Package leaflet: Information for the user

HyQvia 100 mg/mL solution for infusion for subcutaneous use
human normal immunoglobulin

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What HyQvia is and what it is used for

What HyQvia is

HyQvia contains 2 solutions for infusion (drip) under the skin (subcutaneous or SC infusion).
It is supplied as a package containing:
- one vial of human normal immunoglobulin 10% (the active substance)
- one vial of recombinant human hyaluronidase (a substance which helps the human normal immunoglobulin 10% reach your blood).

Human normal immunoglobulin 10% belong to a class of medicines called “human normal immunoglobulins”. Immunoglobulins are also known as antibodies and are found in healthy people’s blood. Antibodies are part of the immune system (the body’s natural defences) and help your body to fight infections.

How HyQvia works

The recombinant human hyaluronidase is a protein that makes it easier for the immunoglobulins to be infused (dripped) under the skin and to reach your blood system.

The vial of immunoglobulins has been prepared from the blood of healthy people. Immunoglobulins are produced by the human body’s immune system. They help your body to fight infections caused by bacteria and viruses or maintain the balance in your immune system (referred to as immunomodulation). The medicine works in the same way as the immunoglobulins naturally present in the blood.

What HyQvia is used for

Replacement therapy in adults and children (0to 18 years)

HyQvia is used in patients with a weak immune system,who do not have sufficient antibodies in their blood and tend to get frequent infections, including the following groups:

- patients with an inborn inability or reduced ability to produce antibodies (primary immunodeficiencies).
- patients who experience severe or recurrent infections due to a weakened immune system resulting from other conditions or treatments (secondary immunodeficiencies).

Regular and sufficient doses of HyQvia can raise abnormally low immunoglobulin levels in your blood to normal levels (replacement therapy)

Immunomodulatory therapy in adults, children and adolescents (0 to-18 years)

HyQvia is used in adults, children and adolescents (0 to 18 years) patients with chronic inflammatory demyelinating polyneuropathy (CIDP), a form of autoimmune disease. CIDP is characterised by chronic inflammation of the peripheral nerves that causes muscle weakness and/or numbness mainly in the legs and arms. It is believed that the body's own defense system attacks the peripheral nerves and causes nerve damage and inflammation. Immunoglobulins present in HyQvia are thought to help protect the nerves from being damaged by the immune system.

2. What you need to know before you use HyQvia

Do not inject or infuse HyQvia

- if you are allergic to immunoglobulins, hyaluronidase, recombinant hyaluronidase or any of the other ingredients of this medicine (listed in section 6, "Contents of the pack and other information").
- if you have antibodies against immunoglobulin A (IgA) in your blood. This may occur if you have IgA deficiency. Since HyQvia contains trace amounts of IgA, you might have an allergic reaction.
- into a blood vessel (intravenously) or into a muscle (intramuscularly).

Warnings and precautions

Talk to your doctor or nurse before using HyQvia.

► Tell your doctor or healthcare professional prior to treatment if any of the circumstances listed below applies to you:

- You may be allergic to immunoglobulins without knowing it. 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 can occasionally occur even if you have not previously had problems with similar treatments. You are at increased risk of allergic reactions if you have IgA deficiency with anti-IgA antibodies. Signs or symptoms of these rare allergic reactions include:
    - feeling light-headed, 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 any of these signs during the infusion, tell your doctor or nurse immediately. He or she will decide whether to slow down the infusion rate or stop the infusion completely.

Your doctor or nurse will first infuse HyQvia slowly, and carefully monitor you throughout the first infusions so that any allergic reaction can be detected and treated immediately.

- Your doctor will take special care if you are overweight, are elderly, have diabetes, have been bedridden for a long time, have high blood pressure, have low blood volume (hypovolaemia), have problems with your blood vessels (vascular diseases), have an increased tendency for blood clotting (thrombophilia or thrombotic episodes) or have a disease or a condition which causes your blood to thicken (hyper viscous blood). In these circumstances, immunoglobulins may increase the risk of heart attack (cardiac infarction), stroke, blood clots in the lung (lung embolism), or blockage of a blood vessel in the leg, although only very rarely.

