APPROVED PROFESSIONAL INFORMATION FOR CUTAQUIG

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

1. NAME OF THE MEDICINE

CUTAQUIG, 165 mg/ml, solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Human normal immunoglobulin (SCIg)

One ml contains:

Human normal immunoglobulin	165 mg
(purity of at least 95 % IgG)	

Each vial of 6 ml contains: 1 g of human normal immunoglobulin.

Each vial of 10 ml contains: 1,65 g of human normal immunoglobulin.

Each vial of 12 ml contains: 2 g of human normal immunoglobulin.

Each vial of 20 ml contains: 3,3 g of human normal immunoglobulin.

Each vial of 24 ml contains: 4 g of human normal immunoglobulin.

Each vial of 48 ml contains: 8 g of human normal immunoglobulin.

Distribution of the IgG subclasses (approx. values):

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

The maximum IgA content is 300 micrograms/ml.

Produced from the plasma of human donors.

Contains sugar (Maltose 79 mg/ml)

Excipient(s) with known effect

CUTAQUIG contains 33,1 mg sodium per vial of 48 ml and 13,8 mg per vial of 20 ml, see section 4.4.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.

The liquid preparation is clear and colourless.

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

The osmolality of the liquid preparation is 310 to 380 mosmol/kg.

The pH of the solution is 5 – 5,5.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Replacement therapy in adults, children and adolescents (0 - 18 years) in:

- Primary immunodeficiency (PID) syndromes with impaired antibody production (see section 4.4)

- Secondary immunodeficiencies (SID) in patients who suffer from severe or recurrent infections, ineffective antimicrobial treatment and either proven specific antibody failure (PSAF)* or serum IgG level of < 4 g/l.

*PSAF = failure to mount at least a 2-fold rise in IgG antibody titre to pneumococcal polysaccharide and polypeptide antigen vaccines.

4.2 Posology and method of administration

Replacement therapy should be initiated and monitored under the supervision of a physician experienced in the treatment of immunodeficiency.

Posology

The dose and dose regimen are dependent on the indication.

Replacement therapy

CUTAQUIG should be administered via the subcutaneous route.

In replacement therapy, the dose may need to be individualised for each patient dependent on the pharmacokinetic and clinical response.

CUTAQUIG can be administered at regular intervals from daily up to every other week.

The following dose regimens are given as a guideline.

Replacement therapy in primary immunodeficiency syndromes (as defined in 4.1)

The dose regimen should achieve a trough level of IgG (measured before the next infusion) of at least 5 to 6 g/l and aim to be within the reference interval of serum IgG for age. A loading dose of at least 0,2 to 0,5 g/kg (1,2 to 3,0 ml/kg) body weight may be required. This may need to be divided over several days, with a maximal daily dose of 0,1 to 0,15 g/kg.

After steady state IgG levels have been attained, maintenance doses are administered at repeated intervals to reach a cumulative monthly dose of the order of 0,4 – 0,8 g/kg (2,4 to 4,8 ml/kg). Each single dose may need to be injected at different anatomic sites.

Trough levels should be measured and assessed in conjunction with the incidence of infection. To reduce the rate of infection, it may be necessary to increase the dose and aim for higher trough levels.

Replacement therapy in secondary immunodeficiencies (as defined in 4.1.)

The recommended dose administered at repeated intervals (approximately once per week) is to reach a cumulative monthly dose of the order of 0,2 – 0,4 g/kg (1,2 – 2,4 ml/kg). Each single dose may need to be injected at different anatomic sites.

IgG trough levels should be measured and assessed in conjunction with the incidence of infection. Dose should be adjusted as necessary to achieve optimal protection against infections, an increase may be necessary in patients with persisting infection; a dose decrease can be considered when the patient remains infection free.

Special Populations:

Elderly population

As the dose is given by body weight and adjusted to the clinical outcome of the above-mentioned conditions, the dose in the elderly population is not considered to be different from that in subjects 18 to 65 years of age. In the clinical trial **CUTAQUIG** was evaluated in 3 patients older than 65 years. No specific dose-requirements were necessary to achieve the desired serum IgG levels.

Paediatric population

The posology in children and adolescents (0 - 18 years) is not different to that of adults as the posology for each indication is given by body weight and adjusted to the clinical outcome in replacement therapy indications.

CUTAQUIG was evaluated in 38 paediatric subjects (26 children [between 2 and <12 years of age] and 12 adolescents [between 12 and <16 years of age]) with primary immunodeficiency disease. No paediatric-specific dose requirements were necessary to achieve the desired serum IgG levels.

