

HUMULIN®

VIALS

Biosynthetic Human Insulin (rbe)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about HUMULIN.

It does not contain all the available information. It does not take the place of talking with your doctor or pharmacist.

The information in this leaflet was last updated on the date shown on the final page. More recent information on this medicine may be available. Make sure you speak to your pharmacist, nurse or doctor to obtain the most up to date information on this medicine. You can also download the most up to date leaflet from www.lilly.com.au. The updated leaflet may contain important information about HUMULIN and its use that you should be aware of.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking HUMULIN against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with this medicine.

You may need to read it again.

What HUMULIN is used for

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

Diabetes mellitus 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 mellitus:

Type 1 diabetes - also called juvenile onset diabetes.

Type 2 diabetes - also called maturity onset diabetes.

Patients with type 1 diabetes always require insulin to control their blood sugar levels.

Some patients with type 2 diabetes may also require insulin after initial treatment with diet, exercise and tablets.

HUMULIN is identical to the insulin produced by the pancreas.

There are 3 different types of HUMULIN vials:

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

Your doctor will tell you the type of HUMULIN that is best suited to you.

The duration of action of the insulin you inject will vary according to the type being used, the dose, injection site, blood flow, temperature and level of physical activity.

Your doctor may tell you to use a short acting human insulin such as HUMULIN R in combination with a longer acting human insulin such as HUMULIN NPH.

The abbreviation "rbe" indicates the method of genetic engineering used to manufacture the insulin.

This medicine is not addictive.

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

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Before you use HUMULIN

When you must not use it

Do not use HUMULIN if:

1. you have an allergy to:

- any medicine containing insulin
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- redness, swelling, rash and itching at the injection site
- rash, itching or hives on the skin
- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body.

The only time you would take this medicine if you have an allergy to it, is if your doctor has you on a desensitisation program to minimise allergic reactions.

2. you are experiencing low blood sugar levels (a "hypo").

If you have a lot of hypos discuss appropriate treatment with your doctor.

Do not use this medicine after the expiry date printed on the pack or

if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start using this medicine, talk to your doctor.

Before you start to use it

Tell your doctor if you have any allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- kidney problems
- liver problems
- overactive thyroid gland (hyperthyroidism)
- overactive adrenal glands (Cushing's syndrome)
- enlargement of the face, hands and feet (acromegaly)
- tumour of the adrenal gland (phaeochromocytoma)
- fluid retention especially in the hands, ankles or feet
- heart disease.

Tell your doctor if you are pregnant or plan to become pregnant.

Pregnancy may make managing your diabetes more difficult. Insulin needs usually decrease during the first three months of pregnancy and increase during the last six months. Your doctor can discuss with you the risks and benefits involved.

Tell your doctor if you are breast-feeding or plan to breast-feed.

Your doctor/pharmacist can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell them before you start using HUMULIN.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you

get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may affect the way HUMULIN works.

These include:

- oral hypoglycaemic medicines that are used to treat Type 2 (non-insulin dependent) diabetes
- medicines that affect your metabolism (corticosteroids such as prednisone, cortisone)
- medicines used for oral contraception
- medicines used in thyroid replacement therapy
- certain medicines used to treat tuberculosis, such as isoniazid
- medicines such as aspirin or other salicylates
- certain medicines used to treat depression
- certain medicines used to treat asthma, such as salbutamol or terbutaline
- some antibiotics
- certain medicines used to treat high blood pressure or other heart conditions
- certain medicines used to treat people with growth disorders and tumours, such as octreotide
- alcohol
- thiazolidinediones (TZDs), also used to treat type 2 diabetes; when used with insulin there may be an increased risk of fluid retention and heart disease.

Tell your doctor about any other medicines that you are taking.

This is very important. Your doctor will advise you if it is all right to keep taking them or if you should stop taking them.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while using this medicine.

How to use HUMULIN

Your doctor, diabetes education nurse or pharmacist will have shown you how to use HUMULIN.

Carefully follow all the directions.

They may differ from the information contained in this leaflet.

