

HUMULIN[®] R/HUMULIN[®] NPH/HUMULIN[®] 30/70 vials

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 HUMULIN?

HUMULIN contains the active ingredient **biosynthetic human insulin (rbe)**. HUMULIN is used to **reduce high blood sugar (glucose) levels** in patients with diabetes.

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

2. What should I know before I use HUMULIN?

Do not use if you have ever had an allergic reaction to biosynthetic human insulin or any of the ingredients listed at the end of the CMI or when you have hypoglycaemia (low blood sugar).

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 HUMULIN?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with HUMULIN 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 HUMULIN?

Your doctor will tell you what dose of HUMULIN you need to use each day.

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

5. What should I know while using HUMULIN?

Things you should do	<ul style="list-style-type: none">Remind any doctor, dentist, or pharmacist you visit that you are using HUMULIN.Monitor your blood sugar levels regularly.Tell your doctor if you become pregnant or start breastfeeding while using HUMULIN.
Things you should not do	<ul style="list-style-type: none">Do not stop using HUMULIN without first checking with your doctor.Do not change your dose of HUMULIN without checking with your doctor.Do not use HUMULIN when you have hypoglycaemia (low blood sugar) as it will make it worse.
Driving or using machines	<ul style="list-style-type: none">Be careful before you drive or use any machines or tools until you know how HUMULIN affects you.Hypoglycaemia (low blood sugar) may impair your ability to concentrate or react while driving. Do not drive if you feel like your blood sugar levels are low.
Drinking alcohol	<ul style="list-style-type: none">Tell your doctor if you drink alcohol. Alcohol may mask the symptoms of hypoglycaemia (low blood sugar).
Looking after your medicine	<ul style="list-style-type: none">Keep your vials in a fridge between 2°C - 8°C. Do not freeze.After first use of the vial, you may keep the vial below 30°C for up to 28 days. Dispose after 28 days even if the vial contains insulin.

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

6. Are there any side effects?

The most common (and potentially the most severe) side effect of HUMULIN is hypoglycaemia (low blood sugar).

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.

HUMULIN[®] R/HUMULIN[®] NPH/HUMULIN[®] 30/70

vials

Active ingredient: biosynthetic human insulin (rbe)

Consumer Medicine Information (CMI)

This leaflet provides important information about using HUMULIN. **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 HUMULIN.**

Where to find information in this leaflet:

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

1. Why am I using HUMULIN?

HUMULIN contains the active ingredient **biosynthetic human insulin (rbe)**. It is identical to the insulin produced by the pancreas.

There are 3 different types of HUMULIN vials:

- HUMULIN R
- HUMULIN NPH
- HUMULIN 30/70.

They all contain the same active ingredient but **HUMULIN R** is a solution, **HUMULIN NPH** is a suspension and **HUMULIN 30/70** is a pre-mixed suspension. Each will vary with how long they work in your body.

HUMULIN is used to **reduce high blood sugar (glucose) levels** in patients with diabetes.

Diabetes is a condition in which your pancreas does not produce enough insulin to control your blood sugar level. Extra insulin is therefore needed.

There are two types of diabetes:

Type 1 diabetes - patients with type 1 diabetes always need insulin to control their blood sugar levels.

Type 2 diabetes - some patients with type 2 diabetes may also need insulin after initial treatment with diet, exercise, and tablets.

2. What should I know before I use HUMULIN?

Warnings

Do not use HUMULIN:

- if you are allergic to biosynthetic human insulin, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.

- when you have hypoglycaemia (low blood sugar).
- **HUMULIN NPH** and **HUMULIN 30/70** vials should not be used in the vein (intravenously).

Check with your doctor if you:

- have previously had an allergic reaction to any medicine used to treat your diabetes.
- are using, or have used, another type or brand of insulin. This may affect the dose of HUMULIN that you are prescribed.
- have or have had overactive thyroid glands (hyperthyroidism), overactive adrenal glands (Cushing's syndrome), enlargement of the face, hands, and feet (acromegaly), or a tumour of the adrenal gland (phaeochromocytoma) as these conditions may affect the dose of HUMULIN that you are prescribed.
- have or have had kidney or liver disease. This may affect the dose of HUMULIN that you are prescribed.
- have or have had heart disease and are also taking a thiazolidinediones, a type of medicine used to treat type 2 diabetes (such as pioglitazone, rosiglitazone). You may be more likely to develop fluid retention (oedema) especially in the hands, ankles, or feet, or heart failure while using HUMULIN.
- are taking any other medications.

