Actrapid® 10 mL vial, Protaphane® 10 mL vial

Insulin (rys)

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 Actrapid® and/or Protaphane®?

Actrapid® and Protaphane® vials contain the active ingredient insulin (rys). Actrapid® and Protaphane® are used to treat diabetes mellitus.

For more information, see Section 1. Why am I using Actrapid® and/or Protaphane®? in the full CMI.

2. What should I know before I use Actrapid® or Protaphane®?

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

Do not use if you are experiencing low blood sugar ("hypo") when your dose is due.

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 Actrapid® or Protaphane®? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with insulin 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 Actrapid® and Protaphane vials?

Carefully follow all instructions given to you by your doctor, nurse educator and pharmacist regarding how to use your medicine, including preparing and injecting it.

More instructions can be found in Section 4. How do I use Actrapid® and Protaphane® vials? in the full CMI.

5. What should I know while using Actrapid® or Protaphane®?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you have diabetes and are using insulin. • Monitor your blood sugar levels regularly • Carry some sugary food or fruit juice with you, in case you experience hypoglycaemia ("a hypo").
Things you should not do	• Do not stop using this medicine unless directed by your doctor to. • Do not refill your insulin vials. • Do not share your insulin or needles with anyone.
Driving or using machines	• If your blood sugar is low or high, your concentration and ability to react might be affected, and, therefore, also your ability to drive or operate machines.
Drinking alcohol	• Alcohol may mask the symptoms of hypos. If you drink alcohol, your need for insulin may change.
Looking after your medicine	• Store Actrapid® and Protaphane® in the fridge between 2 and 8°C • Do not keep in a refrigerator, vials that you are using, or that you are carrying as a spare. You can use them up to 4 weeks after taking them out of the refrigerator. Discard any unused insulin after 4 weeks.

For more information, see Section 5. What should I know while using Actrapid® or Protaphane®? in the full CMI.

6. Are there any side effects?

The most common side effect when using insulin is low blood sugar levels (a hypo). Tell your relatives, friends, close workmates, teachers or carers that you have diabetes. It is important that they can recognise the signs and symptoms of a hypo. 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.

Actrapid® 10 mL vial, Protaphane® 10 mL vial

Active ingredient: *insulin (rys)*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Actrapid® and Protaphane 10 mL vials. **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 Actrapid or Protaphane vials.**

Where to find information in this leaflet:

1. Why am I using Actrapid® and/or Protaphane® ?
2. What should I know before I use Actrapid® or Protaphane® ?
3. What if I am taking other medicines?
4. How do I use Actrapid® and Protaphane® vials?
5. What should I know while using Actrapid® or Protaphane® ?
6. Are there any side effects?
7. Product details

1. Why am I using Actrapid® and/or Protaphane® ?

Actrapid® and Protaphane® vials contain the active ingredient insulin (rys).

Insulin (rys) is characterised by being identical to natural human insulin. The abbreviation "rys" indicates the method of genetic engineering used to manufacture the insulin.

Actrapid® and Protaphane® are used to treat diabetes mellitus.

Diabetes mellitus is a condition where your pancreas does not produce enough insulin to control your blood sugar (glucose) level. Extra insulin is therefore needed.

There are two types of diabetes mellitus:

Type 1 diabetes

Type 2 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 to control their blood sugar levels if initial treatment with diet, exercise and tablets is not enough.

Actrapid® is neutral insulin injection, a fast-acting insulin. This means that it will start to lower your blood sugar level about half an hour after you inject it, and the effect will last for approximately 8 hours.

Actrapid® often used in combination with longer-acting insulin products.

Actrapid® vials are also used by doctors to treat some people with diabetes in emergency situations.

Protaphane® is isophane insulin injection, an intermediate-acting insulin. This means that it will start to lower your blood sugar level about one and a half hours after you inject it, and the effect will last for approximately 24 hours.

Protaphane® is often used in combination with fast- or rapid-acting insulin products.

As with all insulins, the duration of action will vary according to the type of insulin, the dose, injection site, blood flow, temperature and level of physical activity

Insulin is not addictive. Insulin is available only with a doctor's prescription.