Do not inject HUMULIN NPH or HUMULIN 30/70 into a vein.

Any change in dose or type of insulin should be made cautiously and only under medical supervision.

If you change the type of insulin that you use, you may have to use more or less than before. This may happen with the first dose or over a period of time.

More frequent monitoring is recommended when changing insulin dose or type.

If you do not understand the instructions, ask your doctor or pharmacist for help.

How much to use

Your doctor will tell you how much HUMULIN you need to use each day.

It is very important that you manage your diabetes carefully. Too much or too little insulin can cause serious effects.

When to use it

Your doctor will tell you when to use HUMULIN.

How to use it

Checking your HUMULIN vial

Check the HUMULIN vial before each preparation and injection. Make sure you are using the correct vial.

Do not use HUMULIN NPH or HUMULIN 30/70 suspension if it is no longer a cloudy white suspension after shaking or has solid pieces in it.

Do not use HUMULIN if the vial appears frosted. This can occur

when solid white particles stick to the bottom and walls, after mixing. If this occurs, please return to the place of purchase for exchange.

Do not use HUMULIN R if it is thickened, coloured or has solid pieces in it.

Using one insulin type

1. Wash your hands.
2. If you are using cloudy insulin - just before use, roll the vial between your hands until the liquid is white and uniformly cloudy. Do not shake the vial.
3. If using a new vial, flip off the protective plastic cap, but do not remove the stopper.
4. Draw air into a U100 insulin syringe equal to the dose of insulin to be injected.
5. Put the needle through the rubber top of the vial and inject air into the vial.
6. Turn the vial and syringe upside down.
7. Make sure the tip of the needle is in the insulin and withdraw the correct dose of insulin.
8. Before removing the needle from the vial, check the syringe for air bubbles as these reduce the amount of insulin in the syringe. If bubbles are present, hold the syringe vertically and tap its side until the bubbles float to the top. Push them out with the plunger and withdraw the correct dose. Remove the needle from the vial.
9. If you need to put the syringe down, make sure the needle does not touch anything.

Mixing two insulins

Only mix insulins if your doctor has instructed you to.

Only HUMULIN R can be mixed with other insulins.

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 between your hands until the liquid is white and uniformly cloudy. Do not shake the vial.
3. Draw air into your syringe equal to the amount of cloudy insulin you are using. Insert the needle into the cloudy insulin vial and inject the air. Withdraw the needle.
4. Now inject air equal to your dose of clear (shorter-acting) insulin HUMULIN R into that vial in the same manner but do not withdraw the needle.
5. Turn the vial and syringe upside down.
6. Make sure the tip of the needle is in the clear insulin, and withdraw the correct dose into the syringe.
7. Before removing the needle from the vial, check the syringe for air bubbles as these reduce the amount of insulin in the syringe. If bubbles are present, hold the syringe vertically and tap its side until the bubbles float to the top. Push them out with the plunger and withdraw the correct dose. Remove the needle from the vial of clear insulin.
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.
12. If you need to put the syringe down, make sure the needle does not touch anything.

Do not mix insulins in vials with insulins in cartridges.

Injecting a dose

Choose a site for injection.

Inject HUMULIN in the upper arms, thighs, buttocks or abdomen.

Change the injection site so that the same position is not used more than once a month.

This will reduce the chance of local skin reactions developing.

Pinch the skin between two fingers, push the needle into the raised skin and inject the full dose of insulin under the skin. Slowly count to 5 or 6 before pulling the needle out.

Apply gentle pressure over the injection site for several seconds.

Do not rub the area.

After Injecting

Dispose of your insulin syringes safely into a yellow plastic sharps container.

Do not share needles or syringes.

How long to use it

Do not stop using your insulin unless your doctor tells you to.

If you take too much (overdose) - Hypoglycaemia

Your blood sugar level may become too low (you may experience hypoglycaemia or a "hypo") if you:

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

The first symptoms of mild to moderate hypos can come on suddenly. They may include:

- cold sweat, cool pale skin
- fatigue, drowsiness, unusual tiredness and weakness
- nervousness, anxious feeling, tremor, rapid heart beat
- confusion, difficulty concentrating
- excessive hunger
- vision changes
- headache, nausea.

