

Dexamfetamine and Lisdexamfetamine for Narcolepsy Info Sheet		
V3.0	Last reviewed: July 2023 Lisdexamfetamine added: September 2026	Review date: December 2026

Dexamfetamine and Lisdexamfetamine For Narcolepsy

Traffic light classification - AMBER 2
Information sheet for Primary Care Prescribers

Indications

Narcolepsy types 1 or 2

Note – although lisdexamfetamine is **unlicensed** for this indication it is widely used for narcolepsy across the UK and been used in Nottinghamshire for this indication for the past 10 years

Therapeutic Summary

Dexamfetamine is a CNS stimulant, and lisdexamfetamine is a pro-drug of dexamfetamine. Both are established treatments for narcolepsy and if effective and tolerated treatment is envisaged to be lifelong. Locally either would be used third line if modafinil and methylphenidate are ineffective or unsuitable.

Medicines Initiation

Dexamfetamine and Lisdexamfetamine will be initiated by a Sleep Specialist and any decision to use either will be a joint decision made in the Neuro-respiratory Sleep Clinic at NUH or the sister Respiratory Sleep Clinic at Sherwood Forest Hospitals.

Products available

Dexamfetamine sulphate is available generically as 5mg immediate release tablets. Cost for 28 x 5mg tablets is £19.85 .

Dexamfetamine (Amfexa®) costs x 30 x 5mg, 10mg, 20mg immediate release tablets =£19.89, £39.78, £79.56 respectively.

Oral solution is non formulary.

Lisdexamfetamine (Elvanse®) Cost x 28 x 20mg capsules = £54.62, 30mg capsules = £58.24
40mg capsules = £62.82, 50mg capsules = £68.60, 60mg capsules = £75.18, 70mg capsules = £83.16

Dexamfetamine and Lisdexamfetamine are Schedule 2 Controlled Drugs (CD). As such, prescriptions must conform to specific prescription writing criteria and each prescription should by default be for no longer than 30 days treatment unless the specialist feels it appropriate to prescribe a longer course for clinical or practical reasons

See [NICE Guidance NG46 Controlled drugs: safe use and management](#).

Dexamfetamine has the potential for misuse and diversion. Lisdexamfetamine has been shown in studies to have lower abuse potential as it requires conversion in the blood to become active, which prevents the rapid "high" associated with immediate-release stimulants.

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Patients should be advised to avoid alcohol which may exacerbate the central nervous system (CNS) side-effects of amfetamines.. Amfetamines can cause a significant elevation in plasma corticosteroid levels. This increase is greatest in the evening. Amfetamines may interfere with urinary steroid determinations.

Contraindications and cautions

This information does not replace the Summary of Product Characteristics (SPC) and should be read in conjunction with it. Please see [BNF](#) & [SPC](#) for comprehensive information

Contraindications

- Known hypersensitivity to the active substance, any of the excipients, or sympathomimetic amines
- Glaucoma
- Pheochromocytoma
- Certain pre-existing cardiovascular disorders constitute contraindications unless specialist cardiac advice is obtained and documented. These include; structural cardiac abnormalities and/or moderate or severe hypertension, heart failure, arterial occlusive disease, angina, haemodynamically significant congenital heart disease, cardiomyopathies, myocardial infarction, potentially life-threatening arrhythmias and channelopathies (disorders caused by the dysfunction of ion channels)
- Advanced arteriosclerosis
- Agitated states
- Concomitant use of monoamine oxidase inhibitors (MAOI) or within 14 days of MAOI treatment
- Hyperthyroidism or thyrotoxicosis.
- Severe depression, anorexia nervosa/anorexic disorders, suicidal ideation, hyperexcitability, psychotic symptoms, severe and episodic (Type I) Bipolar (affective) Disorder (that is not well-controlled), schizophrenia, psychopathic/borderline personality disorder
- Gilles de la Tourette syndrome or similar dystonias
- Cerebrovascular disorders (cerebral aneurysm, vascular abnormalities including vasculitis or stroke)
- Porphyria
- History of drug abuse or alcohol abuse
- Moderate hypertension
- Pregnancy (see [pregnancy and breast-feeding](#) section)

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Cautions:

