

Core CMI for Human and Analogue Insulins (*text in italics is instructional for the CMI writer only*)

[Medicine name][®] (*If you want to include phonetic spelling, the Second Edition of the Usability Guidelines suggests using the system outlined in the Webster's International Dictionary*).

Generic name

For copy of a large print leaflet, please telephone [insert relevant Company telephone number] or visit [insert Company website address]

Consumer Medicine Information

Date of Dispensing

Consumer Name

Pharmacist Name

Consumer Address

Pharmacist Address

Consumer Address

Pharmacist Address

This Core leaflet covers both human and analogue insulin injectable products, and therefore must be modified to suit the particular product being written about.

What is in this leaflet¹

This leaflet answers some common questions about [Medicine name].

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

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

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

Keep this leaflet with the medicine. You may need to read it again.

What [Medicine name] is used for

Your medicine 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.

[Medicine name] is identical to the insulin produced by the pancreas.

There are 'x' different types of this medicine (*include if this is appropriate and include the names of the different types*).

As appropriate, include a description of the type of insulin, e.g. human insulin, analogue.

Your doctor will tell you the type of insulin 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 [Medicine name] in combination with a longer acting human insulin such as [Medicine name].

The abbreviation "rys" or "rbe" (*as appropriate*) indicates the method of genetic engineering used to manufacture this insulin.

If appropriate, include the statement: A neutral solution of human insulin is also used by doctors in emergency situations to treat some people without diabetes.

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.

¹ Depending on the length of the CMI, consider using a table of contents (see Second Edition of the Usability Guidelines)

Core CMI for Human and Analogue Insulins *(text in italics is instructional for the CMI writer only)*

Before you use [Medicine name]

When you must not use it

Include all relevant

Contraindications that appear in the PI (examples below).

Do not use the medicine 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.
- *(add any other specific reactions listed in the PI).*

2 you are experiencing a low blood sugar level (a “hypo”) when the dose is due.

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

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

Do not use this medicine/it 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.

Before you start to use it

Include all relevant information from the Precautions section of the PI (examples below). Do not duplicate any information from the previous section.

Tell your doctor if you have 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;
- *other relevant medical conditions as per the PI*

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.

Any other precautions, as per PI.

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

Taking other medicines

Tell your doctor 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 and [Medicine name] may interfere with each other. These include:

- oral hypoglycaemic medicines that are used to treat type 2 (non-insulin dependent) diabetes.
- non-selective beta-blocking agents used to treat high blood pressure and certain heart conditions.
- some medicines used to treat asthma, such as salbutamol or terbutaline.
- *other medicines as noted in the PI.*

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 [Medicine name]

The following information will be product specific, and consistent with the approved PI. The subheadings and order of information is suggested, but will depend upon the particular product and the amount of information to be given.

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

Carefully follow all the directions. They may differ from the information contained in this leaflet.

Include or reference any special device instructions.

If relevant, include the statement:

Do not inject [Medicine name] 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.

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

Core CMI for Human and Analogue Insulins (*text in italics is instructional for the CMI writer only*)

How much to use

Your doctor will tell you how much of this medicine 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 your medicine.

Include, as appropriate, product specific instructions, e.g. before food.

How to use it

Checking your [Medicine name] vial/cartridge/pen (*as appropriate*):

Check the vial/cartridge/pen (*as appropriate*) **before each preparation and injection. Make sure you are using the correct vial/cartridge/pen** (*as appropriate*).

Include product specific information. For example:

Do not use this medicine if it is no longer a cloudy white suspension after shaking or if it has bits in it.

AND/OR

Do not use this medicine if the vial/cartridge/pen (*as appropriate*) **appears frosted. This can occur when solid white particles stick to the bottom and walls after mixing. If this occurs, return the vial/cartridge/pen** (*as appropriate*) **to the place of purchase for exchange.**

AND/OR

Do not use this medicine if it is thickened, coloured, or has solid bits in it.

AND/OR

Always check your insulin injection device for insulin flow (priming) before use.

The priming procedure may highlight a malfunction with your insulin injection device. Priming also removes any air bubbles and helps

indicate whether or not a needle is broken.

Include, as appropriate, product specific instructions for vials/cartridges/pens.

For insulin vials

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. draw air into a U100 insulin syringe equal to the dose of insulin to be injected.
4. put the needle through the rubber top of the vial and inject air into the vial.
5. turn the vial and syringe upside down.
6. make sure the tip of the needle is in the insulin and withdraw the correct dose into the syringe.
7. *include an instruction to check for air in the syringe. For example:*
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 (*for clarity, advise which end should be up*) 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.
OR
pull the needle out of the vial. Expel any air from the syringe and check that the dose is correct.
8. 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.

If appropriate include product specific instructions concerning incompatibility 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 the 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 without drawing up any insulin.
4. draw air into the syringe equal to the amount of clear (shorter-acting) insulin you are using. Insert the needle into the clear (shorter-acting) insulin vial and inject the air. 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. *include an instruction to check for air in the syringe. For example:*
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 (*for clarity, advise which end should be up*) 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.
OR
pull the needle out of the clear insulin vial. Expel any air from the syringe and check that the dose is correct.
8. insert the needle into the vial of the cloudy insulin.
9. turn the vial and syringe upside down.

Core CMI for Human and Analogue Insulins (*text in italics is instructional for the CMI writer only*)

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.

Injecting a dose**Choose a site for injection.**

Inject the medicine into the abdomen, thighs, upper arms or buttocks (*as appropriate*).

Change the injection site so that the same position is not used more often 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 and syringes.

For insulin cartridges/pens

If appropriate, include product specific instructions on the device to be used with the cartridge/pen.

