

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PATIENT MEDICATION INFORMATION

cutaquir[®]

Immunoglobulin (human) subcutaneous

16.5% Solution for injection (165 mg/mL)

Read this carefully before you start taking cutaquir[®] and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about cutaquir[®].

Serious Warnings and Precautions

- Rarely, human normal immunoglobulin can induce a fall in blood pressure with anaphylactic reaction, even in patients who had tolerated previous treatment with human normal immunoglobulin. Suspicion of allergic or anaphylactic type reactions requires immediate discontinuation of the injection. In case of shock, standard medical treatment should be administered.
- There is clinical evidence of an association between the administration of immunoglobulins and thromboembolic events such as myocardial infarction, stroke, pulmonary embolism and deep vein thrombosis. Therefore, caution should be exercised when prescribing and administering immunoglobulins.
- Risk factors for thromboembolic events include: advanced age, use of estrogens, in-dwelling central vascular catheters, history of vascular disease or thrombotic episodes, acquired or inherited hypercoagulable states, prolonged periods of immobilization, severe hypovolemia, diseases which increase blood viscosity and cardiovascular risk factors (including obesity, hypertension, diabetes mellitus, history of atherosclerosis and/or impaired cardiac output).
- Thrombosis may occur even in the absence of known risk factors.

What is cutaquir[®] used for?

cutaquir[®] is used to treat primary immunodeficiency (PID) and secondary immunodeficiency (SID) in people who need immune globulin replacement therapy. People with PID and SID can get many infections. cutaquir[®] helps to lower the number of infections.

How does cutaquir[®] work?

Normally, our immune system protects us against infections by recognizing potentially harmful bacteria and viruses that enter our body every day. In response, the immune system produces

special proteins called antibodies (Immune Globulins or Immunoglobulins) that fight these infective agents. When our immune system is not working properly, it is unable to produce these antibodies.

This product can help prevent infections by providing a protective role of these antibodies in patients who suffer from a poorly functioning immune system.

What are the ingredients in cutaquir®?

Medicinal ingredients: Human normal immunoglobulin G (IgG)

Non-medicinal ingredients: Maltose, Polysorbate 80, Water for Injections

cutaquir® comes in the following dosage forms:

cutaquir® is a 165 mg/mL solution for subcutaneous injection, provided in the following dosage forms:

Size	Grams Protein
6 mL	1
10 mL	1.65
12 mL	2
20 mL	3.3
24 mL	4
48 mL	8

Do not use cutaquir® if:

- You are hypersensitive to this drug or to any ingredient in the formulation or component of the container.
- You have experienced anaphylactic or severe systemic reactions to the administration of human normal immunoglobulin or to components of cutaquir®

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take cutaquir®. Talk about any health conditions or problems you may have, including:

- If you have a history of allergic or other reactions to immunoglobulins.
- If you have a history of (cardio)vascular disease.
- If you have a history of thromboembolic events (e.g. deep vein thrombosis, blockage of blood vessels, blood clots, stroke).
- If you have hypertension or diabetes mellitus.
- If you have a kidney disease.
- If you have been previously advised that you have IgA deficiency.
- If you are pregnant or think you may be pregnant.

- If you are nursing.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with cutaquig[®]:

cutaquig[®] should not be mixed with other products.

The passive transfer of antibodies by cutaquig[®] may interfere with the response to live virus vaccinations.

cutaquig[®] contains maltose which can be misinterpreted as glucose by certain types of blood glucose testing systems. Due to the potential for falsely elevated glucose readings, only testing systems that are glucose-specific should be used to test or monitor blood glucose levels in diabetic patients.

How to take cutaquig[®]:

Detailed patient handling instructions for administration of cutaquig[®]

cutaquig[®] is for subcutaneous administration only. Do not inject into a blood vessel.

Only use cutaquig[®] at home once you have been properly instructed and trained by your healthcare professional.

Follow the administration guidance below step by step and use aseptic/sterile technique when administering cutaquig[®]. Use gloves if you have been told to do so when preparing the infusion.

1. Prepare the necessary number of cutaquig[®] vials

- If stored in the fridge put the vials at room temperature at least 90 minutes prior to infusion.
- Do not heat the vials or put them into the microwave.
- Do not shake the vials to avoid foaming.

2. Getting ready for infusion

- Choose and prepare a clean work area using antiseptic wipes or disinfecting solution (Figure 1).



