

HYQVIA®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using HYQVIA?

HYQVIA contains the active ingredient normal immunoglobulin (human) with vorhyaluronidase alfa. HYQVIA is used in patients who do not have enough antibodies in their blood. HYQVIA can be used as antibody replacement therapy to raise antibody levels in your blood to normal levels. The vorhyaluronidase alfa component of HYQVIA helps more immunoglobulin gets absorbed into the body.

For more information, see Section [1. Why am I using HYQVIA?](#) in the full CMI.

2. What should I know before I use HYQVIA?

Do not use HYQVIA if you have severe immunoglobulin A (IgA) deficiency and history of hypersensitivity to human immunoglobulin treatment. Do not use if you have ever had an allergic reaction to HYQVIA or any of the ingredients listed at the end of the CMI. **Talk to your**

doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use HYQVIA?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with HYQVIA and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use HYQVIA?

- HYQVIA should be used exactly as your doctor has told you.
- HYQVIA must be infused under the skin.

More instructions can be found in Section [4. How do I use HYQVIA?](#) in the full CMI.

5. What should I know while using HYQVIA?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using HYQVIA.
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	<ul style="list-style-type: none"> • Talk to your healthcare provider before travelling. It is important to obtain a written statement from your physician, explaining the reasons why you need to have this medicine and injecting devices with you, otherwise you may not be allowed to bring it into the country of travelling.
<p>Things you should not do</p>	<ul style="list-style-type: none"> • Do not stop using this medicine or lower the dosage, without checking with your doctor, unless you have an allergic reaction.
<p>Driving or using machines</p>	<ul style="list-style-type: none"> • HYQVIA has no, or negligible, influence on the ability to drive or use machines. • If you experience adverse reactions, such as dizziness and nausea, you should wait for these to resolve before driving or operating machines.

Looking after your medicine	<ul style="list-style-type: none">● Store at 2°C - 8°C in a refrigerator for the duration of its shelf life. Do not freeze.● Store in the original package to protect from light.
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For more information, see Section [5. What should I know while using HYQVIA?](#) in the full CMI.

6. Are there any side effects?

Common side effects include decreased appetite, migraine, headache, dizziness, burning sensation, hypertension, blood pressure decreased, nasal congestion, nausea, abdominal pain, vomiting, diarrhoea, chest pain, oral pain, infusion site swelling, redness, or itching, fever or chills, back and muscle pain or joint pain, fatigue, swelling of hands, ankles or feet unusual weakness, feeling abnormal.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

HYQVIA®

Active ingredient(s): *normal immunoglobulin 10% (Human) with vorhyaluronidase alfa*

Consumer Medicine Information (CMI)

This leaflet provides important information about using HYQVIA. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using HYQVIA.**

Where to find information in this leaflet:

- [1. Why am I using HYQVIA?](#)
- [2. What should I know before I use HYQVIA?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use HYQVIA?](#)
- [5. What should I know while using HYQVIA?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using HYQVIA?

HYQVIA contains the active normal immunoglobulin 10% (Human) with vorhyaluronidase alfa. HYQVIA belongs to a class of medicines called "human 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. If you do not have enough antibodies you may not be able to fight off infections.

HYQVIA is used in patients who do not have enough antibodies in their blood. HYQVIA can be used as antibody replacement therapy to raise antibody levels in your blood to normal levels.

HYQVIA should only be used in adults.

2. What should I know before I use HYQVIA?

Warnings

About blood products

When medicines are made from human blood or plasma, processes are used to prevent infections being passed from the blood/plasma donor to the person receiving the medicine.

These processes include careful selection of the people who donate blood and plasma to make sure that those who might be carrying infections are excluded. In addition, each donation and pools of donations are tested for indicators of virus or virus infection(s).