  ► If you notice any of these signs and symptoms, including shortness of breath, pain, swelling of a limb and chest pain during the infusion, tell your doctor or nurse immediately. They will decide whether to slow the infusion rate or stop it completely.

Your doctor or nurse will carefully monitor you throughout the infusions so that any thromboembolic events can be detected and treated immediately.

- You will receive this medicine in high doses either on 1 day or 2 days, and if you have a blood group A, B, or AB and have an underlying inflammatory condition. In these circumstances, it has been commonly reported that immunoglobulins increase the risk of the breakdown of red blood cells (haemolysis).
- Inflammation of the membranes that surround the brain and spinal cord (Aseptic meningitis syndrome) has been reported to occur in association with immunoglobulin treatment.

  ► If you notice any of these signs and symptoms, including severe headache, neck stiffness, drowsiness, fever, photophobia, nausea, and vomiting after the infusion, tell your doctor or nurse immediately.

Your doctor will decide if further tests are necessary and whether HyQvia should be continued.

Infusion speed

It is very important to infuse the medicine at the correct speed. Your doctor or nurse will advise you on the appropriate infusion speed to use when you are infusing HyQvia at home (see section 3, "**How to use HyQvia**").

Monitoring during infusion

Certain side effects may occur more frequently if:
- you are receiving HyQvia for the first time.
- you have received another immunoglobulin and have been switched to HyQvia.
- there has been a long interval (e.g., more than 2 or 3 infusion intervals) since you last received HyQvia.

  ► In such cases, you will be closely monitored during your first infusion and for the first hour after your infusion has stopped.

In all other cases you should be monitored during the infusion and for at least 20 minutes after you receive HyQvia for the first few infusions.

Home treatment

Before you start home treatment you should assign a person as guardian. You and your guardian will be trained to detect early signs of side effects, especially allergic reactions. This guardian should help you keep an eye on potential side effects. During the infusion you must look out for the first signs of side effects (for further details see section 4, "**Possible side effects**").

- ► If you experience any side effects, you or your guardian must stop the infusion immediately and contact a doctor.
- ► If you experience a severe side effect, you or your guardian must seek emergency treatment immediately.

Spread of localised infections

Do not infuse HyQvia into or around an infected or red swollen area on your skin because it may cause the infection to spread.

No long-term (chronic) changes in the skin were observed in the clinical studies. Any long-term inflammation, lumps (nodules) or inflammation that occur at the infusion site and last more than a few days should be reported to your physician.

Effects on blood tests

HyQvia contains many different antibodies, some of which can affect blood tests (serological tests).

- ► Tell your doctor about your treatment with HyQvia before any blood test.

Information on the source material of HyQvia

The human normal immunoglobulin 10% of HyQvia and human serum albumin (an ingredient of the recombinant human hyaluronidase) are made from human plasma (the liquid part of 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, and
- the testing of each donation and pools of plasma for signs of viruses/infections.

Manufacturers of these products also include 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 used, 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 for the manufacture of HyQvia are considered effective for enveloped viruses such as human immunodeficiency virus (HIV), hepatitis B virus and hepatitis C virus and for the non-enveloped 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 HyQvia, are protective.

- ► It is strongly recommended that every time you use HyQvia, the following data are recorded in your treatment diary:
  - the date of administration,
  - the batch number of the medicine, and
  - the injected volume, flow rate, the number and location of infusion sites.

Children and adolescents

Replacement therapy

The same indications, dose and frequency of infusion as for adults apply for children and adolescents (0 to18 years).

Immunomodulatory therapy in CIDP patients

The safety and effectiveness of HyQvia have not been established in children and adolescents (0 to 18 years) with CIDP.

Other medicines and HyQvia

Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines.