Figure 1

- Gather your infusion equipment:
 - Infusion pump (optional) & compatible syringe(s)
 - Needle (for drawing up product from the vial)
 - Infusion set
 - Infusion tubing and Y-connector (if required)
 - Alcohol & alcohol wipes/antiseptic wipes
 - Gauze or transparent dressing and tape
 - Sharps container
 - Treatment diary and pen
- Wash your hands thoroughly and let them dry (Figure 2). Use disinfectant gel as has been shown to you during training.



Figure 2

- If necessary program the pump according to the user manual and as you have been shown during the training by your healthcare professional.

3. Checking & opening the vials

- Inspect each vial carefully for:
 - Correct labelled dose based on your prescription,
 - Check the appearance of the solution (it should be clear and colorless to pale yellow or light brown),

- Make sure the protective cap has not been broken or is missing,
 - Check the expiry date and batch number.
 - Do not use the solution if it is cloudy or contains particles.
- Remove the protective cap.
 - Disinfect the rubber stopper by using an antiseptic wipe and allow it to dry (Figure 3).



Figure 3

4. Preparing and filling the syringe

- Open sterile syringe and needle.
- Attach the needle to the syringe with a screw action.
- Draw back on the plunger to fill the syringe with air which should be roughly equal to the amount of solution needed from the vial.
- Insert the needle into the vial and turn the vial upside down. Inject air - ensuring the tip of the needle is not in the solution to avoid foaming.
- Next, making sure the needle remains always in the solution, slowly draw up the cutaquig[®] (Figure 4).

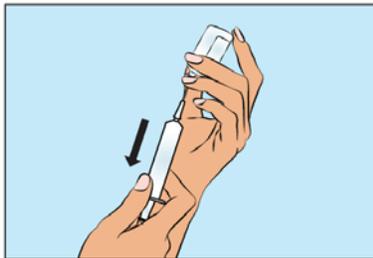


Figure 4

- Withdraw the needle from the vial.
- This procedure might need to be repeated if you need multiple vials for the calculated dose.
- When finished remove the needle and dispose it into the sharps bin.
- Immediately proceed to the next step as the IgG solution should be used promptly.

5. Preparing the infusion pump and tubing (optional)

- Follow the manufacturer's instructions for preparing the infusion pump.
- To prime the administration tubing attach filled syringe to the infusion tubing and gently push the plunger to fill the tubing with cutaquig[®] and to remove all air. (Figure 5).

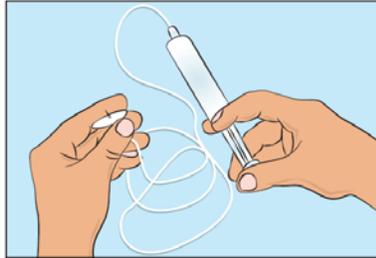


Figure 5

6. Deciding on infusion sites and inserting the infusion needle(s)

- cutaquig[®] can be infused in the following areas: abdomen, thigh, upper arm, and/or upper leg/hip area (Figure 6).

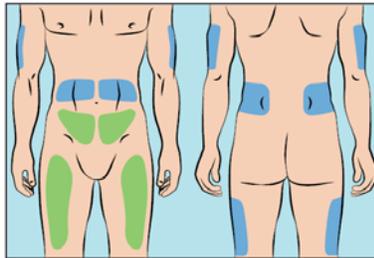


Figure 6

- The infusion sites should be at least 5 cm apart.
- Use different infusions sites than you used for the previous administration.
- Avoid inserting the needle into scars, tattoos, stretch marks or injured/inflamed/red skin areas.
- Clean your skin at your selected infusion site(s) with an antiseptic skin wipe and let the skin dry.

- Pinch the skin between your thumb and forefinger around the injection site (Figure 7), carefully remove the needle cover and insert the needle into the skin (Figure 8). The angle of the needle will depend on the type of infusion set being used.

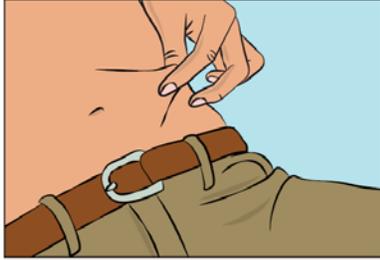


Figure 7

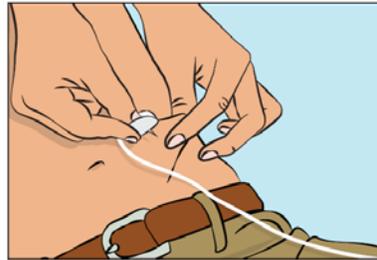


Figure 8

7. Checking the infusion

- The solution should not be infused into a blood vessel.
- Secure the needle in place by applying sterile gauze and tape or a transparent dressing (Figure 9).