- History of epilepsy (review dose of amfetamines or antiepileptic drugs and consider amfetamine withdrawal if seizures occur)
- Mild hypertension, history of cardiovascular disease, or concomitant medications that elevate blood pressure
- Susceptibility to angle-closure glaucoma
- Psychiatric and neuropsychiatric symptoms or disorders, including manic or psychotic symptoms, aggressive or hostile behaviour, tics, anxiety/agitation, or bipolar disorder
- Depressive symptoms; patients should be screened for risk of bipolar disorder, including psychiatric and family histories.
- Renal and hepatic insufficiency (due to lack of data).
- Family history of sudden cardiac or unexplained death or malignant arrhythmia
- Breast-feeding (see [pregnancy and breast-feeding](#) section)
- Potential for abuse, misuse, or diversion.

Dosages and route of administration

Dexamfetamine for narcolepsy will be given initially in a dose of 5 mg once a day, increasing by 5mg weekly up to a usual maintenance dose of 10-20mg per day taken in 2-4 divided doses. Occasionally, doses of up to 60mg a day may be required (in 2-4 divided doses), but only on advice of the joint Neurology-Respiratory Narcolepsy clinic.

Tablets can be halved. Dexamfetamine should not be taken too late after lunch time to avoid disturbances of sleep. Dexamfetamine may be taken with or without food. If a dose is missed, then the next scheduled dose should be taken as usual; a double dose must not be taken to make up for a missed dose.

Lisexamfetamine for narcolepsy will be given initially in a dose of 20 mg once a day in the morning, increasing by 10mg weekly up to a usual maintenance dose of 70mg per day. Doses up to 140mg have been found to be safe and may be used under direct specialist instruction in occasional cases.

Late afternoon doses are best avoided because of the potential for insomnia, except in individual cases if deemed appropriate by the specialist. Lisdexamfetamine may be taken with or without food. In the event of a missed dose, dosing should just resume the next day.

Duration of treatment

Following an adequate treatment response, treatment with medication for narcolepsy should be continued for as long as it remains clinically effective.

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Monitoring Requirements and Responsibilities

Baseline investigations and ongoing monitoring

Baseline/ pre-treatment investigations* (usually performed by the specialist)

- Medical history and cardiovascular assessment, taking into account conditions that may be contraindicated), risk of pregnancy (where applicable) and mental health concerns
- A risk assessment for substance misuse and drug diversion
- Blood pressure (BP) and heart rate (for cardiovascular status)
- Weight and ideally body mass index (BMI)
- Electrocardiogram (ECG) is only required if the patient has any of the following:
 - o History of congenital heart disease or previous cardiac surgery
 - o Sudden death in a first-degree relative under 40 years suggesting a cardiac disease
 - o Shortness of breath on exertion compared with peers
 - o Fainting on exertion or in response to fright or noise
 - o Palpitations
 - o Chest pain suggestive of cardiac origin
 - o Signs of heart failure, heart murmur or hypertension
 - o Current treatment with a medicine that may increase cardiac risk

*Baseline investigations are usually performed by specialists, but there are some cases where primary care maybe requested to carry out these, such as initial clinic consultations carried out by phone for patients living a long way from the specialist centre.

Ongoing monitoring requirements

Ongoing monitoring	Frequency
Heart rate and blood pressure and assessment for cardiovascular signs or symptoms	Baseline* then every 6 months. Also before and after each dose change recommended by specialist team** Refer to NICE guidelines for hypertension in adults
Weight and appetite	Baseline* then every 6 months. Also before and after each dose change recommended by specialist team** Consider BMI monitoring if weight has been affected
Mental health Assessment for new or worsening psychiatric and	Baseline* then every 6 months. Also before and after each dose change recommended by specialist team **.

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neurological signs or symptoms (e.g. tics, anxiety, symptoms of bipolar disorder)	
Difficulties with sleep	Every 6 months, and after any change of dose recommended by specialist team**.
Medication related side-effects	At each visit.
Risk of diversion, misuse / abuse	At each visit.
ECG	Not recommended unless there is a clinical indication (as above).
Routine blood tests	Not recommended unless there is a clinical indication.

