a skeletal muscle relaxant for short-term relief (two weeks) compared with placebo.3

The cyclobenzaprine extended-release formulation has been shown to deliver a sustained plasma cyclobenzaprine concentration over a 24-hour period, allowing for once-daily dosing.4 The once-daily cyclobenzaprine extended-release formulation 30 mg and the three-times-daily cyclobenzaprine immediate-release formulation 10 mg produced comparable systemic exposure to cyclobenzaprine. The cyclobenzaprine extended-release formulation was characterised by a single daily peak in cyclobenzaprine concentration versus three peaks per day with the cyclobenzaprine immediate-release formulation. With once-daily dosing of the cyclobenzaprine extended-release formulation, the cyclobenzaprine concentration is sustained over 24 hours. The cyclobenzaprine extended-release formulation 30 mg provides approximately twice the exposure as the cyclobenzaprine extended-release formulation 15 mg.4

A study that compared the pharmacokinetics and tolerability of single oral doses of cyclobenzaprine extended-release 15 mg and 30 mg capsules demonstrated that both exhibited qualitatively similar concentration time profiles. Both doses of the cyclobenzaprine extended-release formulation were generally well tolerated.5

Precautions

General

Myprocam® has been found to be ineffective in the treatment of spasticity associated with cerebral or spinal cord disease, or in children with cerebral palsy.16

The use of Myprocam® is contraindicated in patients with dysrhythmias, heart block conduction disturbances or congestive heart failure.1

Cyclobenzaprine is structurally related to the TCAs, such as amitriptyline and imipramine. As a result, some of the more serious CNS reactions noted with the TCAs have occurred. TCAs have cardiotoxic potential and have been reported to produce dysrhythmias, sinus tachycardia, and the prolongation of conduction time, leading to myocardial infarction and strokes.1

Myprocam® frequently causes drowsiness. Therefore, patients using it should not drive or operate machinery.1
It may also enhance the effects of alcohol, barbiturates and other CNS depressants.\(^1\)

Hyperpyretic crisis seizures and death have occurred in patients using Myprocam® concomitantly with monoamine oxidase inhibitors (MAOIs).\(^1\)

Cyclobenzaprine should be used with caution in patients with angle-closure glaucoma or with increased intraocular pressure as cyclobenzaprine has an atropine-like action.\(^2\)

**Pregnancy and lactation**

The safe use of Myprocam® has not been established in pregnancy or lactation.\(^1\)

There are no adequate or well-controlled studies on cyclobenzaprine use during human pregnancy. Effects on embryo-foetal development were not observed during animal studies. Owing to the lack of human data, and because animal studies are not always indicative of human response, cyclobenzaprine should only be used during pregnancy if it is clearly needed.\(^2\)

Lactation studies have not been conducted with cyclobenzaprine. It is not known whether or not cyclobenzaprine is excreted in human milk. Until more data are available, caution should be used when considering the use of cyclobenzaprine in lactating women as risks to the infant cannot be eliminated.\(^2\)

**Major adverse effects**

The most common side-effects which have occurred in > 3% of subjects in clinical trials include a dry mouth, dizziness, fatigue, constipation, somnolence, nausea and dyspepsia. In addition, adverse effects reported in 1-3% of patients included asthenia, having an unpleasant taste in the mouth, blurred vision, headaches, and nervousness and confusion.\(^1\)

**Drug interactions**

The following drug interactions have been reported:

- **MAOIs**: Myprocam® is contraindicated in patients using MAOIs, and for at least 14 days after the discontinuation of MAOIs as life-threatening interactions may occur.\(^1\)

- **Alcohol, barbiturates and CNS depressants**: Myprocam® may enhance the effects of alcohol, barbiturates and other CNS depressants.\(^1\)

- **Guanethidine**: Myprocam® may block the antihypertensive action of guanethidine and similarly acting compounds.\(^1\)

- **Tramadol**: Myprocam® may enhance the risk of seizures in patients taking tramadol.\(^1\)

**Cost: SEP (including VAT)**

The cost of Myprocam® is as follows:

- R330.60 per 30 extended-release capsules (15 mg).\(^6\)
- R528.96 per 30 extended-release capsules (30 mg).\(^6\)

**Patient information**

Doses must be taken at approximately the same time each day, and the duration of use should not exceed 2-3 weeks.\(^1\)

Patients using Myprocam® should not drive or operate machinery.\(^1\)

Myprocam® is not effective in treating spasticity associated with cerebral or spinal cord disease, or in children with cerebral palsy.\(^1\)

**References**