Manufacturers of these medicines also include steps in the processing of blood or plasma that inactivate or remove viruses. A three-step viral inactivation/reduction has been applied during the manufacturing of the Normal Immunoglobulin Infusion. Despite the stringent

measures, which have been put in place during the manufacturing processes, the risk of contamination by viral and other unknown agents cannot be totally excluded.

The measures taken during manufacturing are considered effective for enveloped viruses such as human immunodeficiency virus (HIV), hepatitis B virus and hepatitis C virus, and for the non-enveloped viruses hepatitis A (HAV) and B19 virus (B19V).

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

HYQVIA must not be used if

You are allergic to immunoglobulins, hyaluronidase, vorhyaluronidase alfa or are allergic to any ingredients in HYQVIA (see "Product Description").

Do not use HYQVIA if:

- you have had a history of anaphylactic or severe systemic reactions to the administration of IgG
- you have antibodies against immunoglobulin A (IgA) in your blood. This may occur if you have IgA deficiency
- you have systemic hypersensitivity to hyaluronidase or vorhyaluronidase alfa, or any of the other excipients
- have allergies to any other medicines, or if you have ever had an allergic reaction to an injection
- Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- have any other medical problems
- have had a vaccination recently.

Your doctor may request regular monitoring of your kidney function after you started receiving HYQVIA.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

3. What if I am taking other medicines?

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

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect HYQVIA.

4. How do I use HYQVIA?

- Always use HYQVIA exactly as your doctor has told you. Check with your doctor if you are not sure
- HYQVIA has to be infused under the skin
- 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
- **Always wash your hands before doing the following procedures. Use germ-free methods during the making up procedure and during injection**
- HYQVIA must not be mixed with other injectable medicines
- Do not inject HYQVIA near an infected or inflamed area of the body
- Follow the instructions provided and HYQVIA until your doctor tells you to stop.

How to use HYQVIA

If you do not understand the instructions, ask your doctor or health professional.

Always follow the specific instructions given by your healthcare provider. The steps listed below are general guidelines for using your medicine.

For the ease of identification the vorhyaluronidase alfa (Hyaluronidase) vial is labelled HY and the Normal Immunoglobulin Infusion 10% (human) vial is labelled IG.

1. Check each vial of HYQVIA before using:

- **Expiration date:**

Do not use beyond expiration date.

- **Colour:**

- The vorhyaluronidase alfa should be clear and colourless
- The Normal Immunoglobulin Infusion should be clear and colourless or pale yellow
- If either liquid is cloudy or has particles, do not use.

- **Cap:**

Protective cap is on the dual vial unit. Do not use the product if it does not have the cap.

2. Prepare for infusion:

- Gather supplies: HYQVIA dual vial unit(s), ancillary supplies, sharps container and infusion pump (program pump per physician recommendation following manufacturer's instructions)
- Prepare a clean work area
- Wash hands.

If the Normal Immunoglobulin Infusion 10% (Human) and vorhyaluronidase alfa are pooled into separate containers, skip to Step 5.

3. Prepare the vorhyaluronidase alfa of HYQVIA (Labelled as "HY"):

- Remove the protective cap
- Wipe each stopper with a sterile alcohol wipe and allow to dry
- Attach a syringe to a needle/needle-less transfer device
- Pull back on plunger of the syringe to fill the syringe with air equal to the amount in the HY vial
- Insert needle into the centre of the vial stopper
- Inject air into the vial and withdraw the full contents of the HY vial(s) into a syringe
- Attach the syringe containing the vorhyaluronidase alfa to the subcutaneous needle set
- Point the syringe tip up and push the plunger of the syringe to remove the air and fill the needle set up to the needle hub with the HY.

