Canadian Adverse Drug Reaction Monitoring Program

SUSPECTED ADVERSE DRUG REACTION MONITORING

Patient Reporting Project

Parents: Please fill in one form for each child.

Notice to potential reporters of suspected adverse reaction (side effect);
In order for NSAI to process this report as an Adverse Drug Reaction,the following key information is needed:
⇑An identifiable patient (#1 &/or #2) ⇑ A suspected reaction (#7) ⇑ A suspected drug (#8) ⇑ An identifiable reporter (#17)

1. Patient initials:_____(first)_____(last)
2. Date of birth:_____(day)____(month)_____(year)
3. ☐ Male ☐ Female
4. Weight:_____(lbs/kg) 5. Height:_____(feet/cm)
6. What is your race:_____

7. Describe the **side effect(s)** that you had in the spaces below:	This effect started on:
Most Serious side effect: Did the side effect go away on it's own ☐Yes ☐No ☐Don't know/can't remember Did you think the side effect was life threatening? ☐Yes ☐No ☐Don't know/can't remember	_____/_____/_____ day month year And lasted for (give #): _____hours _____days _____months
Unexpected side effect: Did the side effect go away on it's own: ☐Yes ☐No ☐Don't know/can't remember Did you think the side effect was life threatening? ☐Yes ☐No ☐Don't know/can't remember	_____/_____/_____ day month year And lasted for (give #): _____hours _____days _____months
Other side effect: Did the side effect go away on it's own: ☐Yes ☐No ☐Don't know/can't remember Did you think the side effect was life threatening? ☐Yes ☐No ☐Don't know/can't remember	_____/_____/_____ day month year And lasted for (give #): _____hours _____days _____months

8. List the drug(s) that you suspect/think caused your side effect(s):

_____

_____

9. What other medication(s) were you taking **at the same time** as the drugs? (Listed above)

☐ over-the-counter ☐ prescription ☐ non-prescription drugs: (please list)

_____

☐ complementary medicines or natural health products, such as herbals, vitamins, minerals: (please list)

_____

10. Do you think, or were you told by a health professional that there was an interaction between 2 drugs?

☐ No ☐ Not sure ☐ Yes - which ones:

_____

_____

11. The next four questions ask you about the outcome/result of your side effect(s) as described in question #7:

a) Were you hospitalized because of the side effect(s)? ☐ Yes ☐ No

b) Were you left with a disability? (Significant, persistent or permanent change, impairment, damage or disruption in body function/structure, physical activities and/or quality of life)

☐ No ☐ Yes - explain:

_____

_____

c) Did you need surgery/treatment to prevent damage or permanent disability? ☐ Yes ☐ No

d) Did you receive any other medications to treat the side effect? ☐ Yes ☐ No

12. Have you ever received a bood transfusion, or received Immunoglobulin Preparations, or other Blood Products? ☐Yes ☐No

13. Have you ever had/do you currently experience any of these adverse reactions while taking Neupogen (filgrastim, G-CSF)

☐nausea/vomiting	☐skeletal pain(bone pain)	☐alopecia	☐diarrhea
☐neutropenic fever	☐mucositis	☐fever	☐fatigue
☐anorexia	☐dyspnea	☐headache	☐cough
☐skin rash	☐chest pain	☐sore throat	☐generalized weakness
☐stomatitis	☐constipation	☐pain (unspecified)	
☐blood pressure problems	☐palpable splenomegaly	☐osteoporosis	☐skin disorder
☐injection site reaction	☐anemia	☐thrombocytopenia	
☐skin ulcers	☐vascilitis	☐myocardial infarctions	
☐arrhythmias	☐other		

comments:_____

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14. Have you ever had/do you currently have:
    - ☐ bone marrow test abnormality (cytogenetic abnormalities-including monosomy 7, ras oncogene mutations, G-CSF-R mutations, etc.)
    - ☐ (AML) leukemia
    - ☐ a bone marrow transplant

    Comments:

_____

_____

_____

15. Do you think the disorder Neutropenia (not the drugs) may have caused the side effect you had?
    ☐Yes ☐No ☐Not Sure

16a.In approximately what **year** and **month** were you diagnosed with Neutropenia:_____.

16b.Type of Neutropenia:

☐cyclic	☐idiopathic or chronic idiopathic
☐autoimmune	☐autoimmune Leukopenia
☐contenital/or Kostmann's syndrome	☐autoimmune Granulocytopenia
☐Schwachman's-Diamond syndrome	☐myelokatlexis syndrome
☐not sure	

16c.Have you been told by your physician that you are:

☐severe chronic neutropenia	-neutropenia less than 0.5 x 109/L
☐moderate or chronic benign neutropenia	-neutropenia 0.5-1.0 x 109/L
☐mild neutropenia	-neutropenia 1.0-1.8 x 109/L

Any information related to the reporter and patient identifiers is kept confidential to the fullest extent of the law

To respect patient confidentiality, Dr. Melvin Freedman has graciously consented to receive and analyze information. A follow up report, without any names, addresses, etc., will be forwarded to N.S.A.I. and possibly Health Canada Therapeutic Products Program and/or other post-approval drug surveillance systems in other countries.

Return Address: Dr. Melvin Freedman, chief haematologist
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Submission of a report does not constitute an admission that the product caused or contributed to the adverse event.