*Baseline investigations are usually performed by specialists, but there are some cases where primary care maybe requested to carry out these, such as initial clinic consultations carried out by phone for patients living a long way from the specialist centre.

** After every change of dose: The specialist should determine the appropriate timing for this monitoring.

The specialist will determine the duration of treatment and frequency of review. After each review they will advise primary care whether treatment should be continued and if so whether it needs to be adjusted, document the ongoing dose, and confirm if the ongoing monitoring outlined above requires adjustment.

Adverse effects and other management

Any serious adverse reactions should be reported to the MHRA via the Yellow Card scheme. Visit www.mhra.gov.uk/yellowcard

For information on incidence of ADRs see relevant summaries of product characteristics

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Explicit criteria for review and discontinuation of the medicine

As well as responding to absolute values in laboratory tests, a rapid change or a consistent trend in any value should prompt caution and extra vigilance.

Situation for review	Action for primary care
Resting HR greater than 120bpm, arrhythmia/palpitations, clinically significant increase in systolic BP - Systolic blood pressure greater than the 95th percentile (or a clinically significant increase) measured on two occasions	- In context of recent dose increase, revert to previous dose and discuss with specialist for ongoing management
Patient fails to attend for physical monitoring	Arrange a further appointment in a timely manner. If follow up appointments are not attended, do not provide further prescriptions and inform specialist team.
Insomnia, sleep disturbance/nightmares, sedation, sexual dysfunction	May respond to dose reduction or timing adjustment. Give advice on sleep hygiene. Discuss with specialist team.
Reduced appetite and / or clinically significant weight change	Exclude other reasons for weight loss. May respond to dose reduction, treatment break, or change of medication. Discuss with specialist team.
Nausea, diarrhoea, abdominal cramps, constipation, dry mouth, headache, dizziness, enuresis, increased daytime urination, tics	Continue treatment unless severe. Some symptoms may be alleviated by concomitant food intake. Discuss with specialist if required
Development or worsening of psychiatric disorders (anxiety, depression, psychotic symptoms, mania, behavioural changes) NB: psychosis may occur following consumption of very high doses.	Withhold and discuss with specialist team in a timely manner. Consider referral to acute mental health team if suicidal thoughts, mania, or psychosis are present
Seizures with no previous history	Withhold and discuss with specialist team immediately. Discontinuation may be indicated.
Clear, sustained increase in seizure activity in patients with previous history of seizures	Withhold and discuss with specialist team immediately. Discontinuation may be indicated.
Symptoms of serotonin syndrome, e.g. agitation, hallucinations, coma, tachycardia, labile blood pressure, hyperthermia, hyperreflexia, incoordination, rigidity, nausea, vomiting, diarrhoea	Discontinue dexamfetamine as soon as possible. Management depends on severity; use clinical judgement but inform specialist team. Discuss with specialist team before deciding whether dexamfetamine can be re-started
Suspected drug misuse / diversion	Discuss with specialist team in a timely manner.

For a full list of side effects refer to the [BNF](#) or [SPC](#).

IF YOU ARE IN ANY DOUBT ABOUT ANY POTENTIAL ADVERSE REACTION, PLEASE CONTACT THE SPECIALIST TEAM.

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Pregnancy, paternal exposure and breastfeeding

It is the responsibility of the specialist to provide advice on the need for contraception to male and female patients on initiation and at each review, but the ongoing responsibility for providing this advice rests with both the primary care prescriber and the specialist.

Pregnancy:

Dexamfetamine / Lisdexamfetamine

Amfetamines are contraindicated during pregnancy, unless benefits clearly outweigh risks, as judged by the specialist. There is insufficient data to confirm they are safe to use. The limited data available for dexamfetamine show a risk of premature birth and reduced birth weight. The limited data available for lisdexamfetamine show an increased risk of premature birth and preeclampsia. With both drugs neonates may develop withdrawal symptoms such as dysphoria, hyperexcitability and pronounced exhaustion. Hence, female patients should be advised to use effective contraception during treatment with amfetamines. In the event of a female patient wishing to start a family whilst taking them, she should be advised to contact the specialist as soon as possible and before stopping contraception. In the event they fall pregnant on amfetamines, they should contact their specialist immediately and the specialist will reassume prescribing responsibilities for the course of the pregnancy