Always carry some sugary food or fruit juice with you.

If you experience any of these symptoms of a hypo, immediately

eat some sugary food or have a drink, e.g. lollies, biscuits or fruit juice.

Tell your relatives, friends, close workmates or carers that you have diabetes. It is important that they recognise the signs and symptoms of a hypo.

Make sure they know to give you some sugary food or fruit juice for mild to moderate symptoms of a hypo.

If you lose consciousness, make sure they know:

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

This is because you could choke.

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, eat some sugary food or have a drink as soon as you are conscious again.

If you do not feel better after this, contact your doctor, diabetes education nurse, or go Accident and Emergency at the nearest hospital.

If you do not respond to glucagon treatment, you will have to be treated in a hospital.

See your doctor if you keep having hypo reactions, or if you have ever become unconscious after using insulin.

Your insulin dose may need to be changed.

If a severe hypo is not treated, it can cause brain damage and death.

If you miss a dose - Hyperglycaemia

If you forget your insulin dose, test your blood sugar level as soon as possible.

If you are not sure what to do, talk to your doctor, diabetes education nurse or pharmacist.

Do not use a double dose of your insulin.

If it is almost time for your next dose, skip the dose you missed and use your next dose when you are meant to.

Otherwise, use it as soon as you remember, and then go back to using it as you would normally.

Your blood sugar levels may become high (hyperglycaemia) if you:

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

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

Contact your doctor immediately if your blood sugar level is high or you recognise any of the following symptoms.

Symptoms of mild to moderate hyperglycaemia include:

- drowsy feeling
- 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.

Symptoms of severe hyperglycaemia include:

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

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

Discuss any worries you may have about this with your doctor or pharmacist.

While you are using HUMULIN

Things you must do

Measure your blood sugar levels regularly.

Make sure all friends, relatives, workmates or carers know that you have diabetes.

It is important to keep using your medicine even if you feel well.

This medicine helps to control your condition, but does not cure it.

Tell your doctor if you often have hypos (low blood sugar levels).

Your doctor may need to adjust your insulin dose.

Always carry some sugary food or fruit juice with you.

If you experience any of the symptoms of a hypo, immediately eat some sugary food or have a drink, e.g. lollies, biscuits or fruit juice.

Tell your doctor if you have trouble recognising the symptoms of hypos.

Under certain conditions, the early warning signs of hypos can be different or less obvious. Your doctor may need to adjust your insulin dose.

Make sure that you tell every doctor, dentist, pharmacist or other health care professional who is treating you that you have diabetes and are using insulin.

Tell your doctor, diabetes education nurse or pharmacist if you are travelling.

Ask your doctor for a letter explaining why you are taking injecting devices with you. Each country you visit will need to see this letter, so you should take several copies.

You may need to inject your insulin and eat your meals at different times

because of time differences in and between countries.

You may not be able to get the same type of insulin in the country you are visiting.

Your doctor, diabetes education nurse or pharmacist can provide you with some helpful information.

Tell your doctor if you are having trouble/difficulty with your eyesight.

Visual disturbances in uncontrolled diabetes are reversed during the early stages of treatment.

Once established on insulin, if your vision changes, see your doctor as soon as possible.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are using HUMULIN.

If you become pregnant while using this medicine, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are using this medicine.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Always carry a supply of HUMULIN vials and syringes with you.

Always carry something to show you have diabetes.

Things you must not do

Do not stop using your medicine unless your doctor tells you to.

Do not use this medicine if you think it has been frozen or exposed to excessive heat.

It will not work as well.

Do not use HUMULIN to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not adjust the dosage of your medicine without checking with your doctor.

Things to be careful of

Be careful driving or operating machinery until you know how the insulin affects you.

Tell your doctor if you drink alcohol.

Alcohol may mask the symptoms of hypos.

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.

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

Emotional disturbances may change your insulin needs.

Tell your doctor if you are exercising more than usual.

