APPROVED PATIENT INFORMATION LEAFLET

WARNING: THROMBOSIS

- **Thrombosis may occur with immune globulin products, including CUTAQUIG. Risk factors may include: advanced age, prolonged immobilization, hypercoagulable conditions, history of venous or arterial thrombosis, use of estrogens, indwelling vascular catheters, hyperviscosity, and cardiovascular risk factors.**
- **For patients at risk of thrombosis, administer CUTAQUIG at the minimum dose and infusion rate practicable. Ensure adequate hydration in patients before administration. Monitor for signs and symptoms of thrombosis and assess blood viscosity in patients at risk of hyperviscosity.**

SCHEDULING STATUS: S4

CUTAQUIG, 165 mg/ml, solution for injection

Human normal immunoglobulin (SCIg)

Contains sugar (Maltose 79 mg/ml)

Read all of this leaflet carefully before you start using CUTAQUIG

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or health care provider.
- CUTAQUIG has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What CUTAQUIG is and what it is used for
2. What you need to know before you use CUTAQUIG
3. How to use CUTAQUIG
4. Possible side effects
5. How to store CUTAQUIG
6. Contents of the pack and other information

1. What CUTAQUIG is and what it is used for

What CUTAQUIG is

CUTAQUIG belongs to a class of medicines called “human normal immunoglobulins”.
Immunoglobulins are also known as antibodies and are proteins found in healthy people’s blood. Antibodies are part of
the immune system (the body’s natural defence) and help your body to fight infections.

How Cutaquig works

CUTAQUIG contains immunoglobulins that have been prepared from the blood of healthy people. The medicine works in exactly the same way as the immunoglobulins naturally present in your blood.

What CUTAQUIG is used for

CUTAQUIG is used in patients who do not have enough antibodies to fight off infections and therefore tend to have frequent infections. Regular administration of sufficient doses of CUTAQUIG can raise abnormally low immunoglobulin levels in your blood to normal levels (replacement therapy).
CUTAQUIG is prescribed to adults and children (aged 0 -18 years) in the following situations:

- Treatment of patients who are born with a reduced ability or inability to produce antibodies (primary immunodeficiency).
- Patients with an acquired deficiency of antibodies (secondary immunodeficiency) due to specific diseases and/or treatments and experiencing severe or recurrent infections.

2. What you need to know before you use CUTAQUIG

Do not use CUTAQUIG:

- if you are hypersensitive (allergic) to human normal immunoglobulin, or any of the other ingredients of CUTAQUIG (listed in section 6).

Do not inject CUTAQUIG into a blood vessel.

Warnings and precautions

Talk to your doctor or pharmacist before using Cutaquig.

You may be allergic (hypersensitive) to immunoglobulins without knowing it.

True allergic reactions such as sudden fall in blood pressure or anaphylactic shock (a sharp fall in blood pressure with other symptoms such as swelling of the throat, breathing difficulties and skin rash) are rare but they may occur occasionally even if you received human immunoglobulins previously and tolerated them well. It may happen particularly if you do not have enough of the immunoglobulin type A (IgA) in your blood (IgA deficiency) and have antibodies against IgA.

- Tell your doctor or health care provider before being given the injection if you have an immunoglobulin type A (IgA) deficiency. CUTAQUIG contains residual amounts of IgA that might cause an allergic reaction. In these rare cases, allergic reactions such as a sudden fall in blood pressure or shock may occur (see also section 4). Signs and symptoms of these rare allergic reactions include:
  - feeling lightheaded, dizzy or faint
  - skin rash and itchiness, swelling in the mouth or throat, difficulty breathing, wheezing
  - abnormal heart rate, chest pain, blueness of lips or fingers and toes
  - blurred vision

  If you notice such signs during the infusion of CUTAQUIG, tell your doctor immediately. He or she will decide whether to slow down the infusion rate or whether to stop the infusion completely.
- Tell your doctor if you have a history of heart or blood vessel disease or blood clots, have thick blood, or have been immobile for some time. These things may increase your risk of having a blood clot after using CUTAQUIG. Also tell your doctor what medicines you are using, as some medicines, such as those that contain the hormone oestrogen (for example, birth control pills), may increase your risk of developing a blood clot. Contact your doctor immediately if you

experience signs and symptoms such as shortness of breath, chest pain, pain and swelling of a limb, weakness or numbness on one side of the body after receiving CUTAQUIG.

- Contact your doctor if you experience the following signs and symptoms: severe headache, neck stiffness, drowsiness, fever, photophobia, nausea, and vomiting after receiving CUTAQUIG. These may be signs of aseptic meningitis. Your doctor will decide if further tests are necessary and whether CUTAQUIG should be continued.
- CUTAQUIG contains blood group antibodies that may cause destruction of red blood cells and therefore anaemia (low number of red blood cells).