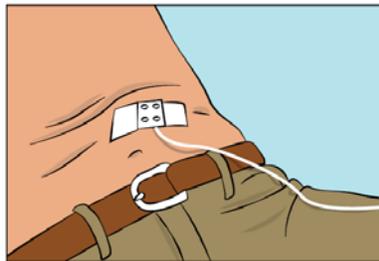


Figure 9

8. Starting the infusion

- Start the infusion. If an infusion pump is used for administration, follow the manufacturer's instructions.

9. Recording the infusion

- On each vial of cutaquig[®] you will find a peel off label giving the batch number details. Stick this label in your patient's treatment diary or infusion log book. Record details of the dose, date, time, infusion site location and any infections, side effects or other comments in connection with this infusion.

10. After the infusion is complete

- Gently remove the needle(s) and immediately place into the sharps bin.
- If necessary press a small piece of gauze on the needle site and apply a dressing.

- Throw away all used disposable supplies as well as any unused product and the empty vial(s) as recommended by your healthcare professional and according to local requirements.
- Tidy up and securely store all the reusable equipment (e.g. pump) until the next infusion.

Usual dose:

Your doctor or healthcare professional will individualize your dose based on your clinical response to cutaquirg[®] therapy and on serum immunoglobulin G (IgG) trough levels.

Doses may be adjusted over time to achieve the desired clinical response and serum IgG levels.

Overdose:

Consequences of an overdose are not known with cutaquirg[®].

If you think you have taken too much cutaquirg[®], contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

Inform your doctor or health care professional if you missed a dose. A missed dose should be administered as soon as possible to ensure an adequate IgG serum level.

What are possible side effects from using cutaquirg[®]?

These are not all the possible side effects you may feel when taking cutaquirg[®]. If you experience any side effects not listed here, contact your healthcare professional. Please also see WARNINGS AND PRECAUTIONS.

No related serious adverse drug reactions were observed in subjects treated with cutaquirg[®] during the clinical studies evaluating its safety.

Injection site reactions (such as redness, swelling, itching, pain, tenderness, and feeling of warmth) are a common occurrence with SCIG infusions and this side effect is expected. Overall the adverse events were mild or moderate in intensity.

Other side effects have also been observed less frequently: fever, headache, abdominal pain, vomiting, fatigue, and muscle pain.

Tell your doctor right away or go to the emergency room if you have hives, trouble breathing, wheezing, dizziness, or fainting. These could be signs of a bad allergic reaction.

Tell your doctor right away if you have any of the following symptoms. They could be signs of a serious problem.

- Severe headache with nausea, vomiting, neck stiffness, fever, and sensitivity to light. These could be signs of a brain swelling called meningitis.
- Pain, swelling, warmth, redness, or a lump in your legs or arms, unexplained shortness of breath, chest pain or discomfort that worsens on deep breathing, unexplained rapid pulse, numbness or weakness on one side of the body, sudden confusion, or trouble speaking. These could be signs of a blood clot.
- Fever over 100°F (37.8°C). This could be a sign of an infection.

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

3 ways to report:

- Online at [MedEffect](#);
- By calling 1-866-234-2345 (toll-free);
- By completing a Patient Side Effect Reporting Form and sending it by:
 - Fax to 1-866-678-6789 (toll-free), or
 - Mail to: Canada Vigilance Program
Health Canada, Postal Locator 1908C
Ottawa, ON
K1A 0K9

Postage paid labels and the Patient Side Effect Reporting Form are available at [MedEffect](#).

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

cutaquig[®] can be stored at +2 °C to +8 °C for up to 24 months from the date of manufacture. Within its shelf-life, the product may be stored at room temperature up to +25 °C for up to 6 months without being refrigerated again during this period, and must be discarded if not used after this. Do not use after expiry date.

Do not freeze. Keep the vial in the outer carton to protect it from light. Discard any remaining contents after use.

Keep out of reach and sight of children.

If you want more information about cutaquig[®]:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes

this Patient Medication Information by visiting the Health Canada website; the manufacturer's website <http://www.octapharma.ca>, or by calling 1-888-438-0488.

This leaflet was prepared by Octapharma Pharmazeutika Produktionsges.m.b.H

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