Actrapid® and Protaphane® vials are for use with U100 insulin syringes.

2. What should I know before I use Actrapid® or Protaphane® ?

Warnings

Do not use Actrapid® or Protaphane®:

- If you are allergic to insulin, or any product containing insulin, or any of the ingredients listed at the end of this leaflet.
- If you are experiencing low blood sugar level (a hypo) when your dose is due.
- If the expiry date printed on the pack has passed, or if the packaging is torn or shows signs of tampering.
- if the protective colour-coded, tamper-proof plastic cap is loose or missing.
- In insulin infusion pumps

Do not inject Protaphane® into a vein.

Check with your doctor if you:

- are experiencing a lot of hypos, and follow their advice
- have any other medical conditions, such as: kidney liver, adrenal gland, pituitary gland or thyroid gland problems
- take any medicines for any other condition
- have an infection or fever
- are planning to travel

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 can make managing your diabetes more difficult, and may require adjustment of how much insulin you need.

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

Heart disease or a history of stroke

Tell your doctor as soon as possible if you experience signs of heart failure such as unusual shortness of breath or rapid increase in weight or localised swelling (oedema). Some patients with long-standing type 2 diabetes mellitus and heart disease or previous stroke, and who are treated with a class of medicines known as thiazolidinediones in combination with insulin can develop heart failure.

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.

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

Medicines that may <u>increase</u> the effect of insulin, and therefore reduce insulin requirements include:

- other medicines used to treat type 2 diabetes
- octreotide - used to treat gastrointestinal endocrine tumours and enlargement of parts of the body (e.g. hands, feet, head) caused by abnormal growth hormone levels
- lanreotide - used to treat enlargement of parts of the body (e.g. hands, feet, head) caused by abnormal hormone levels
- monoamine oxidase inhibitors (MAOIs) - used to treat depression
- non-selective beta-blockers - used to treat certain heart conditions and high blood pressure
- alpha-blockers - used to treat high blood pressure and to relieve difficulty in passing urine caused by an enlarged prostate
- angiotensin converting enzyme (ACE) inhibitors - used to treat certain heart conditions, high blood pressure and elevated protein/albumin in the urine
- salicylates, e.g. aspirin - used to relieve pain and lower fever
- anabolic steroids - used to promote growth
- quinine - used to treat malaria and relieve muscle cramps
- quinidine - used to treat heart problems
- sulphonamides - a type of antibiotic used to treat bacterial infections.

Medicines that may <u>reduce</u> the effect of insulin, and increase insulin requirements include:

- oral contraceptives ("the pill") - used for birth control
- thiazides, frusemide or ethacrynic acid - used to treat high blood pressure or fluid retention (oedema)
- glucocorticoids (except when applied locally) - used to treat inflammatory conditions
- thyroid hormones - used to treat malfunction of the thyroid gland
- sympathomimetics - used to treat asthma
- octreotide - used to treat gastrointestinal endocrine tumours and enlargement of parts of the body (e.g. hands, feet, head) caused by abnormal growth hormone levels
- lanreotide - used to treat enlargement of parts of the body (e.g. hands, feet, head) caused by abnormal hormone levels
- growth hormone - used to treat growth disorders
- diazoxide - used to treat high blood pressure
- asparaginase - used to treat leukaemia and lymph gland tumours
- nicotinic acid - used to treat high cholesterol levels in the blood
- oxymetholone - used to treat certain blood disorders
- danazol - used to treat endometriosis, menorrhagia, fibrocystic breast disease and hereditary angioedema.

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

4. How do I use Actrapid® and Protaphane® vials?

How much to use

Carefully follow all instructions given to you by your doctor, nurse educator and pharmacist regarding how to use your medicine.

- Your doctor or diabetes education nurse 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 Actrapid® and/or Protaphane®

- Your doctor or diabetes education nurse will tell you when and how often to inject your insulin.