Method of administration

For subcutaneous use only.

Subcutaneous infusion for home treatment should be initiated and monitored by a health care provider experienced in the guidance of patients for home treatment.

The patient and/or a caregiver must be instructed in the use of the infusion device, the infusion techniques, aseptic handling technique, the keeping of a treatment diary, recognition of and measures to be taken in case of severe adverse reactions (see annex 1 Administration guidelines).

CUTAQUIG may be injected into sites such as abdomen, thigh, upper arm, and lateral hip.

Infusion rate

Adjustment of the infusion rate and infusion volume per site is based on subject tolerability.

It is recommended to use an initial administration rate of 15 ml/h/site. From infusion 7 on, if well tolerated (see section 4.4), the infusion rate can be gradually increased to 25 ml/h/site.
Recommended infusion rate per hour for all sites combined: 30 ml/h for first 6 infusions, then gradually increase to 50 ml/h and, if well tolerated to 80 ml/h.
More than one infusion device can be used simultaneously.

Infusion volume per site

The amount of **CUTAQUIG** infused into a particular site varies. In infants and children, infusion site may be changed every 5 - 15 ml. In adults doses over 30 ml may be divided according to patient preference. There is no limit to the number of infusion sites. Infusion sites should be at least 5 cm apart.

4.3 Contraindications

- Hypersensitivity to the active substance (human immunoglobulins) or to any of the excipients listed in section 6.1 (see section 4.4).
- **CUTAQUIG** must not be given intravascularly.
- It must also not be administered intramuscularly in case of severe thrombocytopenia and in other disorders of haemostasis.

4.4 Special warnings and precautions for use

It is strongly recommended that every time that **CUTAQUIG** is administered to a patient, the name and batch number of the product are recorded in order to maintain a link between the patient and the batch of the product.

CUTAQUIG contains maximally 90 mg of maltose per ml as an excipient. The interference of maltose in blood glucose assays may result in falsely elevated glucose readings and, consequently, in the inappropriate administration of insulin, resulting in life threatening hypoglycaemia and death. Also, cases of true hypoglycaemia may go untreated if the hypoglycaemic state is masked by falsely elevated glucose readings (see section 4.5). For acute renal failure see below.

CUTAQUIG is for subcutaneous use only. If **CUTAQUIG** is accidentally administered into a blood vessel patients could develop shock.

The recommended infusion rate given under section 4.2 must be closely followed. Patients must be closely monitored and carefully observed for any symptoms throughout the infusion period.
Certain adverse reactions may occur more frequently in patients who receive human normal immunoglobulin for the first time or, in rare cases, when the human normal immunoglobulin product is switched or when there has been a long interval since the previous infusion.

Potential complications can often be avoided by:

- initially injecting the product slowly (see section 4.2).
- ensuring that patients are carefully monitored for any symptoms throughout the infusion period. In particular, patients naïve to human normal immunoglobulin, patients switched from an alternative immunoglobulin product or when there has been a long interval since the previous infusion should be monitored during the first infusion and for the first hour after the first infusion, in order to detect potential adverse signs.

All other patients should be observed for at least 20 minutes after administration.

In case of adverse reaction, either the rate of administration must be reduced or the infusion stopped. Suspicion of allergic or anaphylactic type reactions requires immediate discontinuation of the injection. The treatment required depends on the nature and severity of the adverse reaction. In case of shock, standard medical treatment for shock should be implemented.

Hypersensitivity

True allergic reactions are rare. They can particularly occur in patients with anti-IgA antibodies who should be treated with particular caution. Patients with anti-IgA antibodies, in whom treatment with subcutaneous IgG products remains the only option, should be treated with **CUTAQUIG** only under close medical supervision.

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.

Thromboembolism

Arterial and venous thromboembolic events including myocardial infarction, stroke, deep venous thrombosis and pulmonary embolism have been associated with the use of immunoglobulins. Patients should be sufficiently hydrated before use of immunoglobulins. Caution should be exercised in patients with preexisting risk factors for thrombotic events (such as advanced age, hypertension, diabetes mellitus and a history of vascular disease or thrombotic episodes, patients with acquired or inherited thrombophilic disorders, patients with prolonged periods of immobilisation, severely hypovolemic patients, patients with diseases which increase blood viscosity).

Patients should be informed about first symptoms of thromboembolic events including shortness of breath, pain and swelling of a limb, focal neurological deficits and chest pain and should be advised to contact their physician immediately upon onset of symptoms.