Vaccinations

HyQvia may reduce the effect of some virus vaccines such as measles, rubella, mumps and chicken pox (live virus vaccines). Therefore, after receiving HyQvia, you may have to wait for up to 3 -months before receiving certain vaccines. You may have to wait for up to 1 year after receiving HyQvia before you can receive your measles vaccine.

- ► Please tell your vaccinating doctor or nurse about your treatment with HyQvia.

Pregnancy, breast-feeding and fertility

The data on the effects of long-term use of recombinant human hyaluronidase on pregnancy, breast-feeding and fertility are limited. HyQvia should only be used by pregnant and breast-feeding women after discussion with your physician.

Driving and using machines

Patients may experience side effects (for example dizziness or nausea) during treatment with HyQvia that might affect the ability to drive and use machines. If this happens, you should wait until the reactions have disappeared.

HyQvia contains sodium

This medicine contains 5.0 to 60.5 mg sodium (main component of cooking/table salt) in each recombinant human hyaluronidase vial of HyQvia. This is equivalent to 0.25 to 3% of the recommended maximum daily dietary intake of sodium for an adult. The IG 10% component is essentially sodium-free.

3. How to use HyQvia

Always use this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

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

Treatment with HyQvia will be started by your doctor or nurse, but you may be allowed to use the medicine at home once you have received the first few infusions under medical supervision and you (and/or your guardian) have been adequately trained. You and your doctor will decide if you can use HyQvia at home. Do not begin treatment with HyQvia at home until you have received complete instructions.

Dosing

Replacement therapy

Your doctor will calculate the correct dose for you based on your body weight, any previous treatment you may have received and your response to treatment. The recommended starting dose is one that

supplies 400 to 800 mg of active substance per kg of bodyweight per month. In the beginning you will receive one quarter of this dose at 1-week intervals. This will be increased step-wise to larger doses at 3- to 4-week intervals with the next infusions. Sometimes your doctor may recommend that larger doses are split and given at 2 sites at once. Your doctor may also adjust your dose depending on your response to treatment.

Immunomodulatory therapy

Your doctor will calculate the correct dose for you based on the previous treatments you may have received and your response to treatment. Therapy typically begins 1-to 2-weeks after your last immunoglobulin infusion, delivered subcutaneously at the calculated weekly equivalent dose. Your doctor may adjust the dose and frequency based on your response to treatment.

In case the maximum daily dose is exceeded (>120 g) or if you can't tolerate the immunoglobulin infusion volume, the dose may be divided and given over multiple days, with 48 to 72 hours between doses for proper absorption and the administration of hyaluronidase should also be divided appropriately.

Starting treatment

Your treatment will be started by a doctor or nurse experienced in treating patients with a weak immune system (immunodeficiency) and CIDP in guiding patients for home treatment. You will be watched carefully throughout the infusion and for at least 1 hour after stopping the infusion to see how well you tolerate the medicine. In the beginning your doctor or nurse will use a slow infusion speed and gradually increase it during the first infusion and in the following infusions. Once the doctor or nurse has found the right dose and speed of infusion for you, you may be allowed to give the treatment to yourself at home.

Home treatment

Do not use HyQvia at home until you get instructions and training from your healthcare professional.

You will be instructed in:
- Germ-free (aseptic) infusion techniques,
- The use of an infusion pump or syringe driver (if needed),
- Keeping a treatment diary, and
- Measures to be taken in case of severe side effects.

You must carefully follow your doctor’s instructions regarding the dose, infusion speed and schedule for infusing HyQvia so that your treatment works for you.