How to inject Actrapid® and/or Protaphane® from a vial

- Use U100 insulin syringes.
- Inject insulin under the skin (subcutaneous injection) as shown to you by your doctor or diabetes education nurse.
- Check each vial before every preparation and injection to make sure you are using the correct type and strength of insulin.
- Remove the protective cap.
- Disinfect the rubber membrane with a medicinal swab.
- **Do not use your Actrapid® vial unless the insulin appears clear and colourless. Do not use it if the insulin appears thickened or has bits in it.**
- **Do not use your Protaphane® vial if the insulin is no longer a cloudy, white suspension after rolling (see below), or if it has bits in it.**

Preparing one insulin type for injection

- Wash your hands.
- If you are using Protaphane® - just before use, roll the vial between your hands until the liquid is white and uniformly cloudy. Do not shake the vial.

- Draw air into a U100 syringe equal to the dose of insulin to be injected.
- Insert the needle into the vial and inject the air into the vial.
- Turn the vial and syringe upside down.
- Make sure that the tip of the needle is in the insulin and withdraw the correct insulin dose into the syringe.
- Then pull the needle out of the vial. Expel any air from the syringe and check that the dose is correct.
- If you need to put the syringe down, make sure the needle does not touch anything

Mixing two types of insulin for injection

- **Only mix insulins if your doctor or diabetes education nurse has instructed you to.**
- Follow your doctor's or diabetes education nurse's instructions on whether to mix your insulins ahead of time or just before you inject. It is important to be consistent in your method.
- Wash your hands.
- Roll the vial of Protaphane® (cloudy insulin) between your hands until the liquid is white and uniformly cloudy. Do not shake the vial.
- Draw air into the syringe equal to the dose of Protaphane® you are using.
- Insert the needle into the Protaphane® vial and inject the air. Withdraw the needle without drawing up any insulin.
- Draw air into the syringe equal to the dose of the fast- or rapid-acting (clear) insulin you are using.
- Insert the needle into the vial of clear insulin and inject the air. Do not withdraw the needle.
- Turn the vial and syringe upside down.
- Make sure the tip of the needle is in the clear insulin and withdraw the correct dose of clear insulin into the syringe.
- Pull the needle out of the vial of clear insulin. Expel any air from the syringe and check that the dose is correct.
- Insert the needle into the vial of Protaphane®.
- Turn the vial and syringe upside down.
- Make sure the tip of the needle is in the insulin and withdraw the correct dose of Protaphane® into the syringe.
- Remove the needle from the vial. Expel any air from the syringe and check that the dose is correct.
- If you need to put the syringe down, make sure the needle does not touch anything.
- **Always mix the two insulins in the same order as described above.**

Choose a site for injection

- **Inject the medicine into the abdomen, thighs, upper arms or buttocks.** Note that your insulin will work more quickly if you inject into the abdomen.
- Change the injection site so that the same position is not used more often than once a month. This reduces the risk of developing lumps or skin pitting.
- 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 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.**
- If you are using Actrapid®, it is recommended that you eat a meal or a snack containing carbohydrate within 30 minutes of the injection.
- **Do not share needles and syringes.**

If you forget to inject your insulin - hyperglycaemia

Actrapid® and Protaphane® must be used strictly as advised by your doctor or nurse educator.

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 inject 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.

If you are using Actrapid®, make sure you eat some carbohydrate within 30 minutes of the injection.

If you use too much insulin - hypoglycaemia

If you think that you have used too much insulin, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), 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 Actrapid® or Protaphane®?

Hypoglycaemia

Your blood sugar level may become too low (you may experience hypoglycaemia (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.

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.

Do not inject any insulin if you feel a hypo coming on.

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 as you may 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.

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 convulsions, brain damage and even death.

Hyperglycaemia

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.

Things you should do

Measure your blood sugar levels regularly.

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

If your child has diabetes, it is important to tell their teachers and carers.

Keep using your insulin even if you feel well. It helps to control your diabetes, but does not cure it.

Always carry some sugary food or fruit juice with you.

Tell your doctor if you are feeling sick, especially if you are experiencing nausea or vomiting.

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

Remind any doctor, dentist or pharmacist you visit that you have diabetes and are using insulin.

Tell your doctor if your diet changes or you are exercising more.

Tell your doctor if you notice any skin changes at the injection site.