Exercise may lower your need for HUMULIN. Exercise may also speed up the effect of a dose of HUMULIN, especially if the exercise involves the area of injection site (e.g. the leg should not be used for injection prior to jogging or running).

Tell your doctor if your diet changes.

Changes in diet may cause your insulin needs to change.

Side effects

Tell your doctor, diabetes education nurse or pharmacist as soon as possible if you do not feel well while you are using HUMULIN.

This medicine helps most people with type 1 or type 2 diabetes, but it may have unwanted side effects in a

few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor, diabetes nurse educator or pharmacist to answer any questions you may have.

The most common side effect when using insulin is low blood sugar levels (a hypo).

Tell your doctor or pharmacist if you notice any of the following:

- hypos (mild to moderate)
- redness, swelling or itching at the injection site (local allergy)
Usually these symptoms disappear within a few weeks during continued use.
- a depression or thickening of the skin around the injection site (lipodystrophy)
- fluid retention, particularly in the ankles, feet and hands (oedema).

This list includes the more common side effects of your medicine.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

More severe symptoms of low blood sugar levels, including:

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

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

If a severe hypo is not treated, it can cause brain damage and death.

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- skin rashes over a large part of the body
- shortness of breath, wheezing

- swelling of the face, lips or tongue
- fast pulse
- sweating.

This list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After using HUMULIN

Storage

Keep your insulin in a refrigerator where the temperature is between 2°C - 8°C. Do not freeze.

While in use, the vials can be kept under refrigeration between 2°C - 8°C or at room temperature (below 30°C) for up to 28 days.

If HUMULIN vials are only used occasionally, keep them refrigerated.

Dispose of unrefrigerated vials after 28 days, even if the vial still contains HUMULIN.

Do not store HUMULIN or any other medicine in the bathroom or near a sink. Do not put it near heat or in the sun.

Keep it where children cannot reach it.

A locked cupboard or compartment at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

Dispose of your insulin syringes safely into a yellow plastic sharps container.

If your doctor tells you to stop using this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product Description

What it looks like

The HUMULIN product range is differentiated by colour and by symbols on the carton and vial labels.

HUMULIN R (regular neutral soluble human insulin (rbe)) is a clear colourless solution, with a water-like appearance and consistency. It is available in 10 mL vials. The carton and label have a golden yellow band with a white diamond symbol.

HUMULIN NPH (isophane human insulin (rbe)) is a milky or cloudy white suspension. It is available in 10 mL vials. The carton and label have a lime green band with a white square symbol.

HUMULIN 30/70 (mixture of 30% R regular neutral soluble human insulin (rbe) and 70% NPH isophane human insulin (rbe)) is a milky or cloudy white suspension. It is available in 10 mL vials. The carton and label have a tan band with a symbol consisting of a square with triangles on three sides.

Ingredients

HUMULIN R contains 100 units of insulin per mL as the active ingredient.

It also contains:

- metacresol
- glycerol
- hydrochloric acid (for pH adjustment)
- sodium hydroxide (for pH adjustment)
- water for injections.

HUMULIN NPH and HUMULIN 30/70 contain 100 units of insulin per mL as the active ingredient.

They also contain:

- metacresol
- glycerol
- zinc oxide
- dibasic sodium phosphate heptahydrate

- protamine sulfate
- phenol
- hydrochloric acid (for pH adjustment)
- sodium hydroxide (for pH adjustment)
- water for injections.

Supplier

HUMULIN is supplied in Australia by:

Eli Lilly Australia Pty. Ltd
Level 9, 60 Margaret Street
Sydney NSW 2000
AUSTRALIA

HUMULIN is supplied in New Zealand by:

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

Australian Registration Numbers

HUMULIN R vials
AUST R 14635

HUMULIN NPH vials
AUST R 14634

HUMULIN 30/70 vials
AUST R 39656

Further Information

You can get more information about diabetes and insulin from:

Diabetes Australia

- freecall helpline 1300 136 588
- www.diabetesaustralia.com.au

Diabetes New Zealand

- tollfree helpline 0800 DIABETES
(0800 342 238)
- www.diabetes.org.nz

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