The following infusion rates of the IG 10% are recommended per infusion site:

	Subjects < 40 kg		**Subjects ≥ 40 kg**	
Interval/Minutes	First 2 Infusions (mL/hour/infusion site)	Subsequent 2 to 3 Infusions (mL/hour/infusion site)	First 2Infusions (mL/hour/infusion site)	Subsequent 2 to 3 Infusions (mL/hour/infusion site)
10 minutes	5	10	10	10
10 minutes	10	20	30	30
10 minutes	20	40	60	120
10 minutes	40	80	120	240
Remainder of infusion	80	160	240	300

The infusion rates above are for a single infusion site. In case the patient requires 2 or 3 infusion sites the infusion rates may be adjusted accordingly, (i.e., doubled or tripled based on the maximum infusion rate of the pump)

If you have an infusion site leakage

Ask your doctor or pharmacist or nurse if another needle size would be more appropriate for you. Any change of needle size would have to be supervised by the treating physician.

If you use more HyQvia than you should

If you think that you used more HyQvia than you should, speak to your doctor as soon as possible.

If you forget to use HyQvia

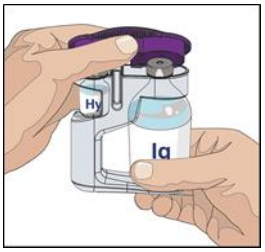
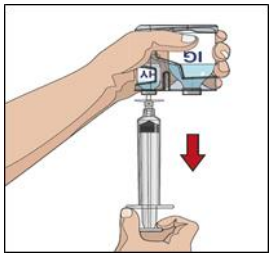
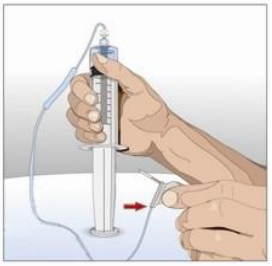
Do not infuse a double dose of HyQvia to make up for a missed dose. If you think that you have missed a dose speak to your doctor as soon as possible.

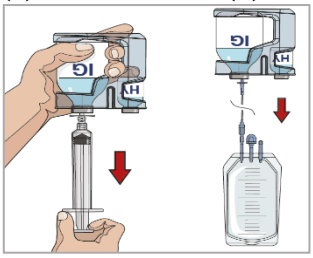
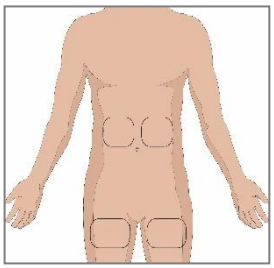
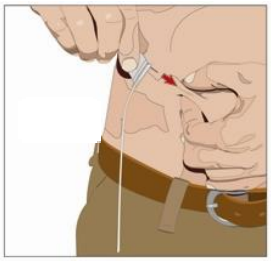
If you have any further questions on the use of this medicine, ask your doctor, or pharmacist or nurse.

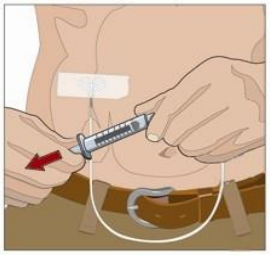
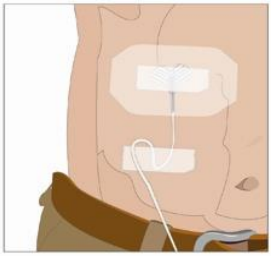
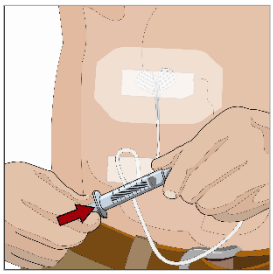
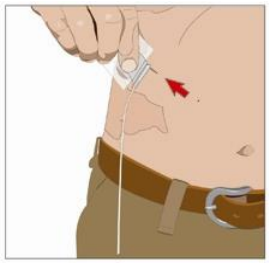
Detailed Instructions for Use are provided in the section below.

1.	**Remove HyQvia from the box:**
	• Allow vials to reach room temperature. This may take up to 60 minutes. Do not use heating devices including microwave.
	• **Do not heat up or shake HyQvia.**
	• *Check each vial of HyQvia before using*:
	  • **Expiry date:** Do not use beyond expiration date.
	  • **Colour:**
	  ○ The recombinant human hyaluronidase should be clear and colourless.
	  ○ The human normal immunoglobulin 10% should be clear and colourless or pale yellow.
	  ○ If either liquid is cloudy or has particles, do not use.
	  • **Cap:** Purple protective cap is on the dual vial unit. Do not use the product if it does not have the cap.	