4. Prepare Normal Immunoglobulin Infusion 10% (Human) of HYQVIA (Labelled as "IG"):

- Wipe each stopper with a sterile alcohol wipe and allow to dry
- Transfer the vial(s) labelled IG into either syringe(s), infusion bag or directly from the vial as shown by your healthcare professional:

a. If using syringe(s):

1. Attach a sterile syringe to a vented spike
2. Insert the vented spike into the centre of the IG vials
3. Turn the vial upside down and pull back on the plunger to pull the IG into the syringe(s)
4. Repeat these steps, if using multiple vials to achieve the desired dose.

b. If using an infusion bag:

1. Insert the vented spike into the centre of each IG vial
Open the vent
2. Turn the vial upside down and fill the bag with the IG
Repeat this step, if using multiple vials to achieve the desired dose
3. Remove the filling tube(s) of the bag and place a sterile cap over the open end of the bag and close the clamp on bag
4. Insert the spike of the administration pump tubing into the bag and fill as directed by your healthcare professional.

c. If directly from the IG vial:

1. Insert the spike of the vented pump tubing into centre of the stopper of the IG vial(s). Fill the administration pump tubing and set aside until the vorhyaluronidase alfa has been administered

Repeat the steps above for each remaining vial of the IG.

5. Prepare the infusion site(s):

- Potential sites for infusion include the middle to upper abdomen and thighs
- Avoid: bony prominences, blood vessels, scars, or areas that are inflamed or infected
- If two sites are desired, a bifurcated needle set may be used on opposite sides of the body, for doses above 600mL
- Rotate sites by choosing opposite sides of the body between successive infusions.

Cleanse the infusion site(s) with a sterile alcohol wipe beginning at the centre of each infusion site and moving outward in a circular motion. Allow the infusion site(s) to dry (at least 30 seconds).

6. Insert and secure the 24 gauge subcutaneous needle:

- Pinch at least one inch (2 to 2.5 cm) of skin between two fingers. Insert the needle at a 90-degree angle into the subcutaneous tissue and secure the needle with sterile tape
- Check placement: gently pull back on the plunger of attached syringe and monitor for any blood return in the tubing
 - If blood is seen in the tubing, remove and discard the needle and repeat steps 3, 5 and 6 with a new subcutaneous needle and infusion site
- Secure the needle in place with a sterile protective dressing.

7. Administer the vorhyaluronidase alfa of HYQVIA:

Administer the entire vorhyaluronidase alfa dose first. Start at a rate of 1 to 2 mL per minute per site or as tolerated. If more than one site is used, divide the contents equally between sites. At the end of infusion, disconnect the empty syringe and attach pump tubing/ syringe containing the Normal Immunoglobulin of HYQVIA to the same subcutaneous needle set.

8. Administer the Normal Immunoglobulin of HYQVIA:

Within approximately 10 minutes of completing the infusion of the vorhyaluronidase alfa of HYQVIA, start the variable rate program of the infusion pump to initiate the infusion of the full therapeutic dose of Normal Immunoglobulin Infusion of HYQVIA. At the end of infusion, flush infusion tubing up to the needle with normal saline or 5% Glucose in water, if directed by your healthcare professional.

9. Remove subcutaneous needle(s) from the infusion site(s):

After the infusion is complete, remove the needle set and cover with a protective dressing.

10. Document the infusion:

Remove the peel-off label from each Normal Immunoglobulin Infusion vial of HYQVIA used and affix to the patient's treatment record or infusion log. In addition, record the time, date, dose, infusion site location and any reactions after each infusion.

For self-administration, provide the patient with instructions and training for infusion in the home or other appropriate setting.

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 use too much HYQVIA

The effects of an overdose of HYQVIA are not known. Please tell your doctor if you accidentally use more than instructed.

5. What should I know while using HYQVIA?

Things you must do

- Stop the infusion immediately and contact your doctor, if you experience allergic reactions such as skin rash, itching, chest tightness, wheezing, dizziness, hives, faintness, chills, flushing, rapid heartbeat, shortness of breath and/or a swollen face
- Always follow your doctor's instructions carefully
- Tell all the doctors, dentists and pharmacists who are treating you that you are using HYQVIA

- If you are about to be started on any new medicine, tell your doctor and pharmacist that you are using HYQVIA
- If you become pregnant while you are using your medicine, tell your doctor
- Talk to your healthcare provider before travelling. Plan to bring enough medicine for your treatment during this time. It is important to obtain a written statement from your physician, explaining the reasons why you need to have this medicine and injecting devices with you, otherwise you may not be allowed to bring it into the country of travelling.