Further information: [USE OF THERAPEUTIC AMFETAMINES IN PREGNANCY – UKTIS](#)

Breastfeeding:

Dexamfetamine / Lisdexamfetamine

There is no published evidence for safety of amfetamines in breastfeeding. Amfetamines are excreted in human milk, therefore a risk to infants cannot be excluded. A specialist decision must be made whether to discontinue breastfeeding or to discontinue/abstain from amfetamines, taking into account the benefit of breastfeeding for the child and the benefit of therapy for the woman. High doses may interfere with lactation, although this is not confirmed in practice. If breastfeeding does take place, infants should be monitored for symptoms of CNS stimulation (e.g. decreased appetite/weight gain, sleep disturbances, irritability), accepting these may be difficult to detect.

Paternal exposure:

No evidence regarding adverse outcomes following paternal exposure was identified.

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Clinically relevant medicine interactions and their management

The following list is not exhaustive. Please see [BNF](#) or [SPC](#) for comprehensive information and recommended management.

The following medicines must not be prescribed without consultation with the specialist:

Monoamine oxidase inhibitor (MAOIs) and other sympathomimetics (e.g. rasagiline, selegiline, safinamide)	Additive hypertensive effect . Amfetamines should not be administered during or within 14 days following the administration of monoamine oxidase inhibitors (MAOI) because it can increase the release of norepinephrine and other monoamines, causing severe headaches and other signs of hypertensive crisis.
Clonidine	Increased duration of action of amfetamines, reduced antihypertensive action of clonidine

Other clinically significant interactions:

Agents that acidify urine (ammonium chloride, sodium acid phosphate, etc)	Increase urine excretion. Both decrease the half-life of amfetamine.
Alcohol	May exacerbate the CNS adverse reactions of psychoactive medicines, including amfetamines. It is therefore advisable for patients to abstain from alcohol or minimise alcohol use during treatment
Antacids:(sodium bicarbonate, etc) and urinary alkalinizing agents (e.g. acetazolamide, some thiazides)	May increase exposure to amfetamines
Anticonvulsants	Amfetamines may delay the absorption of ethosuximide, phenobarbital, primidone, and phenytoin. Dose adjustment may be required when stopping or starting amfetamines.
Antihistamines	Sedative effect may be counteracted
Antihypertensives including guanethidine	Effects may be reduced by amfetamines
Antipsychotics (chlorpromazine, haloperidol and lithium carbonate)	May reduce the effects of amfetamines
Apraclonidine	Effects decreased by amfetamines

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Beta-blockers (e.g. propranolol)	Risk of severe hypertonia. May reduce effects of amfetamines
Coumarin anticoagulants, anticonvulsants, selective serotonin reuptake inhibitors (SSRIs), serotonin and noradrenaline reuptake inhibitors (SNRIs) and tricyclic antidepressants (TCAs)	Metabolism may be inhibited by amfetamines. Dose adjustment may be required when starting or stopping amfetamines It is recognised that SSRIs and SNRIs may sometimes be required to treat the cataplexy that occurs in narcolepsy syndromes
Cytochrome P450 (CYP450) substrates, inducers or inhibitors:	Use with caution; role of CYP450 in amfetamine metabolism is not known
Gastrointestinal acidifying agents (eg ascorbic acid, fruit juices) and urinary acidifying agents (e.g. ammonium chloride, sodium acid phosphate)	May reduce exposure to amfetamines
Halogenated anaesthetics	Risk of sudden blood pressure increase during surgery. Avoid amfetamine on the day of planned surgery.
Haloperidol, lithium, phenothiazines	May reduce the effects of amfetamines
Serotonergic drugs eg bupropion, linezolid, SSRIs, tapentadol, triptans, tramadol	Risk of serotonin syndrome
TCAs and nabilone	May increase risk of cardiovascular adverse events.
Opioids	Analgesic effects may be increased and the depressant effects (e.g. respiratory depression) may be decreased by amfetamines
Ritonavir, tipranavir	May increase exposure to amfetamines
Urinary alkalizing agents (acetazolamide, some thiazides)	Decrease urinary excretion. Both groups of agents increase blood levels and efficacy of amfetamines.