2.	**Gather all supplies:** Collect *all items* for your infusion. Items include dual vial unit(s) of HyQvia, infusion supplies (subcutaneous needle set, solution container (bag or syringe), sterile clear bandage and tape, pump tubing, transfer devices, syringes, gauze and tape), sharps container, pump, and treatment logbook and other supplies as needed.	
3.	**Prepare a clean work area.**	
4.	**Wash hands:** Wash your hands thoroughly. Place all gathered supplies and open them as directed by your healthcare professional.	

5. Open HyQvia dual vial unit(s): • Remove purple protective cap(s) and make sure the blue vial caps are removed. If not, manually remove the blue caps to expose the vial stoppers. • Prepare to transfer the recombinant human hyaluronidase component of HyQvia by wiping each vial stopper with an alcohol swab, if directed and allow to air dry (at least 30 seconds).	
6. Prepare recombinant human hyaluronidase vial (HY): • Remove the smaller sterile syringe from package and attach it to a nonvented spike or needle (device). • Pull back on the plunger, fill the smaller syringe with air equal to the amount of recombinant human hyaluronidase in the HY vial(s). • Remove the cap of needle/non-vented transfer device. • Insert the tip of the needle/non-vented transfer device into the centre of the vial stopper and push straight downward. Push the air into the vial. • Turn the vial upside down, with the needle/non-vented transfer device remaining in the vial. The syringe tip will be pointing upward. • Withdraw the full contents of the recombinant human hyaluronidase into the syringe. • Repeat Step 6, if more than one vial of recombinant human hyaluronidase is needed for your dose. • If possible, combine all of the recombinant human hyaluronidase needed for the entire dose of IgG into the same syringe. • Point the syringe tip up and remove any air bubbles by pointing the syringe tip up and gently tapping the syringe with your finger. Slowly and carefully push the plunger to remove any remaining air.	
7. Prepare the needle set with the recombinant human hyaluronidase (HY): **IF using the push method to deliver (HY):** • Attach the syringe filled with recombinant human hyaluronidase to the needle set • Push the plunger of smaller syringe to remove the air and fill the needle set up to the needle wings with the recombinant human hyaluronidase. • *Note*: Your healthcare professional may recommend using a "Y" connector (for more than one site) or other needle set configuration. **IF using the pump method to deliver (HY):** • Attach the syringe filled with recombinant human hyaluronidase (HY) to the pump tubing and attach the needle set • Push the plunger of syringe (size may vary due to a larger volume) to remove the air and fill the pump tubing and needle set up to the needle wings with the recombinant human hyaluronidase.	

8.	**Prepare human normal immunoglobulin 10% vial:** • Prepare to transfer the immunoglobulin 10% component of HyQvia by wiping each vial stopper with a separate alcohol swab, if directed and allow to air dry (at least 30 seconds). • The human normal immunoglobulin 10% of HyQvia may be infused either ○ by pooling from the vials either into larger syringe **(a)** or an infusion bag **(b)** as directed by your healthcare professional, depending upon the pump to be used; or ○ directly from the IG vial. Insert the spike of the vented pump tubing or spike and venting needle into human normal immunoglobulin 10% vial(s). Fill the administration pump tubing and set aside until the recombinant human hyaluronidase has been administered. • If more than one vial is required for a full dose, spike subsequent vials after the first vial has been fully administered.	**(a)** **(b)** 
9.	**Prepare the pump:** Follow the manufacturer's instructions for preparing the pump.	
10.	**Prepare the infusion site:** • Choose an infusion site(s) in either the middle to upper abdomen or thigh. See image for infusion site locations. ○ Select sites on the opposite sides of the body if instructed to infuse in two sites for doses above 600 mL. ○ If using three sites, the sites should be 10 cm apart • Avoid bony areas, visible blood vessels, scars and any areas of inflammation or infection. • Rotate infusion sites by choosing opposite sides of the body between future infusions. • If instructed by your health care professional, clean the infusion site(s) with an alcohol swab. Allow to dry (at least 30 seconds).	 
11.	**Insert the needle:** • Remove the needle cover. Firmly grasp and pinch at least 2 to 2.5 cm of skin between two fingers. • Insert needle completely to the wings of the needle with a rapid motion straight into the skin at a 90degree angle. Wings of needle should lay flat on the skin. • Secure needle in place with sterile tape. • Repeat this step if you have a second or third infusion site.	90-degree angle to skin 

