

Immune Treatment Programme Drugs' Common Side Effects Patient Information Leaflet

The prescribing doctor believes that this medicine would work well for your condition even though it is licensed for a different condition – when a medicine is used for a condition not stated in its licence, it is said to be "unlicensed"

Granulocyte-Colony Stimulating Factor (G-CSF)

G-CSF is a cytokine (molecules that aid cell to cell communication in immune responses and stimulate the movement of cells towards sites of inflammation) which stimulates neutrophilic granulocyte proliferation.

Indication: Found to possibly reduce anti-miscarriage activity. Based on research trials, G-CSF has been shown to be safe and tolerated well for mothers throughout pregnancies and for new-borns without signs of abnormality. No noticeable side effects were reported.

Studies: In certain studies G-CSF was used in a series of women with unexplained recurrent miscarriage in whom previous treatment with other therapies failed. It showed G-CSF effective in recurrent miscarriages.

In one particular study, 29 out of 35 women delivered a healthy baby whereas in the placebo group this figure was 16 out of 33.

However, further studies are needed to confirm the effectiveness of this treatment in women with unexplained recurrent miscarriage.

Dose: 300mcg Injection for intramuscular use. Your doctor will provide instructions on the timing of the injections in line with your treatment plan.

Side effects: Bone pain (you may have some discomfort or a dull ache in the bones of your pelvis, back, arms or legs), red and/or itchy skin (your skin may become red and itchy around the area in which the injection of G-CSF is given), fever and chills (simple painkillers, such as paracetamol can help to reduce your temperature and prevent chills, fluid retention (this may lead to swelling of the ankles or breathlessness).

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Storing G-CSF

Filgrastim and pegylated filgrastim should be stored in the fridge.

NB: The dosage of GCS-F is calculated on weight therefore the dose may be taken more frequently.

G-CSF in a Natural Cycle

- One vial to be taken 300mcg of G-CSF subcutaneous on day 6 after ovulation.
- Then do a pregnancy test 5 days after the injection which is equivalent to 11 days after ovulation. If the next pregnancy test is negative you do not undertake further injections until day 6 post ovulation of your next cycle.
- If pregnancy test is positive, you will need to take one vial 300mcg of G-CSF subcutaneous once every 3 days until 10 weeks gestation.

G-CSF in assisted conception

- 5 days prior to embryo transfer take 300mcg of G-CSF subcutaneous.
- A further 300mcg injection to be taken 3 days after initial injection.
- At positive pregnancy test you need to take 1 vial 300mcg G-CSF subcutaneous once every 3 days until 10 weeks gestation.
- If pregnancy test is negative you do not need to undertake further G-CSF injections.

Reference:

- Zeidler.c. Grote.U. et al. Haemalogica, 2014 Aug, 99(8) 1395-1402
 Outcome and Management of pregnancies in severe Chronic Neutropenia patients by the EU branch of the Severe Chronic Neutropenia International Registry.
- Scarpellini. F and Sbracia. M. Human Reproduction, Vol 24, No11 Pp 2703-2708 2009
 Use of Granulocyte Colony-Stimulating Factor for the treatment of unexplained
 recurrent miscarriage a randomised trial.
- For further information please see the "Response" Trial. www.responseresearchstudy.co.uk