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ACCESS AND CONTACT POINTS

In working hours:

Telephone: 0115 924 9924 extension 84777 (Dr Singhal's secretary)

Email: s.singhal@nhs.net

Pharmacy Medicines Information

Nottingham University Hospitals - Tel: 0115 970 9200 (patient line)

0115 924 9924 Extension 84185/81200 (**Healthcare professionals only**)

Out of Hours

Neurologist on-call contact via QMC Switchboard 0115 924 9924 (**GPs only**)

Email: s.singhal@nhs.net

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Information Given to Patient

- The specialist will provide, where relevant, written information to people with narcolepsy and their families and carers about diagnosis, assessment, support groups, self-help, psychological treatment, medicine treatment and possible side-effects.
- When prescribing lisdexamfetamine the specialist will mention that it will be prescribed “off license” for narcolepsy and what that means
- The patient must be warned to report any suspected adverse reactions to the GP for assessment and to report to their GP or specialist without delay:
 - o Any significant mood changes, such as depression, paranoia, anxiety or agitation, psychosis, mania, and suicidal ideation
 - o Any cardiovascular effects (eg. palpitations, chest pain or syncope)
 - o Any new neurological symptoms as (eg. severe headache or problems with memory of vision)
 - o Abdominal pain, malaise, jaundice or darkening of urine
 - o Skin rashes, or bruising easily Onset or increase in seizures.
- Female patients of childbearing potential must be warned to inform the specialist of any pregnancy or planned pregnancy.
- Female patients of childbearing potential must be advised to use effective and reliable contraception or to discuss this with their GP or specialist.

The patient/carers should be advised:

- to discuss any plans to stop medication with their specialist before doing so wherever possible.
- to store this medication securely at home and, if applicable, at work.
- To attend regularly for monitoring and review appointments with primary care and specialist and keep contact details up to date with both prescribers. It may not be safe to continue prescribing without regular review, and patients should be aware that their medicines could be stopped if they do not attend appointments.
- That amfetamines can affect impair cognitive function and are subject to drug driving laws, therefore patients must ensure their ability to drive is not impaired before driving. For information on 2015 legislation regarding driving whilst taking certain controlled drugs, including amfetamines, see [drugs and driving: the law](#). People who drive must inform the DVLA if their narcolepsy or medicines affect their ability to drive safely. See <https://www.gov.uk/adhd-and-driving> or <https://www.gov.uk/narcolepsy-and-driving>.
- [To avoid excess alcohol while taking amfetamines as this may make some side effects worse.](#)
- [Avoid recreational drugs which are in any case illegal because of the unpredictable effects on the brain especially when taken with amfetamines.](#)

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- Due to the risks of severe depression, over-activity, extreme fatigue as well as changes in the EEG during sleep, abrupt withdrawal after a prolonged period of intake of high doses of dexamfetamine or lisdexamfetamine should be avoided. Patients wishing to reduce their dose or stop dexamfetamine/ lisdexamfetamine treatment should discuss with their specialist before doing so.
- Dexamfetamine and Lisdexamfetamine are a schedule 2 controlled drugs. Patients may be required to prove their identity when collecting prescriptions and should store dexamfetamine/ lisdexamfetamine safely and securely. It must not be shared with anyone else. There are restrictions on travelling with controlled drugs: see <https://www.gov.uk/guidance/controlled-drugs-personal-licences>.

Driving

Patients must tell the DVLA of their narcolepsy diagnosis. Please refer to government advice on driving and narcolepsy. Patients should be warned about the potential of dexamfetamine/ lisdexamfetamine to affect their ability to drive as it is an offence to drive if impaired whilst taking it. When driving, patients should be advised to carry suitable evidence that the medicine was prescribed to treat a medical problem, and that it was taken according to the instructions given by the prescriber, or information provided with the medicine (e.g, a repeat prescription form or the medicine's patient information leaflet or clinic letter).