12.	**Check for proper needle placement before starting the infusion if instructed by your healthcare professional.**	
13.	**Secure the needle to the skin:** • Secure the needle(s) in place by putting a sterile clear bandage over the needle. • Check infusion site(s) occasionally throughout the infusion for dislodgement or leaking.	
14.	**Administer the recombinant human hyaluronidase infusion first:** Divide the contents equally between all sites, if more than one site is used. **If using the push method to deliver HY:** • Slowly push the plunger of the smaller syringe with the recombinant human hyaluronidase at an initial rate per infusion site to approximately 1 to 2 mL per minute and increase as tolerated. **If using the pump method to deliver HY:** • If using a pump, prepare the pump to infuse the recombinant human hyaluronidase at an initial rate per infusion site of 60 to 120 mL/hour/site and increase as tolerated.	
15.	**Administer the human normal immunoglobulin 10%:** After infusing all of the content of the smaller syringe (recombinant human hyaluronidase), remove the syringe from the hub of the needle set/pump tubing. Attach the pump tubing to the IG container/vial or, the larger syringe containing human normal immunoglobulin 10% to the needle set. Administer the human normal immunoglobulin 10% with a pump at the rates prescribed by your healthcare professional and start the infusion.	
16.	**Flush the pump tubing when the infusion is complete if instructed by your healthcare professional:** • If instructed by your healthcare professional, attach a sodium chloride solution bag to the pump tubing/needle set to push the human normal immunoglobulin 10% up to the needle wings.	
17.	**Remove needle set:** • Remove the needle set by loosening the dressing on all edges. • Pull the needle wings straight up and out. • Gently press a small piece of gauze over the needle site and cover with a protective dressing. • Throw away the needle(s) into the sharps container. ○ Dispose of the sharp's container using instructions provided with the container or contact your healthcare professional.	

18. Record the infusion: • Remove the peel-off label from HyQvia vial, which has the product lot number and expiry date and place the label in your treatment record/logbook. • Write down the date, time, dose, site(s) of infusion (to assist in rotating sites) and any reactions after each infusion. • Throw away any unused product in the vial and the disposable supplies as recommended by your healthcare professional. • Follow up with physician as directed.	

4. Possible side effects

Like all medicines, this medicine can have side effects, although not everybody gets them. Certain side effects, such as headache, chills, or body aches, may be reduced by slowing the infusion rate.

Serious side effects

Infusions of medicines like HyQvia can occasionally result in serious, but rare, allergic reactions. You may experience a sudden fall in blood pressure and, in isolated cases, anaphylactic shock. Doctors are aware of these possible side effects and will monitor you during and after the initial infusions. Typical signs or symptoms include: feeling light-headed, 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.

- Tell your doctor or nurse immediately if you notice any of these signs during the infusion.
- When using HyQvia at home, you must perform the infusion in the presence of an assigned guardian person who will help you watch out for allergic reactions, stop the infusion, and get help if necessary.
- Please also see section 2 of this leaflet about the risk of allergic reactions and using HyQvia at home.

Very common side effects (may affect more than 1 in 10 infusions):

Local reactions at infusion site (includes all of the infusion site reactions listed below). These reactions usually go away within a few days.

