

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Stemgen®. It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Stemgen® against the benefits it is expected to have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist. Read this leaflet carefully before you start Stemgen® and keep it with the medicine. You may need to read it again.

What Stemgen® is used for

Stemgen® is a man-made form of a naturally-occurring substance which stimulates the growth of certain blood cells called progenitor cells. These cells are the very early forms of blood cells that mature to become red blood cells, white blood cells and platelets.

Stemgen® is given with another medicine called Neupogen® as an injection under the skin. This increases the number of progenitor cells in the blood (peripheral blood progenitor cells, PBPCs). These cells are then collected from the blood, stored and given back to you after chemotherapy. This procedure is called a PBPC transplant and helps recovery of blood cells after treatment.

There is limited experience with Stemgen® in children. Your doctor will discuss the risks and benefits of using Stemgen® in children.

If you have any questions about using Stemgen® ask your doctor.

Before you receive Stemgen®

You must tell your doctor if:

1. **You have ever suffered from asthma or an allergic reaction to any other medicines or any other substances such as foods, preservatives or dyes.**

Symptoms of an allergic reaction may include:

- swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing
- asthma, wheezing, shortness of breath
- itching, skin rash or hives
- fainting

2. **You have kidney problems.**
3. **You have any type of cancer or tumour, including cancers of the blood, lung or skin (melanoma).**
4. **You are pregnant or breastfeeding or intend to become pregnant or breastfeed.**
Like most medicines, Stemgen® is not recommended during pregnancy or while breastfeeding. Your doctor will discuss the risks and benefits of using Stemgen®.
5. **You have any other medical condition.**

If you have not told your doctor about these things, tell him/her before you start using Stemgen®.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines you buy without a prescription from a pharmacy, supermarket or health food shop.

Only limited information is available on possible interactions between Stemgen® and other medicines.

Before you start Stemgen®

When you must not use Stemgen®

Do not use Stemgen® if:

1. **You have an allergy to Stemgen®, any product prepared using the bacteria *E. coli* or any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction may include:

- swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing
- asthma, wheezing, shortness of breath
- itching, skin rash or hives
- fainting.

2. **You have had chemotherapy or radiotherapy within the last 24 hours or are due to have it in the next 24 hours.**

It may not be safe to use Stemgen® in the period 24 hours before to 24 hours after chemotherapy and radiotherapy.

3. **You have not started using the antihistamines prescribed for you by your doctor within the last 12 to 24 hours or you have not used the inhaler prescribed for you by your doctor in the last 30 to 60 minutes.**

If you do not use these medicines before starting Stemgen®, you may have a serious allergic reaction to it. See "While you are using Stemgen®" below.

4. **The expiry date printed on the pack has passed.**
5. **The powder in the bottle is discoloured or the solution, after it is mixed, is not clear and colourless.**
6. **The packaging is torn or shows signs of tampering.**

While you are using Stemgen®

Things you must do

Make sure you start taking the antihistamines prescribed by your doctor 12 to 24 hours before you receive Stemgen® and continue until 2 days after the last injection of Stemgen®. Follow the doctor's directions for the antihistamines and make sure that you take a dose 60 to 90 minutes before each dose of Stemgen®. You must use the inhaler 30 to 60 minutes before each dose of Stemgen®.

If you do not use these medicines, the risk of having an allergic reaction to Stemgen® is increased.

If you miss a dose of antihistamine, take it as soon as you remember then go back to your normal schedule. Tell your doctor about this missed dose.

How Stemgen® is used

How Stemgen® is injected

Your doctor or nurse will give the injection.

Stemgen® is only given by an injection under the skin. This is called a subcutaneous injection.

If it is accidentally given into a vein, a serious allergic reaction may occur. Your doctor or nurse will have appropriate medication and/or equipment on hand to reverse this reaction.

You will be monitored for an hour after the injection to make sure you do not suffer an allergic reaction.

Stemgen® should not be given without Neupogen®. However, Stemgen® and Neupogen® must be given as separate injections at different sites.