Patient information:

- Narcolepsy UK – dexamfetamine. <https://www.narcolepsy.org.uk/resources/dexamfetamine>
- Narcolepsy UK – lisdexamfetamine. <https://www.narcolepsy.org.uk/?s=lisdexamfetamine>
- NHS – Narcolepsy - <https://www.nhs.uk/conditions/narcolepsy/>

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References

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2. Elvanse 20mg hard capsules – Takeda UK Ltd. Summary of product characteristics [01/26] available at <https://www.medicines.org.uk/emc/product/11004/smpc> [accessed 19/6/26]
3. The Electronic Drug Tariff. Accessed via [dm+d browser \(nhsbsa.nhs.uk\)](https://www.nhs.uk/dm+d-browser) on 16/09/2026
4. BNF, Dexamfetamine, Lisdexamfetamine Accessed via <https://bnf.nice.org.uk/> on 03/07/2023
5. Hypertension in adults: diagnosis and management. NICE Clinical Guideline 136 (Feb 2026 2019). Available: <https://www.nice.org.uk/guidance/ng136>
6. DVLA. Narcolepsy and driving [accessed 03/07/2023]. Available from: <https://www.gov.uk/narcolepsy-and-driving>
7. Dexamfetamine sulfate Prescribing Support (risk minimisation materials). Accessed via <http://www.dexamfetamine-guide.co.uk/> on 03/07/23
8. Home Office. Guidance: List of most commonly encountered drugs currently controlled under the misuse of drugs legislation. Updated August 2022. Accessed via <https://www.gov.uk/government/publications/controlled-drugs-list-2/list-of-most-commonly-encountered-drugs-currently-controlled-under-the-misuse-of-drugs-legislation> on 03/07/2023
9. NICE. NG46: Controlled drugs: safe use and management. April 2016. Accessed via <https://www.nice.org.uk/guidance/ng46/> on 03/07/2023

Other relevant national guidance

- NHSE guidance – Responsibility for prescribing between primary & secondary/tertiary care. Available from <https://www.england.nhs.uk/publication/responsibility-for-prescribing-between-primary-and-secondary-tertiary-care/>
- NHSE guidance Dexamfetamine for patients within adult services . Available at [NHS England » Shared Care Protocols \(SCPs\)](#)
- General Medical Council. Good practice in prescribing and managing medicines and devices. Shared care. Available from <https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/good-practice-in-prescribing-and-managing-medicines-and-devices/shared-care>
- NICE NG197: Shared decision making. Last updated June 2021. <https://www.nice.org.uk/guidance/ng197/>.

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Version Control- Dexamfetamine and Lisdexamfetamine in Narcolepsy Amber 2 Information Sheet			
Version	Author(s)	Date	Changes
3.0	Alisha Brown, Specialist clinical pharmacist (neurology and neurosurgery), Nottingham University Hospitals, NUH Dr Sumeet Singh, Consultant Neurologist, Nottingham University Hospitals, NUH Dr Jill Baker, Respiratory Consultant, Nottingham University Hospitals, NUH	June 2026	Added in lisdexamfetamine following APC approval
2.1	Vimbayi Mushayi, Specialist Interface Medicine Optimisation Pharmacist. Nottingham and Nottinghamshire ICB	April 2026	Extended review date to December 2026 as ICB is clustering
2.0	Vimbayi Mushayi, Specialist Interface Medicine Optimisation Pharmacist. Nottingham and Nottinghamshire ICB in consultation with Dr Sumeet Singhal, Consultant Neurologist, Nottingham University Hospitals,	July 2023	- Header and version control - Added link to NICE guidance on CDs - Added additional information regarding potential misuse, alcohol use and effects on blood tests results - Updated formulations available and prices - Added administration advice - Added advice on omitted doses - Updated monitoring requirements (baseline ongoing monitoring) as per RMOC SCP - Updated adverse effects management requirements as per RMOC SCP - Updated contraindications and cautions as per RMOC SCP and moved this a couple pages up - Updated pregnancy and breastfeeding advice as per RMOC SCP - Added advice on paternal exposure

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			- Updated interactions as per RMOCP SCP and formatted in a table - Updated advice to patients and carers as per RMOCP SCP and added link to patient information - Updated contact details - Updated references - Added links to other relevant national guidance
1.1	Dr Sumeet Singhal, Consultant Neurologist, Nottingham University Hospitals, Professor Jill Baker, Respiratory Consultant, Nottingham University Hospitals, Lynne Kennell, Interface and Formulary Pharmacist, Nottinghamshire APC	January 2021	