Aseptic Meningitis Syndrome (AMS)

Aseptic meningitis syndrome has been reported to occur in association with subcutaneous immunoglobulin treatment; the symptoms usually begin within several hours to 2 days following treatment. Discontinuation of immunoglobulin treatment may result in remission of AMS within several days without sequelae.

Patients should be informed about first symptoms which encompass severe headache, neck stiffness, drowsiness, fever, photophobia, nausea, and vomiting.

Renal dysfunction/failure

Severe renal adverse reactions have been reported in patients receiving immune globulin treatment, particularly those products containing sucrose (**CUTAQUIG** does not contain sucrose). These include acute renal failure, acute tubular necrosis, proximal tubular nephropathy and osmotic nephrosis.

Factors that increase the risk of renal complications include, but are not limited to preexisting renal insufficiency, diabetes mellitus, hypovolaemia, concomitant nephrotoxic medicinal products, age over 65, sepsis, hyperviscosity and paraproteinemia.

Haemolysis

IgG products can contain blood group antibodies that may act as haemolysins and induce *in vivo* coating of red blood cells (RBCs) with immunoglobulin, causing a positive direct antiglobulin (Coombs') test result and, rarely, may cause haemolysis.

Monitor Immunoglobulin product recipients for clinical signs and symptoms of haemolysis.

Sodium content

CUTAQUIG contains 33,1 mg sodium per vial of 48 ml and 13,8 mg per vial of 20 ml, equivalent to 1,7 % and 0,7 %, respectively of the WHO recommended maximum daily intake of 2 g sodium for an adult.

Interference with serological testing

After injection of immunoglobulin the transitory rise of the various passively transferred antibodies in the patient's blood may result in misleading positive results in serological testing.

Passive transmission of antibodies to erythrocyte antigens, e.g. A, B, D may interfere with some serological tests for red cell antibodies for example the direct antiglobulin test (DAT, direct Coombs' test).

Transmissible agents

Standard measures to prevent infections resulting from the use of medicines prepared from human blood or plasma include selection of donors, screening of individual donations and plasma pools for specific markers of infection and the inclusion of effective manufacturing steps for inactivation/removal of viruses. Despite this, when medicines prepared from human blood or plasma are administered, the possibility of transmitting infective agents cannot be totally excluded.

This also applies to unknown or emerging viruses and other pathogens.

The measures taken are considered effective for enveloped viruses such as human immunodeficiency virus (HIV), hepatitis B virus (HBV) and hepatitis C virus (HCV).

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

There is a reassuring clinical experience regarding the lack of hepatitis A or parvovirus B19 transmission with immunoglobulins and it is also assumed that the antibody content makes an important contribution to the viral safety.

Paediatric population

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

4.5 Interactions with other medicinal products and other forms of interaction

Live attenuated virus vaccines

Immunoglobulin administration may impair for a period of at least 6 weeks and up to 3 months the efficacy of live attenuated virus vaccines such as measles, rubella, mumps and varicella. After administration of **CUTAQUIG**, an interval of 3 months should elapse before vaccination with live attenuated virus vaccines. In the case of measles, this impairment may persist for up to 1 year. Therefore, patients receiving measles vaccine should have their antibody status checked.

Blood glucose testing

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.

Paediatric population

The listed interactions apply both to adults and children.

4.6 Fertility, pregnancy and lactation

Pregnancy

The safety of **CUTAQUIG** for use in human pregnancy has not been established in controlled clinical trials and therefore should only be given with caution to pregnant women and breastfeeding mothers. Immunoglobulin products have been shown to cross the placenta, increasingly during the third trimester. Clinical experience with immunoglobulins suggests that no harmful effects on the course of pregnancy, or on the foetus and the neonate are to be expected.

Breastfeeding

Immunoglobulins are excreted into the milk and may contribute to protecting the neonate from pathogens which have a mucosal portal of entry.

Fertility

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

4.7 Effects on ability to drive and use 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.

4.8 Undesirable effects

a. Summary of the safety profile

Adverse reactions such as chills, headache, dizziness, fever, vomiting, allergic reactions, nausea, arthralgia, low blood pressure and moderate low back pain may occur occasionally.

Rarely human normal immunoglobulins may cause a sudden fall in blood pressure and, in isolated cases, anaphylactic shock, even when the patient has shown no hypersensitivity to previous administration.

Local reactions at infusion sites: swelling, soreness, redness, induration, local heat, itching, bruising and rash, may frequently occur. These reactions normally decrease in frequency with ongoing treatment.