The injection site should be rotated to help prevent changes to the fatty tissue under the skin, such as skin thickening, skin shrinking or lumps under the skin. The insulin may not work very well if you inject into a lumpy, shrunken or thickened area. Change the injection site with each injection to help prevent these skin changes.

Things you should not do

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

Do not refill your insulin vials.

Do not give your insulin to anyone else, even if they have diabetes.

Do not share needles.

Drinking alcohol

Tell your doctor if you drink alcohol.

Alcohol may mask the signs of a hypo. Carefully monitor your blood sugar levels when drinking.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how the insulin affects you.

If your blood sugar is low or high your concentration and ability to react might be affected, and therefore also your ability to drive or operate a machine.

Bear in mind that you could endanger yourself or others. Please ask your doctor whether you can drive a car, especially if:

• you have frequent hypos

• you find it hard to recognise hypos.

Looking after your medicine

- Store Actrapid® and Protaphane® 10 mL vials between 2°C and 8°C in the refrigerator (away from the cooling element).
- Vials that you are using, or that you are carrying as a spare, should not be kept in a refrigerator.
- **Protect the insulin in the 10 mL vials from light by keeping them in their cartons when not in use.**
- Do not allow vials to be frozen, or exposed to excessive heat or light.
- **Never use Actrapid® 10 mL vials if the solution is not clear and colourless.**
- **Never use Protaphane® 10 mL vials if the suspension does not become white and uniformly cloudy after resuspending**

Keep it where young children cannot reach it.

In an emergency, Actrapid® 10 mL vial is suitable for injection into a muscle intramuscular administration) or into a vein (intravenous administration) but only by a doctor.

Discard the vial after emergency use.

When to discard your medicine

You can use Actrapid® and Protaphane® vials up to 4 weeks after taking them out of the refrigerator if kept below 25°C.

Discard the vial after 4 weeks even if there is still some insulin left in it.

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.

Never use insulin after the expiry date printed on the vial label and carton after 'Expiry'. The expiry date refers to the last day of that month.

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
Hypoglycaemia (mild to moderate): • 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. **Injection site reactions:** • redness, swelling or itching at the injection site • a depression or thickening of the skin around the injection site. Other effects when you first start using insulin: • visual problems • swelling of your hands • swelling of your feet.	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Serious side effects

Serious side effects	What to do
Hypoglycaemia (severe): • disorientation • seizures, fits, convulsions • loss of consciousness. **Severe allergy - anaphylaxis:** • skin rashes over a large part of the body • shortness of breath, wheezing • swelling of the face, lips or tongue • fast pulse • 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

Insulin is only available with a doctor's prescription.

What Actrapid® 10 mL vial contains

Active ingredient (main ingredient)	Insulin (rys) 100 IU/mL
Other ingredients (inactive ingredients)	glycerol metacresol zinc chloride Water for Injection. hydrochloric acid and sodium hydroxide to adjust the pH.

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

What Protaphane® 10 mL vial contains

Active ingredient (main ingredient)	Isophane insulin (rys) 100 IU/mL
Other ingredients (inactive ingredients)	glycerol metacresol phenol dibasic sodium phosphate dihydrate zinc chloride protamine sulfate Water for Injection. hydrochloric acid and sodium hydroxide to adjust the pH.
Potential allergens	Protamine sulfate is derived from fish

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

What Actrapid® vial looks like:

Actrapid® is a clear, colourless solution for subcutaneous injection, contained in a 10 mL glass vial. (AUST R 169625)

What Protaphane® vial looks like

Protaphane® is a white, cloudy suspension for subcutaneous injection, contained in a glass vial. (AUST R 169637)

Who distributes Actrapid® and Protaphane® 10 mL vial

Actrapid® and Protaphane ® 10 mL vials are supplied in Australia by:

Novo Nordisk Pharmaceuticals Pty Ltd

Level 10

118 Mount Street

North Sydney NSW 2060

Australia

Further information

For further information call Novo Nordisk Medical Information on 1800 668 626.

www.novonordisk.com.au

You can also get more information about diabetes from

Diabetes Australia:

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

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