BNSSG Shared Care Guidance

Section 1: Heading

Drug	Safinamide (Xadago®)
Amber *three months*	
Indication	Idiopathic Parkinson's disease (PD) as an add-on therapy to a stable dose of levodopa alone or in combination with other PD medicinal products in mid-to-late stage fluctuating patients.

Section 2: Treatment Schedule

Usual dose and frequency of administration	Licensed dose: Start at 50mg daily. Can be increased up to 100mg daily if partial response. Dose titration to be managed by secondary care.
Route and formulation	Oral tablets
Duration of treatment	Ongoing

Section 3: Monitoring

Baseline tests - where appropriate
Liver function tests – conducted in secondary care prior to initiation. (safinamide is contraindicated in severe hepatic impairment)
Subsequent tests - where appropriate
Nil. Ongoing review of safinamide will take place in secondary care

Section 4: Side Effects

Side effects and management	**Side effect**	**Frequency/ severity**	**Action/management**
	Dopaminergic side effects (e.g. dyskinesia)	Common	Decrease in levodopa dose may be required. Flag to secondary care consultant if problematic.
	Orthostatic hypotension, dizziness (falls risk), blurred vision, feeling faint	Common	Check lying/standing BP. Flag to secondary care consultant if problematic

	<table><tr><td>Impulse control disorders (like all anti-Parkinson's medications, safinamide may provoke impulse control disorders. Although this has not been observed in any trials of safinamide, it has been observed rarely with other MAO-B inhibitors and so patients and carers should be made aware of the potential for compulsive behaviours such as pathological gambling, hypersexuality, compulsive spending and binge eating).</td><td>Unknown</td><td>Flag to secondary care consultant if occurs.</td></tr></table> For a full list of side effects, refer to summary of product characteristics for Safinamide. The most common side effects include cataract; dizziness; drowsiness; headache; hypotension; injury; nausea and sleep disorders.
Referral back to specialist	Flag to secondary care consultant if impulse control disorder arises or in the event of any other unmanageable adverse effect Additionally, patients should be monitored for any change in condition and be referred back to the specialist as necessary, i.e. decline in symptom control, emergence of side effects, difficulty in swallowing etc.

Section 5: Other Issues
(e.g. Drug Interactions, Contra-indications, Cautions, Special Recommendations)

Issues	**Contraindications** • Hypersensitivity to the active substance or any of the excipients • Concomitant treatment with other monoamine oxidase inhibitors • Concomitant treatment with pethidine • Severe hepatic impairment • Albinism, retinal degeneration, uveitis, inherited retinopathy or severe progressive diabetic retinopathy **Cautions** • Manufacturer advises the maximum daily dose should not exceed 50 mg daily in moderate hepatic impairment **Drug interactions** • **Monoamine oxidase inhibitors** – the concomitant use of safinamide with other MAOIs is contraindicated due to risk of hypertensive crisis. At least 7 days must elapse between the discontinuation of safinamide and initiation of other MAOIs. • **Pethidine** – the concomitant use of safinamide with pethidine is contraindicated. At least 7 days must elapse between the discontinuation of safinamide and initiation of pethidine. • **Selective serotonin uptake inhibitors (SSRI)** – concomitant use requires caution, and the lowest effective dose of SSRI should be used due to risk of

	serotonin syndrome. The concomitant use of safinamide and fluoxetine or fluvoxamine should be avoided. A washout period corresponding to5 half-lives of the SSRI used (refer to the individual SmPC) previously should be considered prior to initiating treatment with safinamide. • **Other antidepressants (SNRIs / Tricyclics / Tetracyclics)** – concomitant use with safinamide requires caution due to risk of serious adverse effects. • **Sympathomimetics (e.g. decongestants such as ephedrine or pseudoephedrine)** – concomitant use requires caution. • **Dextromorphan** – concomitant use requires caution. • **BCRP substrates** (e.g. rosuvastatin, pravastatin, ciprofloxacin, methotrexate, diclofenac) – concomitant use with safinamide requires caution and monitoring. Refer to SmPC to determine whether a dose adjustment is needed. • **Certain OCT1 substrates** (e.g. metformin, aciclovir, ganciclovir) – concomitant use with safinamide requires caution as exposure to these OCT1 substrates may be increased. **Pregnancy / Breastfeeding** • Safinamide should not be given to pregnant women or women of childbearing potential not using adequate contraception. • Safinamide should not be used in breastfeeding.
Reminder to ask patient about specific problems	• Dopaminergic side effects (Impulse control disorders, hallucinations, psychosis, dyskinesia) • Symptoms of orthostatic hypotension (dizziness, light-headedness etc)

Section 6: Advice to the patient

Advice for prescribing clinician to inform patient

1. Somnolence and dizziness may occur during safinamide treatment, therefore patients should be cautioned about using hazardous machines, including motor vehicles, until they are reasonably certain that safinamide does not affect them adversely.
2. Avoid cough and cold remedies that contain sympathomimetics, and dextromethorphan
3. Postural hypotension may occur – take care on standing for the first few weeks of therapy.
4. Report any problematic side effects

Section 7: Generic principles of shared care for SECONDARY CARE

Core responsibilities

1. Initiating treatment and prescribing for the length of time specified in **section 1.**
2. Undertaking the clinical assessment and monitoring for the length of time specified in **section 1** and thereafter undertaking any ongoing monitoring as detailed in **section 3.**
3. Communicate details of the above in 1 and 2 to GP within the first month of treatment. This information should be transferred in a timely manner.
4. Refer patients to GP and provide information of further action where appropriate e.g. if blood test is due.
5. To provide advice to primary care when appropriate.
6. Review concurrent medications for potential interaction prior to initiation of drug specified in **section 1.**
7. Stopping treatment where appropriate or providing advice on when to stop.
8. Reporting adverse events to the MHRA.
9. Reminder to ask patients about particular problems see **section 5.**

Section 8: Generic principles of shared care for PRIMARY CARE

Core responsibilities

1. Responsible for taking over prescribing after the length of time specified in **section 1.**

2. Responsible for any clinical assessment and monitoring if detailed in **section 3** after the length of time specified in **section 1.**
3. Review of any new concurrent medications for potential interactions.
4. Reporting adverse events to the MHRA.
5. Refer for advice to specialist where appropriate.
6. Reminder to ask patients about particular problems see **section 5.**

Section 9: Contact Details

Name	Organisation	Telephone Number	E mail address
Consultant Neurologist	North Bristol NHS Trust	Via switchboard 0117 9505050	
Specialist Registrar	North Bristol NHS Trust	Via switchboard 0117 9505050	
Specialist Neurosciences Pharmacist	North Bristol NHS Trust	Via switchboard 0117 9505050	
Hippolyte Fraser, Frailty Pharmacist	University Hospitals Bristol and Weston NHS Trust	Via switchboard 0117 923 0000 Bleep 1145	

Section 10: Document Details

Date prepared	November 2021
Prepared by	Gemma Bray (Specialist Pharmacist)
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Section 11: Collaboration

All shared care protocols should be BNSSG wide where possible. Specialists in any one discipline are encouraged to collaborate across the health community in preparing shared care guidance. Please give details

1. North Bristol NHS Trust
2. University Hospitals Bristol and Weston NHS Trust

Section 12: References

Please list references

1. Summary of Product Characteristics Xadago 50mg film-coated tablets. Last updated 12 Oct 2021 Accessed via www.medicines.org.uk
2. British National Formulary [Online] Accessed via www.medicinescomplete.com on 23 Nov 2021