

BNSSG Paediatric Shared Care Guidance

Please complete all sections

Section 1: Heading

Drug	Tresiba (Insulin Degludec)
Amber <i>three months</i>	
Indication	100 units/ml -Paediatric patients with Type 1 diabetes 200 units/ml- Paediatric patients with obesity with insulin resistant Type 1 diabetic patients
Speciality / Department	Paediatric Diabetes
Trust(s)	University Hospitals Bristol NHS Trust

Section 2: Treatment Schedule

Usual dose and frequency of administration (Please indicate if this is licensed or unlicensed for this age group)	Child (1 – 17 years) Paediatric patients with type 1 diabetes. Tresiba is to be used once-daily with meal-time insulin and requires subsequent individual dosage adjustments to be guided by secondary care.
Route and preferred formulation (Please indicate licensed or unlicensed preparation)	Subcutaneous injection, Once daily (preferably at the same time of day) Tresiba 100 units/mL solution for injection in pre-filled pen and solution for injection in 3ml cartridge.
Relevant dosing information	Nil
Duration of treatment	Long term therapy or until therapy failure demonstrated.

Section 3: Monitoring

Please give details of any tests that are required before or during treatment, including frequency, responsibilities (please state whether they will be undertaken in primary or secondary care), cause for adjustment and when it is required to refer back to the specialist.

Baseline tests to be done by secondary care
HbA1c is monitored in secondary care at least four times per annum in children and young people with Type 1 diabetes both before and during use of Insulin Degludec. Monitoring and interpretation of this is the ongoing responsibility of secondary care.

BNSSG Shared Care Guidance

Subsequent tests - where appropriate (Please indicate who takes responsibility for taking bloods and interpreting results. If the drug is dosed by weight please also indicate intended frequency of weight monitoring/dose adjustment)

Test	Frequency	Who by	Action/management
Nil	Nil	Nil	Nil

Patients using multiple injection regimens should understand how to adjust their insulin dose according to their carbohydrate intake. Education to do this will be done by specialists. With fixed-dose insulin regimens, the carbohydrate intake needs to be regulated, and should be distributed throughout the day to match the insulin regimen. The intake of energy and of simple and complex carbohydrates should be adequate to allow normal growth and development but obesity must be avoided.

Section 4: Side Effects

Please list the most common side effects and management. Please provide guidance on when the GP should refer back to the specialist.

Side effects and management	Side effect	Frequency/severity	Action/management
	Fat hypertrophy at injection site	Common	Rotate injection site
	Local reactions at injection site	Uncommon in paediatric practice	Manage according to severity
	Transient oedema	Rare in paediatric practice	Manage according to severity
	Hypersensitivity reactions	Rare	Refer back to secondary care
Referral back to specialist	Hypersensitivity to drug		

Section 5: Drug Interactions

Please list clinically significant drug interactions ([eMC link](#) please click here)

Significant Drug Interactions	<p>The following substances may reduce the insulin requirement: Oral antidiabetic medicinal products, GLP-1 receptor agonists, monoamine oxidase inhibitors (MAOI), beta-blockers, angiotensin converting enzyme (ACE) inhibitors, salicylates, anabolic steroids and sulfonamides.</p> <p>The following substances may increase the insulin requirement: Oral contraceptives, thiazides, glucocorticoids, thyroid hormones, sympathomimetics, growth hormone and danazol.</p> <p>Beta-blockers may mask the symptoms of hypoglycaemia.</p> <p>Octreotide/lanreotide may either increase or decrease the insulin requirement.</p> <p>Alcohol may intensify or reduce the hypoglycaemic effect of insulin.</p>
Reminder to ask patient about specific problems	Nil

Section 6: Contra-indications, Cautions and Special Recommendations

Please list

BNSSG Shared Care Guidance

Contra-indications

Hypersensitivity to the active substance or to any of the excipients listed below:

Glycerol

Metacresol

Phenol

Zinc acetate

Hydrochloric acid (for pH adjustment) Sodium hydroxide(for pH adjustment)

Cautions

When changing basal insulin to Tresiba, dose reduction of basal and bolus insulin needs to be considered on an individual basis, in order to minimise the risk of hypoglycaemia.

Section 7: Advice to the patient

Advice for prescribing clinician to inform patient

Nil

Section 8: Responsibilities for Secondary Care

Core responsibilities

1. Initiating treatment and prescribing for the first three months
2. Undertaking the clinical assessment and monitoring for the first three months.
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. blood test is due.
5. To provide advice to primary care when appropriate.
6. Review concurrent medications for potential interaction prior to initiation of Insulin Degludec (Tresiba).
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.

Other specific to drug

Nil

Section 9: Responsibilities for Primary Care

Core responsibilities

1. Responsible for taking over prescribing after the first three months
1. Responsible for the clinical assessment and monitoring after the first three months
2. Review of any new concurrent medications for potential interactions.
3. Reporting adverse events to the MHRA.
4. Refer for advice to specialist where appropriate.
5. Reminder to ask patients about particular problems see section 5.

Other specific to drug

Nil

BNSSG Shared Care Guidance

Section 10: Contact Details

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Section 11: Document Details

Date prepared	May 2018
Prepared by	Emily Knight, Interface Pharmacist with John Barton, paediatric endocrinologist.
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Section 12: Collaboration

Specialists in any one discipline are encouraged to collaborate across the health community in preparing shared care guidance. Please give details

1. Nil

Section 13: References

Please list references

1. Adult Tresiba SCP
2. SCP EMC for tresiba <https://www.medicines.org.uk/emc/product/2944/smpc>
3. BNFC online_ https://www.medicinescomplete.com/#/content/bnfc/_345229829?hspl=tresiba#DMD2193191100001108