Include product specific instructions for loading the cartridge/pen, attaching the needle and administering the insulin injection.

Preparing a dose

1. wash your hands.
2. if your cartridge is already inside your pen, check the amount of insulin remaining. *As appropriate, insert product specific instructions on when to change the cartridge/pens, e.g. when there is not enough insulin for the next dose*

3. if you are using cloudy insulin, just before use, roll the cartridge/pen of insulin between the palms 10 times and invert 10 times until the suspension appears uniformly cloudy or milky. Do not shake. Inspect the cartridge/pen for uniform mixing and roll it again if necessary.
4. put the cartridge into the pen. (*where applicable*)
5. attach a needle. (*insert product specific needle instructions*)

Checking for insulin flow (Priming)

1. remove the needle cap.
2. set the dose to 1 or 2 units.
3. hold the pen with the needle pointing up and tap the side of the pen so that any bubbles float to the top.
4. with the pen still pointing up, press the injection button. Do this until a drop or stream of insulin comes out of the needle. This is very important to help make sure you inject the correct dose.
5. repeat steps 2-4 until you see a drop of insulin at the needle tip. If a drop of insulin still does not appear.....(*include product specific information on failure to prime instructions*)
6. only dial up your required dose after you see a drop of insulin at the needle tip. There may still be some small air bubbles left in the cartridge. These are harmless.
7. if the air bubble is too big, you should prime the cartridge/pen again.
8. if you need to put the pen down, make sure the needle does not touch anything.

Injecting a dose**Choose a site for injection.**

Inject the medicine into the abdomen, thighs, upper arms or buttocks (*as appropriate*).

Change the injection site so that the same position is not used more often 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

Using the outer needle cap, unscrew the needle and dispose of it safely into a yellow plastic sharps container.

Do not share needles, cartridges and pens.

Leave the cartridge in the pen until it needs to be replaced.

Include other product specific information, as appropriate.

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 of this medicine ,
- have too much or unexpected exercise
- delay eating meals or snacks
- eat too little food
- are ill
- *product specific information.*

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

Core CMI for Human and Analogue Insulins *(text in italics is instructional for the CMI writer only)*

- 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 sugary 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 sugary drink as soon as you are conscious again.

If you do not feel better after this, contact your doctor, diabetes education nurse, or the closest 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
- *product specific information.*

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 you doctor or pharmacist.

While you are using [Medicine name]

Things you must do

Measure your blood sugar level regularly.

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

Keep using your insulin even if you feel well.

It 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.

Core CMI for Human and Analogue Insulins (*text in italics is instructional for the CMI writer only*)**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.

The following are some examples from the Usability Guidelines.

Choose whichever is appropriate or amend as necessary. Add additional information as per PI.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are using [Medicine name].**If you become pregnant while taking this medicine, tell your doctor immediately.****If you are about to have any blood tests, tell your doctor that you are using this medicine.****Things you must not do****Do not stop using your medicine unless your doctor tells you to.****Do not use the medicine if you think it has been frozen or exposed to excessive heat.**

It will not work as well.

If relevant, include the following statement:

Do not use empty cartridges again.**Do not use this medicine 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.**

Any other instructions, as per PI.

Things to be careful of

Add helpful hints relevant to the product.

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 exercising more than usual.

Exercise may lower your need for this medicine. Exercise may also speed up the effect of a dose of it, especially if the exercise involves the area of the 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 [Medicine name].

This medicine helps most people with (indication), 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 education nurse or pharmacist to answer any questions you may have.**

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

The side effects listed for a particular product will depend on the PI and the company's disclosure policy.

Take care to include only those symptoms that the consumer can detect and do something about (refer to glossary of plain-English terms available from Medicines Australia or the ASMI website www.asmi.com.au).

The following possible side effect lists are placed in order of increasing urgency of the behaviour required. You may need to include one or more lists, depending on the PI.

Take care not to duplicate side effects in more than one list so the consumer is not confused about the action that is required.

Add side effects in dot points, grouping like symptoms to keep the lists as short as possible.

Tell your doctor if you notice any of the following and they worry you:

- 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).
- other mild side effects, as per PI.

Core CMI for Human and Analogue Insulins *(text in italics is instructional for the CMI writer only)*

This list includes the more common side effects of your medicine. They are usually mild and short-lived (if consistent with the PI).

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
- other very serious side effects, as per PI.

This list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare *(if consistent with the frequencies in the PI)*.

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 [Medicine name]

This information will be product specific. Following are some examples from the Usability Guidelines. Choose whichever is appropriate or amend as necessary.

Storage

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

Include product specific storage information, such as in use shelf life etc.

Keep it where children cannot reach it.

Disposal

Dispose of your insulin syringes, needles and disposable injection devices 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

This information will be product specific. Following are some examples from the Usability Guidelines. Choose whichever is appropriate or amend as necessary.

What it looks like

Include markings, colour and consistency of liquids, pack sizes, etc.

Ingredients

[Medicine name] contains x IU of *(generic name)* as the active ingredient. It also contains:

- *list excipients in dot points*

Where Australia New Zealand Food Standard codes exist, these could follow each Australian Approved name.

Manufacturer/Distributor/Supplier

(use appropriate heading)

[Medicine name] is made/distributed/supplied in Australia by:

Include name and address of sponsor

® = Registered Trademark or

™ = Trademark *(if appropriate)*

This leaflet was prepared in month/year.

Include AUST R number(s)

You may want to include a document code and/or a reference to the approved PI.

Further information

You can get more information about diabetes and insulin from Diabetes Australia:

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

Include instructions for use section where applicable (disposable injector devices).