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. Pregnancy may make managing diabetes more difficult. Insulin needs usually decrease during the first three months of pregnancy and increase during the last six months.

Talk to your doctor if you are breastfeeding or intend to breastfeed. Your doctor may need to change the dose of HUMULIN while you are breastfeeding.

Children (under 18 years)

The use of HUMULIN has not been studied in children under the age of 18.

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.

You may need a lower dose of HUMULIN if you are also taking any of the following medicines:

- anabolic steroids

- other medicines that treat diabetes
- aspirin or other salicylates
- a group of antibiotics, known as sulfonamides, used to treat infections
- certain medicines used to treat depression, such as monoamine oxidase inhibitors
- certain medicines used to treat high blood pressure or other heart conditions such as guanethidine, captopril, enalapril, angiotensin II receptor blockers and beta blockers
- certain medicines used to treat people with growth disorders and tumours, such as octreotide.

You may need a higher dose of HUMULIN if you are also taking any of the following medicines:

- medicines used for oral contraception ('the pill')
- medicines that affect your metabolism (corticosteroids such as prednisone and cortisone, and growth hormones)
- glucagon
- adrenaline
- medicines used in thyroid replacement therapy
- certain antibiotics used to treat tuberculosis, such as isoniazid
- certain medicines used to treat asthma, such as salbutamol or terbutaline
- certain medicines used to treat schizophrenia, bipolar disorder, or nausea and vomiting, such as phenothiazines
- certain medicines used to treat epilepsy, such as phenytoin.

You may need to change (increase or decrease) the dose of HUMULIN if you are also taking the following medicine:

- diuretics, a group of medicines that help remove excessive fluids in the body.

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

4. How do I use HUMULIN?

How much to use

Your doctor will tell you what dose of HUMULIN you need to use each day.

When to use HUMULIN

Your doctor will tell you when to use HUMULIN.

How to use HUMULIN

Checking your HUMULIN vial

1. Check the vial before each preparation and injection. Make sure you are using the correct vial. The solution of **HUMULIN R** should be clear and colourless. The suspension in **HUMULIN NPH** and **HUMULIN 30/70** cartridges should be white and cloudy or milky.

Prepare dose

Using one insulin type

1. Wash your hands.
2. **HUMULIN NPH** and **HUMULIN 30/70** must be rolled between the palms ten times and inverted ten times until the contents are uniformly mixed. Do not shake the vial as this may cause frothing which may interfere with the correct measurement of the dose.
3. If using a new vial, flip off the protective plastic cap but do not remove the rubber stopper.
4. Remove the needle cap/shield and draw air into the syringe that is equal to or slightly greater than the dose to be injected.
5. Put the needle through the rubber stopper and inject air into the HUMULIN vial. Do not remove the needle.
6. Hold the HUMULIN vial and syringe firmly in one hand and turn upside down.
7. Check the tip of the needle is in the insulin solution/suspension and withdraw the correct dose into the syringe.
8. Check the syringe for air bubbles before removing the needle from the vial as these will reduce the amount of insulin in the syringe. If bubbles are present, keep holding the syringe vertically and tap its side until the bubbles float to the top. Push them out with the syringe plunger and withdraw the correct dose.
9. Remove the needle from the vial.

Mixing two insulins

Only mix insulins if your doctor has instructed you to. Only **HUMULIN R** can be mixed with other insulins.

DO NOT mix insulins in vials with insulins in cartridges.

Follow your doctor's instructions on whether to mix your insulins ahead of time or just before giving an injection. It is important to be consistent in your method.

1. Wash your hands.
2. Just before use, roll the vial of cloudy (longer acting) insulin (**HUMULIN NPH** or **HUMULIN 30/70**) between your palms until the liquid is white and uniformly cloudy. Do not shake the vial as this may cause frothing which may interfere with the correct measurement of the dose.
3. Remove the needle cap/shield and draw air into the syringe that is equal to or slightly greater than the amount of cloudy insulin (**HUMULIN NPH** or **HUMULIN 30/70**) you are using. Insert the needle into the cloudy insulin vial and inject the air. Withdraw the needle.
4. Repeat step 3 for **HUMULIN R**, but do not withdraw the needle.
5. Hold the **HUMULIN R** vial and syringe firmly in one hand and turn upside down.
6. Check the tip of the needle is in the clear insulin (**HUMULIN R**) and withdraw the correct dose into the syringe.
7. Check the syringe for air bubbles before removing the needle from the vial as these will reduce the amount of insulin in the syringe. If bubbles are present, keep holding the syringe vertically and tap its side until the bubbles float to the top. Push them out with the syringe plunger and withdraw the correct dose.

