

octagam[®] 10%

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 octagam[®] 10%?

Octagam[®] 10% contains the active ingredient human normal immunoglobulin. Octagam[®] 10% is used in patients who do not have enough antibodies (proteins that help the body fight infection) in their blood.

For more information, see section [1. Why am I using octagam[®] 10%?](#) in the full CMI.

2. What should I know before I use octagam[®] 10%?

Do not use if you have ever had an allergic reaction to any human normal immunoglobulin or to any ingredients listed at the end of the CMI.

Do not use if you have antibodies to human immunoglobulin A in your blood – this may occur if you have human immunoglobulin A deficiency.

There are a number of circumstance in which people may need to use caution when using this medicine. It is important to understand if these apply to you before taking octagam[®] 10% (see Section [2. What should I know before I use octagam[®] 10%?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with OCTAGAM[®] 10% and effect 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 octagam[®] 10%?

Your doctor will administer octagam[®] 10% as a slow injection (infusion) into a vein.

For more information, see Section [4. How do I use octagam[®] 10%?](#) in the full CMI.

5. What should I know while using octagam[®] 10%?

Things you should do
<ul style="list-style-type: none">• Tell your doctor if you become pregnant• Tell your doctor if you are to have any blood glucose tests• Tell your doctor if you are to receive a vaccine• Remind your doctor/pharmacist that you are on octagam[®] 10%? before starting any new medicines

For more information, see Section [5. What should I know while using octagam[®] 10%?](#) in the full CMI.

6. Are there any side effects?

All medicines can have side effects although not everybody will experience them. Do not be alarmed by this list.

Common side effects include chills, headache, fever, vomiting, allergic reactions, nausea, joint/muscle pain, changes in blood pressure, skin rash, fatigue, flushing, sweating, rapid beating of the heart, low back pain and injection site reactions.

Serious potential side effects that require medical attention include sudden signs of allergic reaction (rash, itching/hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing) or signs of blood clot (breathing difficulties, pain/swelling in legs, chest pain, severe headache, changes in eye sight, slurred speech, dizziness, fainting, sudden weakness/numbness in one side or part of the body).

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.

octagam[®] 10%

Active ingredient: Human Normal Immunoglobulin

Consumer Medicine Information (CMI)

This leaflet provided important information about using octagam[®] 10%. 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 octagam[®] 10%.

Where to find information in this leaflet:

1. [Why am I using octagam[®] 10%?](#)
2. [What should I know before I use octagam[®] 10%?](#)
3. [What if I am taking other medicines?](#)
4. [How do I use octagam[®] 10%?](#)
5. [What should I know while using octagam[®] 10%?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I using octagam[®] 10%?

Octagam[®] 10% is a ready-to-use solution that is infused intravenously (into a vein). It contains human normal immunoglobulins. Immunoglobulins (also known as antibodies) are proteins found in human blood that help your body fight infections caused by bacteria or viruses. You might not be able to fight off infections if you do not have enough antibodies.

Octagam[®] 10% is used to

- replace antibodies in patients with no immune system due to a genetic defect or in patients with low or no antibodies due to underlying disease or when medications suppress the immune system
- modulate the immune system when there is an imbalance (such as conditions where the body attacks its own tissues)
- treat or prevent infection after a bone marrow transplant

2. What should I know before I use octagam[®] 10%?

Warnings

Do not use octagam[®] 10% if:

- you are history of allergic to human normal immunoglobulin, or to any of the ingredients listed at the end of this leaflet.

Always check the ingredients to make sure you can use this medicine.

- you have human immunoglobulin A (IgA) deficiency

Check with your doctor if you:

- have any other medical conditions, including:
 - kidney disease
 - diabetes
 - heart or blood vessel conditions (such as stroke, heart attack, angina, high blood pressure, or narrowing or hardening of the arteries, high cholesterol, blood clots in your legs (deep vein thrombosis), lungs (pulmonary embolism) or other parts of your body), or if an immediate family member has, or has had any of these conditions
- have allergies to any other medicines, or if you have ever had an allergic reaction to an injection
- are taking any medicines for any other condition
- are taking the contraceptive pill or hormone replacement treatment, as these may increase your risk of developing a blood clot

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.

It is not known if octagam® 10% can affect the developing baby when administered to a pregnant woman so the medicine should be given to a pregnant woman only if clearly needed. Immunglobulins pass into breastmilk so octagam® 10% should only be given with caution to breastfeeding mothers

Important information about the ingredients in octagam® 10%

Because this product is made from human blood, there is a risk that it could transmit infectious agents, such as known viruses that can cause disease, or other infectious agents which may not have been discovered yet. The risk that octagam® 10% will transmit an infectious agent has been reduced by screening blood donors for prior exposure to certain viruses, testing all donations for the presence of certain viruses and by including steps in the manufacturing process that are known to remove or inactivate viruses. Despite these measures, the risk of contamination by viral and other unknown agents can not be totally excluded.

3. What if I am taking other medicines?

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

Vaccinations: If you are planning on having a vaccination, tell your vaccinating doctor about your treatment with octagam® 10% before receiving any vaccination. Octagam 10% may impair the effects some vaccines such as measles, rubella, mumps and varicella even up to three months later. As such, the use of such vaccines should be delayed for at least three months after octagam® 10% administration.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these interfere with octagam® 10%.