Your health care provider will avoid potential complications by ensuring:

- that you are not sensitive to human normal immunoglobulin.
  The medicine must be infused slowly at first. The recommended infusion rate given under section 3 must be closely followed.
- that you are carefully monitored for any symptoms throughout the infusion period, especially if:
  - you receive human normal immunoglobulin for the first time;
  - you have switched from a different medicine to CUTAQUIG;
  - there has been a long interval (more than eight weeks) since the last infusion.

In these cases, it is recommended that you are monitored during the first infusion and for an hour afterwards. If the points above do not apply for you, it is recommended that you are observed for at least 20 min after administration.

Children and adolescents

The listed warnings and precautions apply both to adults and to children.

Other medicines and CUTAQUIG

- Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)
- Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines
- You must not mix CUTAQUIG with any other medicines.

- Tell your vaccinating doctor prior to a vaccination about your treatment with CUTAQUIG. CUTAQUIG (as all human normal immunoglobulin solutions) may interfere with the effect of some live virus vaccines such as measles, rubella, mumps or chicken pox. Therefore, after receiving CUTAQUIG you may have to wait up to 3 months before receiving your live-attenuated vaccine. In the case of measles vaccination, the impairment may persist for up to one year.

- *Blood Glucose Testing*

  Some types of blood glucose testing systems (so called glucometers) falsely interpret the maltose contained in CUTAQUIG as glucose. This may result in falsely elevated glucose readings during an infusion and for a period of about 15 hours after the end of the infusion and, consequently, in the inappropriate administration of insulin, resulting in life-threatening hypoglycaemia (i.e. a decreased blood sugar level).

  Also, cases of true hypoglycaemia may go untreated if the hypoglycaemic state is masked by falsely elevated glucose readings.

  Accordingly, when administering CUTAQUIG or other maltose-containing products, the measurement of blood glucose must be done with a test-system using a glucose-specific method. Systems based on the glucose dehydrogenase pyrroloquinolinequinone (GDH PQQ) or glucose-dye-oxidoreductase methods should not be used.

  Review carefully the product information of the blood glucose testing system, including that of the test strips, to determine if the system is appropriate for use with maltose-containing parenteral products. If any uncertainty exists, please ask your treating doctor to determine if the glucose testing system you are using is appropriate for use with maltose-containing parenteral products.

CUTAQUIG with food, drink and alcohol

No effects have been observed.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

CUTAQUIG should only be used during pregnancy or breastfeeding after consultation with your doctor or pharmacist.

No clinical studies have been performed with CUTAQUIG in pregnant women. However, medicines that contain immunoglobulins have been used in pregnant and breastfeeding women for years, and no harmful effects on the course of pregnancy or on the baby have been observed.

If you are breastfeeding and receive CUTAQUIG, the immunoglobulins of the medicine can also be found in the breast milk. Therefore, your baby may be protected from certain infections.

Experience with immunoglobulins suggests that no harmful effects on fertility are to be expected.

Driving and using machines

The ability to drive and operate machines may be impaired by some adverse reactions associated with CUTAQUIG. Patients who experience adverse reactions during treatment should wait for these to resolve before driving or operating machines.

CUTAQUIG contains sodium

This medicine contains 33,1 mg sodium (main component of cooking/table salt) per vial of 48 ml and 13,8 mg per vial of 20 ml. This is equivalent to 1,7 % and 0,7 % respectively of the recommended maximum daily dietary intake of sodium for an adult.

Information on what Cutaquig is made of

CUTAQUIG is made from human blood plasma (This is the liquid part of the blood). When medicines are made from human blood or plasma, certain measures are put in place to prevent infections being passed on to patients. These include:

- careful selection of blood and plasma donors to make sure those at risk of carrying infections are excluded
- the testing of each donation and pools of plasma for signs of virus/infections

- the inclusion of steps in the processing of the blood or plasma that can inactivate or remove viruses.

Despite these measures, when medicines prepared from human blood or plasma are administered, the possibility of passing on infection cannot be totally excluded. This also applies to any unknown or emerging viruses or other types of infections.

The measures taken are considered effective for enveloped viruses such as human immunodeficiency virus (HIV – the AIDS causing virus), hepatitis B virus and hepatitis C virus.

The measures taken may be of limited value against non-enveloped viruses such as hepatitis A virus and parvovirus B19.

Immunoglobulins have not been associated with hepatitis A or parvovirus B19 infections possibly because the antibodies against these infections, which are contained in CUTAQUIG, are protective.