Remove the needle from the vial of clear insulin (**HUMULIN R**).

8. Insert the needle into the vial of the cloudy insulin.
9. Turn the vial and syringe upside down.
10. Make sure the tip of the needle is in the insulin and withdraw your dose of cloudy insulin.
11. Remove the needle from the vial.

Injecting dose

HUMULIN should be injected under the skin (subcutaneously). Your doctor or diabetes educator will show you how to properly injection HUMULIN insulin. If required, HUMULIN may also be injected under the muscle (intramuscularly).

If required, HUMULIN R may be injected directly into your veins (intravenously) however, **under no circumstances should HUMULIN NPH or HUMULIN 30/70 be injected intravenously (directly into your veins).**

1. Choose your injection site (upper arms, thighs, buttocks or abdomen). **Use of injection sites should be rotated** so that the same spot is not used more than once a month.
2. Stabilise the skin by spreading it or gently pinching up a large area of skin. Insert the needle as instructed by your doctor.
3. Push the down on plunger as far as it will go.
4. **Slowly count to 5** before pulling the needle out.
5. Release the skin and apply gentle pressure over the injection site for several seconds. Do not rub the area.

After injecting

1. Dispose of your used needles, and syringes safely into a sharps container.

If you forget to use HUMULIN

Test your blood sugar level as soon as possible.

If you use less HUMULIN insulin than you need, a high blood sugar level (hyperglycaemia) may occur. Use it as soon as you remember, and then go back to using it as you would normally. **Do not use a double dose of your insulin.**

If you are unsure, talk to your doctor, diabetes educator, or pharmacist.

If you use too much HUMULIN

Hypoglycaemia (low blood sugar) may occur if you have used more HUMULIN than you need. Check your blood sugar levels.

If your blood sugar is low (mild hypoglycaemia) eat glucose tablets, sugar or drink a sugary drink. Then eat fruit, biscuits, or a sandwich. This will often resolve mild hypoglycaemia or a minor insulin overdose.

If you get worse and your breathing is shallow and your skin gets pale you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling Australia 13 11 26 / New Zealand: 0800 764 766**), or
- contact your doctor, or
- go to the Emergency department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using HUMULIN?

Things you should do

- Remind any doctor, dentist, pharmacist, and diabetes educator you visit that you are using HUMULIN.
- Monitor your blood sugar levels regularly to ensure that your dose of HUMULIN is appropriate. More frequent monitoring is recommended when changing insulin dose or type, or when you start taking a new medicine.
- Always carry a supply of HUMULIN vials and syringes.
- Always carry something to show you have diabetes.
- Always carry glucose or sugary foods in case you get hypoglycaemia (low blood sugar).

Tell your doctor

- if you become pregnant or start breastfeeding while using HUMULIN.
- if you notice changes to your eyesight. This may be a sign that your diabetes is not being controlled appropriately.
- Tell your doctor, pharmacist, or diabetes educator if you plan to travel. You may need to carry a letter explaining why you are taking injecting devices with you. Your doctor, pharmacist, or diabetes educator can provide you with some helpful information.

Things you should not do

- Do not use HUMULIN when you have hypoglycaemia (low blood sugar) as it will make it worse.
- Do not stop using HUMULIN without first checking with your doctor.
- Do not change your insulin (dose or type) without first checking with your doctor.
- Do not give your HUMULIN to anyone else, even if they have the same condition as you. Your doctor has prescribed HUMULIN specifically for you.
- **Do not share needles, vials, or syringes.**
- **Do not re-use needles or syringes.**
- Do not use HUMULIN if the packaging is torn or shows signs of tampering.
- Do not use **HUMULIN R** if the solution is cloudy, thickened, coloured, or has solid pieces in it, as it may no longer be good to use.
- Do not use **HUMULIN NPH** or **HUMULIN 30/70** if the suspension is no longer cloudy white after shaking or if it has solid pieces in it, as it may no longer be good to use.
- Do not use HUMULIN if the vial appears frosted, as it may no longer be good to use.
- Do not use HUMULIN if you think it has been frozen or exposed to excessive heat. It will not work as well.

Hypoglycaemia (low blood sugar)

Your blood sugar level may become too low if you:

- use too much HUMULIN
- exercise too much or excessively
- delay eating meals or snacks
- eat too little food
- are ill.

