

Cabergoline

AMBER 2 (SPECIALIST INITIATION)
Traffic light classification- Amber 2
Information sheet for Primary Care Prescribers

CLINICAL INFORMATION

Key points/interactions

- **Use of cabergoline is no longer recommended unless already established on it and attempts to change to alternative therapy have failed**
- Ergot based agonists can cause pleural, pericardial and retroperitoneal fibrosis and cardiac valve damage and should not be used unless patients cannot tolerate a non-ergot alternative such as ropinirole, pramipexole or rotigotine.
- When patients are taking an ergot based agonist they should undergo 6 monthly monitoring for these complications.

Licensed Indications

Second-line therapy in patients who are intolerant or fail treatment with a non-ergot compound, as monotherapy, or as adjunctive treatment to levodopa plus dopa decarboxylase inhibitor, in the management of the signs and symptoms of Parkinson's disease.

Therapeutic Summary

As per the licensed indication.

NICE recommendations for the use of cabergoline in Parkinson's disease conclude are:

- Do not offer ergot-derived dopamine agonists as first-line treatment for Parkinson's disease.
- Only consider an ergot-derived dopamine agonist as an adjunct to levodopa for people with Parkinson's disease:
 - who have developed dyskinesia or motor fluctuations despite optimal levodopa therapy **and**
 - whose symptoms are not adequately controlled with a non-ergot-derived dopamine agonist.

Medicines Initiation

Consultant neurologist/specialist experienced in the management of PD.

Dose Regimen

- Initial dose 1 mg daily.
- Increased by 0.5-1 mg at 7 or 14-day intervals
- The dosage of concurrent levodopa may be gradually decreased, while the dosage of cabergoline is increased until the optimum balance is determined
- The recommended therapeutic dosage is 2 to 3 mg/day for patients with signs and symptoms of Parkinson's disease.
- Cabergoline should be given as a single daily dose.

Duration of treatment

Cabergoline is a treatment for chronic disease and therefore course length can be many years.

Contraindications

- Hypersensitivity to cabergoline (or any other ergot derivatives) or any of the excipients
- Pregnancy & breastfeeding
- History of fibrotic disorders
- Evidence of cardiac valvulopathy

Precautions

- History of peptic ulcer disease or GI bleeding
- History of cardiovascular disease
- Reynaud's Syndrome
- History of serious mental health disorders especially psychosis
- Acute porphyria
- Severe hepatic insufficiency (dosage adjustment required)

Monitoring

Performed by the specialist before starting treatment and at 6-month intervals thereafter.

- Chest x-ray/ lung function
- ECG
- Echocardiogram
- Renal function
- CRP
- ESR

Adverse Effects

Side Effects	Action
Abdominal pain, dyspepsia, constipation	Usually transient. If persists discuss with neurologist/PD nurse specialist [PDNS]
GI bleed	Discuss with neurologist
Nausea & vomiting	Usually transient but may be quite severe. Unless very minor, prescribe domperidone 10mg tds (or lowest effective dose- see MHRA) during dose titration; this can usually be stopped within a few weeks.
Sedation	Usually transient. Advise patients not to drive/operate machinery if affected. If persists discuss with a neurologist.
Orthostatic hypotension	Usually transient. If persists discuss with neurologist/PDNS
Light-headedness, dizziness	Usually transient. If persists discuss with neurologist/PDNS
Signs of cardiac failure	Discuss with neurologist – need to exclude valvular fibrosis and constrictive pericarditis
Pleuritis, pleural effusion, pleural fibrosis	Discuss with neurologist/PDNS
Dyspnoea, SOB, persistent cough, chest pain	Discuss with neurologist/PDNS
Leg oedema, renal insufficiency, ureteral/abdominal vascular obstruction, pain in the loin/flank, abdominal masses or tenderness that may indicate retroperitoneal fibrosis	Discuss with neurologist/PDNS
Psychotic reactions (other than hallucinations), including delusion, paranoia, delirium.	Discuss with neurologist/PDNS
'Dopamine dysregulation syndrome' Manifests as a change in behaviour, typically with an obsessional, risk-taking, sexual or financial axis.	Discuss with neurologist/PDNS
Hypersensitivity reactions including urticaria, rash, angioedema.	Discontinue and discuss with neurologist/PDNS

Clinically relevant medicine interactions and their management

Patients selected for treatment with cabergoline are almost certain to be taking concomitant medications for their Parkinson's disease. In the initial stages of cabergoline therapy, the patient should be monitored for unusual side effects or signs of potentiation of effect.

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- **Neuroleptic medicinal products and other centrally acting dopamine antagonists** e.g. Sulpiride, metoclopramide - may have an antagonistic effect if used with cabergoline. Avoid concomitant use.
- **Concomitant use of other ergot alkaloids-** avoid
- **Antihypertensives**– increased hypotensive effect
- **Memantine** - enhanced effect.
- **Macrolide antibiotics** e.g. Erythromycin - enhanced effect. Avoid concomitant use.

For further information on contraindications, precautions, adverse effects and interactions refer to the BNF or [Summary of Product Characteristics](#).

Information given to the patient

Patients (and their family members and carers) should be given information on the following:

- The risk of excessive daytime sleepiness and sudden onset of sleep and the need to exercise caution when driving or operating machinery. If affected patients should refrain from driving or operating machinery until these effects have stopped occurring.
- The increased risk of developing impulse control disorders when taking dopamine agonist therapy and that these may be concealed by the person affected. Advice should be given about whom to contact if impulse control disorders develop.
- The risk of psychotic symptoms (hallucinations and delusions) with all Parkinson's disease treatments (and the higher risk with dopamine agonists).
- It is recommended that cabergoline be taken with meals since tolerability is improved when administered with food.

Products available

Cabergoline tablets (generic and Cabaser®)

An estimate of the potential medicine costs (and any additional costs) to primary care

Strength	Size	Price	28 days 2mg/day dose
Cabergoline 500 micrograms	8 tablets	£35.50	£124.25
Cabergoline 1mg	20 tablets	£64.25	£89.95
Cabergoline 2mg	20 tablets	£73.12	£102.37

REFERENCES

British National Formulary via NICE. [Cabergoline](#). [Accessed 26/03/2021]

Summary of Product Characteristics. [Cabaser, Pfizer Ltd](#). Last updated 05/2018.[Accessed 26/03/2021]

[NICE NG71 Parkinson's Disease in adults July 2017](#). Last updated December 2020. [Accessed 26/03/2021]

MHRA Drug Safety Update: Domperidone: risks of cardiac side effects, [May 2014](#)

Version Control- Cabergoline			
Version	Author(s)	Date	Changes
2.1	Shary Walker – Specialist Interface and Formulary Pharmacist	22/04/2021	– price update – info to patient: take with meals – added version control and minor format alterations