Common side effects (may affect up to 1 in 10 infusions):

- headache
- feeling sick (nausea)
- abdominal pain / abdominal tenderness
- redness of the skin (erythema)
- Reactions at infusion site including pain, discomfort, tenderness, redness, swelling, and itching
- Feeling hot, fever
- weakness (asthenia), tiredness (fatigue), lack of energy (lethargy) and feeling generally unwell (malaise)

Uncommon side effects (may affect up to 1 in 100 infusions):

- dizziness
- migraine
- sensations like numbness, tingling, pins and needles (paraesthesia)
- shaking (tremor)

- rapid heartbeat (tachycardia)
- high blood pressure (hypertension)
- stomach swelling (abdominal distension)
- diarrhoea
- vomiting
- rash
- itching (pruritus)
- itchy rash (urticaria)
- muscle pain (myalgia)
- joint pain (arthralgia)
- back pain
- pain in extremity (including limb discomfort)
- musculoskeletal chest pain
- joint stiffnes
- infusion-site reactions (such as discoloration, bruising, redness (haematoma), bleeding (haemorrhage), blood vessel punture, mass (nodule), induration, swelling (Oedema), chills, burning sensation, rash).
- genital swelling

Rare side effects (may affect up to 1 in 1 000 infusions):

- stroke
- low blood pressure (hypotension)
- difficulty breathing (dyspnoea)
- groin pain
- brown urine (haemosiderinuria)
- excessive sweating (hyperhidrosis)
- infusion site inflammation
- infusion site warmth
- sensations like numbness, tingling, pins and needles at infusion site (infusion site paraesthesia)
- positive result of coombs test

Frequency not known (cannot be estimated from the available data):

- inflammation of the membranes that surround the brain and spinal cord (meningitis aseptic)
- allergic reactions (hypersensitivity)
- infusion site leakage
- influenza like illness (flu like illness)

Reporting of side effects

If you get any 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 directly via Yellow Card Scheme www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store HyQvia

Keep this medicine 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 to 8°C). Do not freeze.

Do not shake.

Keep the vials in the outer carton in order to protect them from light.

Do not use this medicine if the solutions are cloudy or have particles or deposits.

After opening, dispose of any unused solutions in the vials.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What HyQvia contains

HyQvia is a dual vial unit containing:
- a solution of recombinant human hyaluronidase (Step 1 of HyQvia/Infuse first) and
- a solution of human normal immunoglobulin 10% (Step 2 of HyQvia/Infuse second).

The contents of each vial are described below:

1. Recombinant human hyaluronidase

This vial contains recombinant human hyaluronidase.

The other ingredients are sodium chloride, sodium phosphate, human albumin, ethylenediaminetetraacetic acid (EDTA) disodium, calcium chloride and water for injections (see also section 2, **"HyQvia contains sodium"**).

2. Human normal immunoglobulin 10%

One mL of the solution in this vial contains 100 mg of human normal immunoglobulin, of which at least 98% is immunoglobulin G (IgG).

The active substance of HyQvia is human normal immunoglobulin. This medicine contains trace amounts of immunoglobulin A (IgA) (not more than 140 micrograms/mL, 37 micrograms on average).

The other ingredients of this vial are glycine and water for injections.

What HyQvia looks like and contents of the pack

HyQvia 100 mg/mL solution for infusion for subcutaneous use (infused under the skin)

HyQvia is supplied as a pack containing:
- one glass vial of recombinant human hyaluronidase, and
- one glass vial of human normal immunoglobulin 10%.

The recombinant human hyaluronidase is a clear and colourless solution.
The human normal immunoglobulin 10% is a clear and colourless or pale-yellow solution.

The following pack sizes are available:

Recombinant human hyaluronidase	**Human normal immunoglobulin 10%**	
Volume (mL)	**Protein (g)**	**Volume (mL)**
1.25	2.5	25
2.5	5	50
5	10	100
10	20	200
15	30	300

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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