For safety information with respect to transmissible agents, see section 4.4.

b. Tabulated list of adverse reactions

Clinical safety data are based on the pivotal Phase III open-label, single-arm, prospective, multicentre study of **CUTAQUIG** in subjects with PID, previously treated with IVIG for at least 6 months. This study was conducted in Europe and North America.

In this study, the safety of **CUTAQUIG** was evaluated in 75 subjects. A total of 4 462 **CUTAQUIG** infusions were administered.

The table presented below is according to the MedDRA system organ classification (SOC and Preferred Term Level).

Frequencies per patient have been evaluated according to the following convention: Very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1 000 to <1/100); rare (≥1/10 000 to <1/1 000); very rare (<1/10 000), not known (cannot be estimated from the available data).

Within each frequency grouping, adverse reactions are presented in order of decreasing seriousness.

Frequency of Adverse Reactions (ADRs) per subject and per infusion in the clinical study with **CUTAQUIG:**

MedDRA System Organ Class (SOC)	**Adverse Reaction**	**Frequency per infusion**	**Frequency per subject**
Nervous system disorders	Headache	Rare	Common

Gastrointestinal disorders	Abdominal distension	Rare	Common
	Abdominal pain	Rare	Common
	Vomiting	Rare	Common
Musculoskeletal and connective tissue disorders	Myalgia	Rare	Common
General disorders and administration site conditions	Injection site reaction	Very common	Very common
	Pyrexia	Rare	Common
Investigations	Coombs test positive	Rare	Common
	Free haemoglobin present	Rare	Common
	Haptoglobin decreased	Rare	Common

307

308 The following adverse reactions have been identified during post-approval use of **CUTAQUIG**.
309 Because these adverse reactions are reported voluntarily from a population of uncertain size, it is not
310 always possible to reliably estimate their frequency or establish a causal relationship to drug
311 exposure.

312

MedDRA System Organ Class (SOC) according to the sequence:	Adverse Reaction (Preferred Term)
Nervous system disorders	Dizziness
Gastrointestinal disorders	Nausea
Skin and subcutaneous tissue disorders	Pruritus
General disorders and administration site conditions:	Fatigue

The following additional adverse reactions have been reported during post approval use of subcutaneous immunoglobulin products: face oedema, tremor, pallor, bronchospasm, dyspnoea, cough, diarrhoea, urticaria, rash, flushing, feeling hot, feeling cold, asthenia, influenza-like illness, malaise, injection site pain, throat tightness, aseptic meningitis, hypertension and thromboembolic events.

c. Description of selected adverse reactions

For description of selected adverse events, such as hypersensitivity reactions, thromboembolism, acute renal failure, aseptic meningitis syndrome and haemolysis, see Section 4.4

d. Paediatric population

Frequency, type and severity of adverse reactions in children are expected to be the same as in adults.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are asked to report any suspected adverse reactions 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



4.9 Overdose

Consequences of an overdose are not known.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

A 30.1 Biologicals (Antibodies)

Pharmacotherapeutic group: immune sera and immunoglobulins: immunoglobulins, normal human, for extravascular administration, ATC-Code: J06BA01.

Human normal immunoglobulin contains mainly immunoglobulin G (IgG) with a broad spectrum of antibodies against infectious agents.

Human normal immunoglobulin contains the IgG antibodies present in the normal population. It is usually prepared from pooled plasma from not fewer than 1 000 donations. It has a distribution of immunoglobulin G-subclasses closely proportional to that in native human plasma. Adequate doses of **CUTAQUIG** may restore abnormally low Immunoglobulin G levels to the normal range.

In a clinical trial a total of 75 subjects with primary immune deficiency syndromes were treated with **CUTAQUIG** during up to 64 weeks. The mean dose administered each week per patient was 0,187 g/kg in adult patients, 0,150 g/kg in young children, 0,164 g/kg in older children and 0,170 g/kg in adolescents. Subjects received a total of 4 462 weekly **CUTAQUIG** infusions.

No serious bacterial infections were reported neither during the wash-in/wash-out period nor during the efficacy period in subjects receiving **CUTAQUIG** within the clinical study.

Paediatric population

No differences were seen in the pharmacodynamic properties between adult and paediatric patients.

5.2 Pharmacokinetic properties

In a clinical Phase III trial, a pharmacokinetic (PK) sub-study was conducted in 37 PID subjects. Blood samples for PK study were collected prior to switching to **CUTAQUIG** (IVIG profile: PK_{IV}), after the 11^{th}-infusion of **CUTAQUIG** (first SC profile: PK_{SC1}) and after the 28^{th} infusion of **CUTAQUIG** (second

SC profile: PK_{SC2}). The objective of the PK sub-study was to compare the AUCs following the IV and SC administration, using a dose correction factor (DCF) of 1,5. By means of a population PK model PK parameter were estimated and simulations were performed.