How much is injected

The usual dose is 20 micrograms of Stemgen® for every kilogram of body weight. Your doctor or nurse will determine exactly how much to inject.

Stemgen® is supplied as a white powder in small glass vials. It is prepared for use by dissolving the powder in 1.2 mL of sterile Water for Injections.

After Stemgen® powder has been dissolved, use the solution as soon as possible (within 1 hour). If the dissolved Stemgen® solution will not be used within 1 hour, it can be stored for up to 24 hours in the refrigerator, between 2°C and 8°C. Do not freeze dissolved Stemgen® solution.

When it is injected

The doctor or nurse will give you the Stemgen® injection at about the same time each day. Your doctor will decide when to start using Stemgen® and when to stop.

Daily injections will be required for at least 5 days, depending on the response of your blood cells.

If an injection is missed

If a Stemgen® injection is missed, tell your doctor, pharmacist or nurse as soon as possible.

If it is still the same day, the missed Stemgen® injection can be given by your doctor or nurse when remembered.

If a complete day is missed, just continue with your normal schedule.

Do not try to make up for a missed Stemgen® injection by taking more than one dose at a time.

If too much Stemgen® is injected (overdose) or it is injected into a vein

Immediately telephone your doctor or Poisons Information Centre for advice (in Australia-telephone 13 11 26; in New Zealand-03 4747 000) or go to Emergency at your nearest hospital if you think you have received too much Stemgen® or it has been injected into a vein. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

If too much Stemgen® has been injected or it goes into a vein, you may have a serious allergic reaction.

Side effects

Check with your doctor as soon as possible if you have any problems while using Stemgen®, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

Like other medicines, Stemgen® can cause some side effects. Some side effects may be serious and need medical attention. Other side effects are minor and likely to be temporary.

Ask your doctor or pharmacist any questions you may have.

A small number of people (about 3 in 100) experience a generalised allergic reaction.

Tell your doctor immediately or go to Emergency at your nearest hospital if you notice any of the following. Do not have another dose of Stemgen®.

- swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing
- asthma, wheezing, shortness of breath
- sudden or severe itching at a place other than the injection site, widespread skin rash or hives
- tight throat or hoarseness
- dizziness or lightheadedness

These symptoms may be serious and could possibly become life-threatening if not treated promptly.

Nearly all people experience redness, itching or swelling at the site of injection of Stemgen® and many people experience bone pain.

Some people have experienced:

- redness, itching, a hives-like rash at the injection site
- darkening of the skin at the injection site which may last several weeks or months
- itching, rash or hives on other parts of the body
- numbness, headache
- feeling sick (nausea)
- fast heart beat
- mild cough, sore throat

Other side effects not listed above may occur in some people.

Tell your doctor if you notice anything that worries you or that is making you feel unwell, even if it is not on this list.

After using Stemgen®

Storage

Stemgen® and needles should be kept where young children cannot reach them.

A locked cupboard at least 1½ metres above the ground is a good place to store the syringes, needles and puncture-proof disposal container.

Stemgen® should be kept in a refrigerator between 2° and 8°C. It should not be frozen or left in direct sunlight.

Disposal

The doctor or nurse will place all used syringes and needles into a special, puncture-proof disposal container.

Your doctor or pharmacist will dispose of the used Stemgen® vial.

Product description

What it looks like

Stemgen® is supplied as a white powder or "cake" in small glass vials.

Ingredients

Active ingredient

The active ingredient in Stemgen® is ancestim.

The pack contains 3-single use vials, each containing 1.875 mg ancestim. The box has a pink stripe and purple dot.

Other ingredients

- mannitol 4.5%
- sucrose 0.5%
- glutamic acid 5 mM
- histidine 10 mM

Stemgen® is free from preservatives.

Supplier

Stemgen® is supplied in Australia by:

Invida Australia Pty Ltd
Level 8, 67 Albert Avenue
CHATSWOOD NSW 2067
ABN 62 116 935 758

Australian Registration Number:

Stemgen® 1.875mg - AUST R 98715

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