4. How do I use octagam® 10%?

How much to take/use

Your doctor will determine how much octagam® 10% you will need. The amount depends on your illness, your current condition and your body weight.

When to take octagam® 10%

Your doctor will determine how often you will need to use octagam® 10% depending on your illness.

How to use octagam® 10%

Octagam® 10% will be administered by your doctor or healthcare professional.

Octagam® 10% will be given as an infusion, that is, an injection given slowly into the vein.

On the day of your treatment, it is important to make sure you have had sufficient fluids as this will help reduce the chance of side effects. Your infusion of octagam® 10% will begin at a slow rate and if tolerated your doctor or healthcare professional may increase the infusion rate until the administration is complete.

If you use too much octagam® 10%

As octagam® 10% is given to you under the supervision of your doctor or trained medical professional, it is very unlikely that you will receive an overdose. If you experience any side-effects, tell your doctor or nurse immediately.

5. What should I know while using octagam® 10%?

Things you should do

- tell your doctor immediately if you become pregnant
- tell your doctor if you are to have a blood or urinary test. The maltose in octagam® 10% can interfere with some blood and urinary glucose tests resulting in falsely elevated glucose readings. Certain antibody levels can rise after octagam® 10% which can result in misleading positive values in some blood tests
- tell your doctor if you are to receive a live vaccine as octagam® 10% may impair the effect of some vaccines
- tell your doctor before starting any new medicines

Remind any doctor, dentist or pharmacist you visit that you are using octagam® 10%.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how octagam® 10% affects you.

This medicine is not expected to affect your ability to drive a car or operate machinery.

Looking after your medicine

You will be given octagam® 10% in hospital. You will probably not need to keep this medicine at home. If you are required to keep this medicine at home follow the instructions on the carton on how to take care of your medicine properly.

Store octagam® 10% in your refrigerator (at 2°C to 8°C). Do not freeze. Keep octagam® 10% in the outer carton provided to protect the medicine from light.

Keep the medicine where children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need this medicine, or it is out of date, take it to any pharmacy for safe disposal.

Do not throw away any medicines via wastewater or household waste.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

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">• General side effects: chills, headache, fever, vomiting, joint/muscle/lower back pain, skin rash, tiredness, weakness• Skin reactions: skin rash, flushing sweating• Reactions at the infusion site: pain, redness, swelling, itching, and discomfort	Speak to your doctor if you have any of these less serious side effects and they worry you

Individuals may react differently to similar doses of the same product. Most side effects tend to be related to the rate of infusion and are likely to reduce or disappear when the rate is slowed down or the infusion stopped.

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • Allergic or anaphylactic reaction symptoms: <ul style="list-style-type: none"> – feeling light-headed, dizzy or faint (signs of a fall in blood pressure) – skin rash and itchiness – swelling of the mouth or throat, throat tightness – difficulty breathing, wheezing • Meningitis like symptoms: <ul style="list-style-type: none"> – Severe headache with nausea, and/or vomiting – drowsiness – neck stiffness – fever – sensitivity to light • Symptoms of blood clots: <ul style="list-style-type: none"> – chest pain or a feeling of heaviness on your chest which may radiate to the left arm – unusual, severe or long-lasting headache – shortness of breath difficulty breathing, wheezing – swelling of the face, lips or tongue or other parts of the body – sudden changes in eyesight (such as loss of vision or blurred vision) – slurred speech or any other difficulties affecting speech – dizziness or fainting – sudden weakness or numbness in one side or part of the body 	<p>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</p>

A condition called aseptic meningitis syndrome may occur occasionally after receiving this medicine. It usually begins within several hours to two days following treatment. The signs include severe headache (migraine-like), neck stiffness, drowsiness, fever, inability to stand bright light, painful eye movements, and nausea and vomiting. The condition reverses without ill effects when treatment is stopped. You may be more susceptible to this syndrome if you suffer from migraine headaches.

In rare cases, the use of octagam® 10% may lead to the formation of blood clots. Very occasionally blood clots may cause serious permanent disabilities, or may even be fatal. Blood clots can form in the veins or the arteries and may result in conditions related to the site of the blood clot, such as heart attack or stroke. The most common symptoms of blood clots are listed in the table of serious side effects.

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

Other sides effects not listed here may also occur in some people

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 your medicines .

7. Product details

This medicine is only available with a doctor's prescription.

What octagam® 10% contains

Active ingredient (main ingredient)	Human normal immunoglobulin
Other ingredients (inactive ingredients)	Maltose Tributyl phosphate Octoxinol 9 Water for injections Human immunoglobulin A (IgA)

Do not take this medicine if you are allergic to any of these ingredients.

What octagam® 10% looks like

Octagam® 10% is a clear, slightly opalescent solution. It is supplied in glass bottles.

Octagam® 10% is available in the following fill sizes:

20 mL AUST R 155601

50 mL AUST R 155602

100 mL AUST R 155603

200 mL AUST R 155604

Who distributes octagam® 10%

Octagam® 10% is supplied by:

Octapharma Australia Pty. Ltd.
Jones Bay Wharf
42/26-32 Pirrama Road
Pyrmont NSW 2009
Australia

Medical Enquiries: 1800 780 169 (Australia toll free)

Email: aumedinfo@octapharma.com

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