Symptoms of **mild to moderate** hypoglycaemia can come on suddenly, and may include:

- weakness, trembling or shaking
- sweating
- light headedness/headache
- lack of concentration
- behaviour change
- dizziness
- tearfulness/crying
- irritability
- numbness around the lips/fingers
- hunger

Tell your doctor if you have trouble recognising these symptoms, if you often have hypoglycaemia or if you have ever become unconscious after using insulin. More frequent monitoring of your blood sugar level may be recommended, or your dose of HUMULIN may need to be changed.

Recognising these mild to moderate symptoms early may allow you to take the necessary steps to avoid more serious hypoglycaemia.

Always carry some sugary food or drink with you.

If you experience symptoms of mild to moderate hypoglycaemia, immediately eat some sugary food or drink, such as jelly beans, fruit juice or glucose tablets.

If you do not feel better after eating/drinking some sugary food or drink, contact your doctor or go to the Emergency department at your nearest hospital.

Tell your relatives, friends, close workmates, or carers that you have diabetes.

It is important that they also recognise the signs and symptoms of hypoglycaemia.

Make sure they know to give you some sugary food or drink for mild to moderate symptoms of hypoglycaemia.

Severe symptoms of hypoglycaemia may include:

- disorientation
- seizures, fits, or convulsions
- loss of consciousness.

If you lose consciousness, make sure your relatives, friends, close workmates, or carers know:

- to turn you on your side and **get medical help immediately.**
- not to give you anything to eat or drink to avoid choking.

Severe hypoglycaemia can lead to unconsciousness and in extreme cases death if not treated.

An injection of the hormone glucagon may speed up recovery from unconsciousness. This can be given by a relative, friend, workmate, or carer who knows how to give it.

If glucagon is used, have some sugary food or drink as soon as you are conscious again.

Hyperglycaemia (high blood sugar)

Your blood sugar levels may become too high if you:

- miss doses of HUMULIN or use less than you need
- have uncontrolled diabetes
- exercise less than usual
- eat more carbohydrates than usual
- are ill or stressed.

Contact your doctor if your blood sugar level is too high and you experience any of the following mild to moderate symptoms:

- drowsiness
- flushed face
- thirst, loss of appetite
- fruity odour on the breath
- blurred vision
- passing larger amounts of urine than usual
- getting up at night more often than usual to pass urine
- high levels of glucose and acetone in the urine.

High blood sugar levels over a long period of time can lead to too much acid in the blood (diabetic ketoacidosis).

Contact your doctor or the Emergency Department immediately if your blood sugar level is too high and you experience any of the following severe symptoms:

- heavy breathing
- fast pulse
- nausea, vomiting
- dehydration
- loss of consciousness.

Severe hyperglycaemia can lead to unconsciousness and in extreme cases death (if left untreated).

Illness

Tell your doctor if you are ill.

Illness, especially with nausea and vomiting, may cause your insulin needs to change. Even if you are not eating, you still require insulin. You and your doctor should design an insulin plan for those times when you are sick.

Emotional disturbances

Tell your doctor if you are feeling particularly excited, upset, or stressed.

Emotional disturbances may impact your dose of HUMULIN.

Exercise

Exercise may lower your need for insulin. Exercise may also make insulin work more quickly, especially if the exercise involves the area around the injection site (e.g., the leg should not be used as an injection site prior to jogging or running).

Tell your doctor if you are exercising more than usual, as your dose of HUMULIN may need to change.

Diet

Changes to your diet may cause your insulin needs to change.

Tell your doctor before making any significant changes to your diet (e.g., removing carbohydrates).

Injection site

If you inject HUMULIN in the same place, the fatty tissue may shrink (lipoatrophy) or thicken (lipohypertrophy).

Lumps under the skin may also be caused by build-up of a protein called amyloid (cutaneous amyloidosis).

To help prevent these skin changes, **do not use the same place for injection more often than once a month.**

HUMULIN may not work very well if you inject into a lumpy, shrunken, or thickened area. **Avoid injecting into these areas.**

Tell your doctor if you are currently injecting into these affected areas before you start injecting in a different area.

Your doctor may tell you to measure your blood sugar more frequently, and to adjust your dose of HUMULIN or other antidiabetic medications.

Driving or using machines

Be careful before you drive or use any machine or tools until you know how HUMULIN affects you.

Do not drive if you feel like your blood sugar level is low.