It is strongly recommended that every time you receive a dose of CUTAQUIG**,** the name and batch number of the medicine are recorded in order to maintain a record of the batches used. (see also Annex I: Administration Guidance).

3. How to use CUTAQUIG

Always use CUTAQUIG exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

CUTAQUIG has to be infused under the skin (subcutaneous or SC administration).

The treatment will be started off by your doctor or nurse experienced in treating patients with a weak immune system.

Once the doctor/nurse has found the right dose and infusion rate for you and once you have received the first few infusions under supervision, you may be allowed to administer the treatment yourself at home or receive it at home by your (trained) caregiver. Your doctor or nurse experienced in guiding patients to home treatment will ensure that you or your caregiver receive training and precise information on

- germ free (aseptic) infusion technique
- the use of the infusion device (if necessary)
- keeping a treatment diary

• what action to take in the event of serious side effects (see also section 4).

As soon as you are able to treat yourself, and if no side effects have arisen during treatment, your doctor may allow you to continue treatment at home.

Dosage

Your individual dosage and infusion rate will be determined by your doctor, who will adapt the dose especially for you, taking into account your weight, any previous treatment you may have received and your response to treatment. Always follow your doctor's instructions.

Replacement therapy in primary immunodeficiency syndromes:

Your doctor will determine whether you need a loading dose (for adults and children) of at least 1,2 to 3,0 ml/kg of body weight divided over several days. Following this, you will receive CUTAQUIG on a regular basis from daily up to every other week. The cumulative dose per month will be about 2,4 to 4,8 ml/kg of body weight. Your health care provider may adjust your dose depending on your response to the treatment.

Replacement therapy in secondary immunodeficiencies:

The recommended dose for CUTAQUIG is a cumulative monthly dose of 1,2 – 2,4 ml/kg administered at repeated intervals (approximately once per week). Each single dose may need to be injected at different anatomic sites. Your health care provider may adjust your dose depending on your response to the treatment.

Do not change the dose or dosing interval without contacting your doctor. If you think you should receive CUTAQUIG more or less frequently, please speak to your doctor. If you think you missed a dose, please speak to your doctor as soon as possible.

Method and route of administration

Selection of infusions site(s):

Suggested areas for subcutaneous infusion of CUTAQUIG are abdomen, thighs, upper arms, or upper leg/hip area. Multiple subcutaneous infusions sites can be used at the same time. The number of infusion sites is unlimited, but infusions sites should be at least 5 cm apart.

Rotate sites with each administration as advised by your doctor or nurse.



The amount infused per site varies but it is recommended to divide large infusion volumes (> 30 ml) and infuse into several infusions sites. In infants and children infusion sites may be changed every 5 - 15 ml.

Infusion rate:

The recommended initial infusion speed is 15 ml/h/site. If well-tolerated, you may gradually increase the infusion rate to 25 ml/h/site.

Recommended infusion speed for all sites combined: 30 ml/h for the first 6 infusions, then gradually increase to 50 ml/h and if well tolerated to 80 ml/h.

Detailed instructions for use are provided below.

CUTAQUIG is for subcutaneous (under the skin) administration only. Do not inject into a blood vessel.

Only use CUTAQUIG at home once you have been properly instructed and trained by your health care provider.

Follow the administration guidance at the end of the package leaflet (Annex I) step by step and use aseptic/sterile technique when administrating CUTAQUIG.

Use gloves if you have been told to do so when preparing the infusion.

Use in children and adolescents

The same indications, dose and frequency of infusion as for adults apply for children and adolescents (age 0 to 18 years).

If you use more CUTAQUIG than you should

If you think, you have infused too much CUTAQUIG, contact your health care provider as soon as possible.

If you forget to use CUTAQUIG

Inform your doctor or health care provider as soon as possible if you missed a dose. Do not infuse a double dose of CUTAQUIG to make up for a missed dose.

4. Possible side effects

CUTAQUIG can have side effects.

Not all side effects reported for CUTAQUIG, are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking CUTAQUIG, please consult your health care provider for advice.

Like all medicines, CUTAQUIG can cause side effects, such as chills, headache, dizziness, fever, vomiting, allergic reactions, nausea, joint pain, low blood pressure and moderate low back pain, although not everybody gets them.

Certain side effects such as headache, chills, or body aches, may be reduced by slowing the infusion rate.

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

You may be allergic (hypersensitive) to immunoglobulins and allergic reactions such as a sudden fall in blood pressure and in isolated cases, shock may occur. Doctors are aware of these possible side effects and will monitor you during and after the initial infusions.