Things you must not do

- Do not give your medicine to anyone else, even if they have the same condition as you
- Do not use your medicine to treat any other complaints unless your doctor tells you to
- Do not stop using your medicine or lower the dosage, without checking with your doctor, unless you have an allergic reaction.

Driving or using machines

HYQVIA has no, or negligible, influence on the ability to drive or use machines.

If you experience adverse reactions, such as dizziness and nausea, you should wait for these to resolve before driving or operating machines.

Looking after your medicine

HYQVIA should be stored at 2°C - 8°C in a refrigerator for the duration of its shelf life. Store in the original package in order to protect from light.

Do not freeze.

Keep out of the reach and sight of children.

Do not use HYQVIA after the expiry date which is printed on the label after the word 'EXP'.

The expiry date refers to the last day of that month.

Getting rid of any unwanted medicine

HYQVIA contains no preservatives.

Discard any medicine left in the vials at the end of your infusion.

Dispose of all materials, including any leftover reconstituted medicine, in an appropriate container.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Are there any 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.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">• Pain, itching, redness or swelling where the injection was given• Nausea or vomiting• Back and muscle pain• Diarrhoea• Headache• Fever or chills• Feeling faint (fall in blood pressure)	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">• Chest pain or tightness• Difficulty breathing• Lightheadedness• Dizziness, nausea, or fainting• Fast heart rate• Swelling in the mouth or throat, wheezing• Abnormal heart rate, blueness of lips or fingers and toes• Blurred vision	Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people. You can ask your doctor or pharmacist for information that is written for healthcare professionals.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side

effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

HYQVIA is a dual vial unit consisting of one vial of Normal Immunoglobulin Infusion 10% (Human) and one vial of vorhyaluronidase alfa.

HYQVIA is a dual vial unit containing:

1. a solution of vorhyaluronidase alfa (Step 1 of HYQVIA/Infuse first) and
2. a solution of Normal Immunoglobulin Infusion 10% (Human) (Step 2 of HYQVIA/Infuse second).

What HYQVIA contains

Active ingredients (main ingredients)	Normal Immunoglobulin 10% (Human) Infusion Vorhyaluronidase alfa
Other ingredients (inactive ingredients)	Glycine, water for injection Dibasic sodium phosphate dihydrate, sodium hydroxide, human albumin 25%, calcium chloride,

	sodium chloride, disodium edetate, water for injection
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Do not take this medicine if you are allergic to any of these ingredients.

What HYQVIA looks like

The Normal Immunoglobulin Infusion is a clear or slightly opalescent and colourless or pale yellow solution.

Vorhyaluronidase alfa is a clear, colourless solution.

The following pack sizes are available:

- Vorhyaluronidase alfa - 1.25mL (volume); Normal immunoglobulin 10% (Human) - 2.5g (protein) 25mL (volume)
- Vorhyaluronidase alfa - 2.5mL (volume); Normal immunoglobulin 10% (Human) - 5g (protein) 50mL (volume)
- Vorhyaluronidase alfa - 5mL (volume); Normal immunoglobulin 10% (Human) - 10g (protein) 100mL (volume)
- Vorhyaluronidase alfa - 10mL (volume); Normal immunoglobulin 10% (Human) - 20g (protein) 200mL (volume)
- Vorhyaluronidase alfa - 15mL (volume); Normal immunoglobulin 10% (Human) - 30g (protein) 300mL (volume)

Not all pack sizes may be marketed.

AUST R 235178

Who distributes HYQVIA

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