Hypoglycaemia (low blood sugar) may impair your ability to concentrate or react while driving.

Drinking alcohol

Tell your doctor if you drink alcohol.

Alcohol may mask the symptoms of hypoglycaemia (low blood sugar) and make it more difficult to recognise them.

Alcohol may also affect the dose of HUMULIN that you are prescribed.

Looking after your medicine

- Keep your vials in a fridge between 2°C - 8°C. Do not freeze.
- You may keep the vials below 30°C for up to 28 days while you are using them. If they are only used occasionally, keep them refrigerated.
- Dispose of unrefrigerated vials after 28 days even if they still contain insulin.
- Do not store the vials in the bathroom or near a sink. Do not put the vials near heat or in the sun.
- **Keep it where young children cannot reach it.**

When to discard your medicine

Discard vials after the expiry date (month, year) stamped on the label has passed.

Getting rid of any unwanted medicine

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

Empty vials, needles, and syringes should be disposed of in a sharps container or similar puncture proof container composed of hard plastic or glass.

Ask your doctor, nurse, pharmacist or diabetes educator where you can dispose of the container once it is full.

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
<p>Blood sugar related:</p> <ul style="list-style-type: none">• Mild to moderate hypoglycaemia (low blood sugar), symptoms may include:<ul style="list-style-type: none">o weakness, trembling or shakingo sweatingo light headedness/headacheo lack of concentrationo behaviour changeo dizzinesso tearfulness/cryingo irritabilityo numbness around the lips/fingerso hunger.	<p>Immediately eat some sugary food or drink, such as jelly beans, fruit juice, or glucose tablets.</p> <p>If you do not feel better after eating/drinking some sugary food or drink, contact your doctor or go to the Emergency Department at your nearest hospital.</p>
<p>Allergy related:</p> <ul style="list-style-type: none">• Local allergy, symptoms may include redness, swelling and itching around the injection site. These symptoms generally disappear within a few weeks of continued use. <p>Skin related:</p> <ul style="list-style-type: none">• Lipodystrophy, symptoms may include a depression in the skin or an enlargement or thickening of the tissue around the injection site.<ul style="list-style-type: none">o A change in injection technique may help resolve the problem. <p>General:</p> <ul style="list-style-type: none">• Oedema (fluid retention), particularly in the ankles, feet and hands.	<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
Blood sugar related: <ul style="list-style-type: none">• Severe hypoglycaemia (low blood sugar), symptoms may include:<ul style="list-style-type: none">o disorientationo seizures, fits, or convulsionso loss of consciousness.	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. If you lose consciousness, make sure friends and family know to turn you on your side and get medical help immediately. They should <u>not</u> give you anything to eat or drink to avoid choking.
Allergy related: <ul style="list-style-type: none">• Generalised allergy, symptoms may include<ul style="list-style-type: none">o rash over a large part of the bodyo shortness of breatho wheezingo low blood pressureo swelling of the face, lips, or tongueo fast pulseo sweating	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.

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

HUMULIN is only available with a doctor's prescription.

What HUMULIN contains

Active ingredient (main ingredient)	biosynthetic human insulin (100 units per mL)
Other ingredients (inactive ingredients)	HUMULIN R <ul style="list-style-type: none">• metacresol• glycerol• hydrochloric acid• sodium hydroxide• water for injections HUMULIN NPH and HUMULIN 30/70 <ul style="list-style-type: none">• metacresol• glycerol• zinc oxide• dibasic sodium phosphate heptahydrate• protamine sulfate• phenol• hydrochloric acid• sodium hydroxide water for injections

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

What HUMULIN looks like

HUMULIN R (AUST R 14635)

HUMULIN R is available in 10 mL vials.

HUMULIN R is a clear colourless solution with a water-like appearance and consistency.

HUMULIN NPH (AUST R 14634)

HUMULIN NPH is available in 10 mL vials.

HUMULIN NPH is a white and cloudy or milky suspension.

HUMULIN 30/70 (AUST R 39656)

HUMULIN 30/70 is available in 10 mL vials.

HUMULIN 30/70 cartridges is a white and cloudy or milky suspension.

Who distributes HUMULIN?

Supplied in Australia by:

Eli Lilly Australia Pty Ltd
Level 9, 60 Margaret Street
SYDNEY NSW 2000

Supplied in New Zealand by:

Eli Lilly and Company (NZ) Limited
PO Box 109 197
Newmarket
Auckland 1149

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