Absorption and distribution

Following subcutaneous administration of **CUTAQUIG**, peak serum levels are achieved after approximately 2 days.

Due to gradual absorption, SCIG administration leads to flatter profiles and lower fluctuations at steady state compared to IVIG treatment: Mean C_{max} was lower after SCIG (13,2 ± 3,4 g/l and 13,5 ± 3,7 g/l for PK_{SC1} and PK_{SC2}, respectively) compared to the end of infusion level after IVIG treatment (18,0 ± 4,5 g/l). Correspondingly, mean serum IgG and IgG subclass trough levels were higher after SC treatment (11,5 and 11,7 g/l for PK_{SC1} and PK_{SC2}, respectively; the overall range from 6,5 to 18,9 g/l compared with that at the end of the IVIG period (10,1 g/l; range: 6,5 g/l to 14,3 g/l).

SC bioavailability was calculated to be 75 % corresponding to a dose correction factor of 1,3 for achievement of equal AUC exposure after body weight based SCIG compared to IVIG treatment.

The PK-based modeling and simulation performed on the data from the clinical study with weekly **CUTAQUIG** dosing, indicated that body weight-adjusted dosing without a DCF for the lower SC bioavailability would suffice to maintain systemic IgG exposure in the therapeutic range, for dose intervals up to 1 week, including more frequently than once a week (e.g. daily) administrations.

Longer dose intervals (esp. at lower IgG baseline levels) increase the risk of falling below IgG trough levels of 5 g/l.

Example: Assuming an IgG baseline level of 4,0 g/l and a dose conversion factor of 1,0 from IVIG to SCIG treatment, the fraction of patients falling below IgG trough level of 5 g/l was predicted to increase to 4 % at a dose interval of 2 weeks compared to 1,4 % at dose intervals ≤ Q1W.

Elimination

IgG and IgG-complexes are broken down in cells of the reticuloendothelial system. Median half-life of IgG after **CUTAQUIG** administration in PID subjects was estimated to be ~16 (9,2 – 36,3) days, as calculated in population PK model, assuming zero endogenous production of IgG.

Paediatric population

No clinically relevant differences were seen in the pharmacokinetic parameters between adult and paediatric PID study patients.

The PK-based modeling and simulation performed on the data from the clinical study with weekly **CUTAQUIG** dosing, indicates that body weight-adjusted dosing will suffice to maintain systemic IgG exposure in the therapeutic range irrespective of age.

5.3 Preclinical safety data

Immunoglobulins are normal constituents of human plasma. Non-clinical data reveal no special hazard for humans based on conventional non-clinical studies on safety pharmacology and local tolerance.

Since clinical experience provides no evidence for carcinogenic or mutagenic potential of immunoglobulins, no experimental studies in heterologous species were performed.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maltose, Polysorbate 80, water for injections**.**

6.2 Incompatibilities

In the absence of compatibility studies, **CUTAQUIG** must not be mixed with other medicines.

6.3 Shelf life

3 years.

Once a vial has been opened, the solution should be used immediately.

6.4 Special precautions for storage

Store in a refrigerator (2 °C – 8 °C). Do not freeze.

Keep the vial in the outer carton in order to protect from light.

Within its shelf life, **CUTAQUIG** 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.

For storage conditions after first opening of **CUTAQUIG**, see section 6.3.

6.5 Nature and contents of container

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 sizes: 1, 10 or 20.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

CUTAQUIG should be brought to room or body temperature before use.

It should be inspected visually for particulate matter and discoloration prior to administration.

Solutions that are cloudy or have deposits should not be used.

Any unused product or waste material should be disposed of in accordance with local requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

OCTAPHARMA SA (Pty) Ltd.

Building # 3

Design Quarter complex

Cnr. Winnie Mandela Drive and Leslie Ave East

Fourways

2191

South Africa

8. REGISTRATION NUMBER

57/30.1/0660

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

23 September 2025

10. DATE OF REVISION OF THE TEXT

23 September 2025

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).

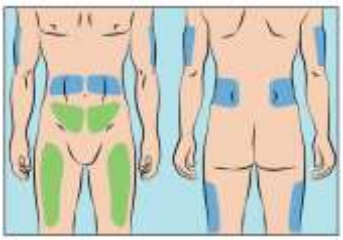


Figure 6

- 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.