Use of subcutaneous lenograstim in paediatric oncology patients

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Version 1
Publication date: November 2018
Review date: November 2020

Introduction

Lenograstim belongs to the cytokine group of biologically active proteins which regulate cell differentiation and cell growth, also known as recombinant human granulocyte colony stimulating factor (GCSF). It stimulates neutrophil precursor cells and induces a marked increase in peripheral blood neutrophil counts within 24 hours of administration. GCSF aims to prevent infection and neutropenic fevers caused by chemotherapy.

Patients greater than 54kg in weight or those whose lenograstim dose is greater than 263 micrograms will receive filgrastim in accordance with adult practice.

This lenograstim administration guideline is intended for use in paediatric oncology patients undergoing chemotherapy with high risk of neutropenia (i.e. primary prophylaxis).

This guideline is not intended for use in paediatric patients undergoing peripheral blood stem cell harvest who should maintain lenograstim supplies from their primary treatment centre. However, information on dosing is included should this be required in the future

Dosage

The dose of lenograstim for primary prophylaxis of neutropenia in paediatric patients undergoing chemotherapy is **5microgram/kg**

Please consult protocol as to length of duration of G-CSF – either administer till neutrophils are ≥ 1 x109/L on two consecutive days or continue for duration specified in protocol.

Lenograstim doses have been banded for ease of administration. Vials will be dispensed for administration of prescribed doses

Neutropenia Dose Banding 5 microgram/kg	**Weight (kg)**	**Dose (microgram)**	**Volume of lenograstim**
For neutropenia doses use 5 microgram/kg and use the 263 microgram/mL vial Note this table is a guide only Clinical decision and/or product availability may require changes	9.2 - 17	79	0.3mL of a 263 mcg/mL Lenograstim vial
	17.1 - 23	105	0.4mL of a 263 mcg/mL Lenograstim vial
	23.1 - 26	132	0.5mL of a 263 mcg/mL Lenograstim vial
	26.1 - 34	158	0.6mL of a 263 mcg/mL Lenograstim vial
	34.1 - 39.3	184	0.7mL of a 263 mcg/mL Lenograstim vial
	39.4 - 47.0	210	0.8mL of a 263 mcg/mL Lenograstim vial
	47.1 - 53.9	263	Use whole 263 mcg/mL Lengorastim vial
	Over 54.0 kg		Use Filgrastim*

* For children> 54kg use Filgrastim. This comes in 300 microgram and 480 microgram pre-filled syringes - prescribe a dose which is rounded up or down to this.

Harvest Dose Banding 10 microgram/kg	Weight (kg)	Dose (microgram)	Volume of lenograstim
For harvest doses use 10 microgram/kg Some doses require the use of filgrastim instead due to available syringe / vial sizes Note this table is a guide only Clinical decision and/or product availability may require changes	9.9 - 11.8	105	0.4mL of a 263 mcg/mL Lenograstim vial
	11.9 - 14.4	132	0.5mL of a 263 mcg/mL Lenograstim vial
	14.5 - 17.1	158	0.6mL of a 263 mcg/mL Lenograstim vial
	17.2 - 19.7	184	0.7mL of a 263 mcg/mL Lenograstim vial
	19.8 - 23.5	210	0.8mL of a 263 mcg/mL Lenograstim vial
	23.6 - 28.1	263	Use whole 263 mcg/mL Lengorastim vial
	28.2 - 33.2	300	Use Filgrastim
	33.3 - 42.0	368	1.4mL of a 263 mcg/mL Lenograstim vial (use 2 vials to make up dose)
	Over 42.0kg		Use Filgrastim

Presentation and Storage

Lenograstim is available as dry powder vials for reconstitution with 1ml water for injection

Lenograstim is available in two strengths: 105 microgram/mL and 263microgram/mL **NB: To minimize risk associated with different strengths of this preparation, we will only supply 263microgram vials to patients**

Lenograstim vials should be stored at room temperature. Do not store vials above + 30°C. Do not freeze

Filgrastim pre-filled syringes should be stored in a normal domestic refrigerator (2°C-8°C)

Administration

Lenograstim 263microgram/mL vials are for single dose use only

Subcutaneous administration is the preferred route of administration

If on 10mcg/kg for pre-harvest doses cannot be given by insuflon

Preparation of the reconstituted lenograstim solution

Using a graduated syringe fitted with a needle, aseptically withdraw the entire extractable contents of one ampoule of solvent for lenograstim. Inject the entire contents of the syringe into the corresponding lenograstim vial

Agitate gently until completely dissolved. Do not shake vigorously. The reconstituted parenteral solution appears transparent and free of particles

After reconstitution or dilution, an immediate use is recommended. However, in-use stability of the reconstituted/diluted medicinal product has been demonstrated for 24 hours at 2°C - 8°C (in a refrigerator)

Preparation for the subcutaneous administration

Keeping the needle and the syringe attached to the vial, withdraw the required volume of reconstituted solution from the vial. Replace the needle used for reconstitution and fit the syringe with an appropriate needle for subcutaneous injection.

Administer immediately by sub-cutaneous injection

Side Effects

The most common side effects with G-CSF include nausea and vomiting, bone pain that can be treated with pain relief medicine, red itchy skin at the site of S/C injection, headache, constipation, diarrhoea and tiredness. The prescriber should be contacted if bone pain persists despite analgesics. Side effects usually improve after G-CSF treatment stops.

Less common side effects include fever and chills, swollen ankles or breathlessness due to fluid retention. Report fever or any sign of infection immediately to the medical team at the Shared Care Hospital in line with treatment pathways for febrile neutropenia.

Very common (≥ 10%)
Elevated LDH, leucocytosis, thrombocytopenia, headache, asthenia, musculoskeletal pain, elevated AST/ALT, elevated Alkaline-phosphatase

Common (≥ 1/100 to < 1/10)
Enlarged spleen size, abdominal pain, pain, injection-site reaction

Uncommon (≥ 1/1000 to ≤ 1/100)
Capillary leak syndrome

Rare (≥ 1/10000 to ≤ 1/1000)
Aortitis, pulmonary oedema, interstitial pneumonia, pulmonary infiltrates, pulmonary fibrosis

Very rare (≤ 1/10000)
Splenic rupture, cutaneous vasculitis, sweet's syndrome, erythema nodosum, pyoderma gangrenosum, lyell's syndrome, allergic reaction, anaphylactic shock

Not known (cannot be estimated from the available data)
Glomerulonephritis

Please refer to the summary of product characteristics (SPC) for further information

Drug Interactions

In view of the sensitivity of rapidly dividing myeloid cells to cytotoxic chemotherapy, the use of lenograstim is not recommended from 24 hours before until 24 hours after chemotherapy ends

Possible interactions with other haematopoietic growth factors and cytokines have yet to be investigated in clinical trials

Disposal of waste and Spillage

As per Trust policy for non-cytotoxic waste

References:

- Granocyte 34 million IU/mL, powder and solvent for solution for injection/infusion. Summary of Product characteristics, UK. Updated 12 July 2018. **https://www.medicines.org.uk/emc/product/7807/smpc**
- Lenograstim administration policy for home administration or shared care hospital, Royal Marsden Hospital
- Policy for safe administration of GCSF injection in the community setting or paediatric oncology shared care unit (POSCU) for children and young people, Royal Marsden Hospital