INTERIM DOCUMENT

Facts About Neupogen®

When a person has received a very high dose of radiation, destruction of the bone marrow, potentially resulting in uncontrolled bleeding and infection, is a major concern. To help the recovery of the bone marrow, growth factors that stimulate the blood cells to multiply can be used. Filgrastim (trade name Neupogen®), is a drug that was approved for use by the FDA in 1991 for cancer patients with bone marrow damage due to chemotherapy or radiotherapy. Treated patients have had fewer infections, less need for intravenous antibiotics, and shortened hospital stays than those who did not receive the drug. Neupogen may also be useful for patients who have bone marrow damage from accidental exposures to high doses of radiation and it is expected to provide similar benefits.

What Neupogen Is

Filgrastim (trade name Neupogen®) is a human granulocyte colony stimulating factor (G-CSF) produced by recombinant DNA technology. It is a specific type of cytokine that stimulates the growth of white blood cells.

What Cytokines Are

Cytokines are hormone-like proteins that act as communicators between cells. They can relay messages between cells, telling them to grow, stop growing, move to a trouble spot, or otherwise change the cell's function. Neupogen® is a specific type of cytokine that stimulates the growth of white blood cells.

Use of Neupogen® to Treat Persons Accidentally Exposed to High Doses of Radiation

Just like a cancer patient who has received chemotherapy or radiation therapy, a person who has received a high dose of radiation may experience bone marrow destruction, possibly resulting in uncontrolled bleeding and infection. Since Neupogen® has been used successfully for cancer patients to stimulate the growth of the white blood cells, making them less vulnerable to infections, it is expected to help patients who have bone marrow damage from very high doses of radiation in much the same way.

How Neupogen® Works

Patients who receive very high doses of radiation often are left with very few white blood cells. The patients' own bone marrow will eventually create new blood cells, but this is a slow process. And until the white blood cell counts rise sufficiently, the patients are at a high risk of death from infection. Neupogen® can speed up the process of white blood cell creation, reducing the time that the patient is vulnerable to infection.

Who Can Take Neupogen

People may be prescribed Neupogen® following chemotherapy or radiation therapy to assist in their recovery. Also, people may be prescribed Neupogen® following a high dose of radiation from a radiation emergency.

Neupogen® is safe for most adults, but should not be taken by people who have known hypersensitivity to *E. coli*-derived proteins, filgrastim, or any component of filgrastim. Children and pregnant women should take Neupogen® with caution. It is not known if Neupogen® is excreted in human milk, so breastfeeding women should take Neupogen® with caution as well.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION
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Side Effects of Neupogen®

The possible side effects of Neupogen® include fever, diarrhea, skin rash and weakness. The most common side effect is mild to moderate bone pain.

How Neupogen® Is Given

Neupogen® is given by injection under the skin or through intravenous infusion.

What the Treatment Plan Is

The treatment plan is to give 5 micrograms per kilogram of patient weight (mcg/kg) of G-CSF filgrastim (Neupogen®) daily for up to 2 weeks, either by injection or intravenous infusion.

Where You Can Get More Information

More detailed information on cytokines can be found at the FDA web site, at:
http://www.fda.gov/bbs/topics/CONSUMER/CON0291f.html

More detailed information on Neupogen® can be found at:
http://www.accessdata.fda.gov/scripts/cder/onctools/labels.cfm?GN=Filgrastim

You can also call the CDC Public Response line at 1-800-311-3435 or visit the web site at http://www.cdc.gov/netinfo.htm to request more information.