Tell your doctor immediately if you notice any of the following:

- feeling light-headed, dizzy or faint,
- skin rash and itchiness, swelling of the mouth or throat, difficulty breathing, wheezing,
- abnormal heart rates, chest pain, blueness of lips or fingers and toes,
- blurred vision.

These are all very serious side effects. If you have them, you may have had a serious reaction to CUTAQUIG**.** You may need urgent medical attention or hospitalisation.

When using CUTAQUIG at home, you may perform the infusion in the presence of your caregiver who will help you watch out for signs of an allergic reaction. In case of any symptoms for an allergic reaction, stop the infusion and get help if necessary.

Please also see section 2 of this leaflet about the risk of allergic reactions.

The following side effects are very common (may affect more than 1 in 10 infusions).

- reactions at the injection site such as redness, swelling, itching, and discomfort.

The following side effects are rare (may affect more than 1 in 10 000 infusions):

- headache

- abdominal pain
- abdominal distension
- vomiting
- muscle pain
- fever
- positive blood test for antibodies
- irregular blood test results showing destruction of red blood cells

Side effects seen with similar medicines

The following side effects have been observed with infusion of subcutaneous human normal immunoglobulin. It is possible that someone using CUTAQUIG may get them.

- shivering
- paleness
- diarrhoea
- itching
- rash
- hives
- pain at the injection site
- rapid reddening of neck/ facial region
- feeling hot
- feeling cold
- weakness
- tiredness
- flu-like symptoms
- feeling unwell
- throat tightness
- difficulties in breathing
- asthma like symptoms

- cough
- facial swelling
- a syndrome called aseptic meningitis (see also section 2 “Warning and precautions”)
- Increase in blood pressure
- clots in blood vessels (see also section 2 “Warnings and precautions”)

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 temporary and reversible, non-infectious swelling of the membranes surrounding the brain and spinal cord (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.

Side effects such as these may occur even when you have previously received human immunoglobulin and tolerated them well.

Please also refer to section 2 for additional details on circumstances which increase the risk if side effects.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the Adverse drug reaction and product quality reporting form, found online under SAHPRA’s E-Services: https://www.sahpra.org.za/ e-Library/GLF-CEM PV-06A

By reporting side effects, you can help provide more information on the safety of CUTAQUIG.

5. How to store CUTAQUIG

- Store all medicines out of the sight and reach of children.

- Do not use this medicine after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.
- Store in a refrigerator (2 °C – 8 °C). **Do not freeze.** Keep the vial in the outer carton in order to protect it from light.
- Within its shelf-life, the product may be stored at room temperature (do not store above 25 °C) for up to 9 months without being refrigerated again during this period and must be discarded if not used after this.
- After first opening, the product should be used immediately.
- Do not use CUTAQUIG if the solution is cloudy or contains particles.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What CUTAQUIG contains

The active substance is human normal immunoglobulin 165 mg/ml (at least 95 % is immunoglobulin G)

- IgG_1 71 %
- IgG_2 25 %
- IgG_3 3 %
- IgG_4 2 %

The other excipients are maltose, polysorbate 80 and water for injections.

The maximum IgA content is 300 micrograms/ml

CUTAQUIG contains ≤ 30 mmol/l sodium

What CUTAQUIG looks like and contents of the pack

CUTAQUIG is a solution for injection.

The solution is clear and colourless.

During storage the solution may turn to slightly opalescent and pale-yellow.

CUTAQUIG is available as:

6 ml of solution in a 10 ml vial (Type I glass) with a grey bromobutyl rubber stopper with a blue flip-off cap.

10 ml and 12 ml of solution in a 20 ml vial (Type I glass) with a grey bromobutyl rubber stopper with a blue flip-off cap.

20 ml and 24 ml of solution in a 30 ml vial (Type I glass) with a grey bromobutyl rubber stopper with a blue flip-off cap.

48 ml of solution in a 50 ml vial (Type I glass) with a grey bromobutyl rubber stopper with a blue flip-off cap.

Pack size of 1, 10 or 20.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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If you are a health care provider and require the Professional Information Leaflet or Afrikaans Patient Information Leaflet electronically, please contact us on

za1-enquiries@octapharma.com

Annex I – Administration guidance

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 health care 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 colourless 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**).**

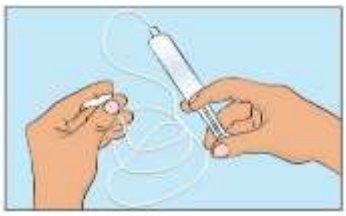


Figure 5

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 logbook. 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 health care professional and according to local requirements.

Tidy up and securely store all the reusable equipment (e.g. pump) until the next infusion.