

Highly Purified Bovine Insulin

### **Consumer Medicine Information**

### What is in this leaflet

This leaflet answers some common questions about **Hypurin**. 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 more information about this medicine than is contained in this leaflet. Also your doctor has had the benefit of taking a full and detailed history from you and is in the best position to make an expert judgement to meet your individual needs.

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

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

# What Hypurin is used for

Hypurin is used to treat diabetes mellitus, a condition in which the body does not produce enough insulin or else the body tissues are not able to use the insulin present. This condition leads to hyperglycaemia (too much sugar in the blood).

There are two types of **Hypurin** available:

- Hypurin Neutral a fast acting insulin
- Hypurin Isophane a slower acting sustained release insulin

There are two types of diabetes mellitus:

- Type I, which is insulin dependent
- Type II, also called non-insulindependent diabetes mellitus (NIDDM) or maturity onset diabetes

Hypurin Neutral is a sterile clear solution. Hypurin Isophane is a sterile milky white suspension; both consist of highly purified bovine (beef) insulin.

### Before you use Hypurin

### When you must not use it

### Do not use Hypurin if:

- you have an allergy to bovine insulin or to any of the ingredients listed at the end of this leaflet.
   Signs of an allergic reaction may include redness, swelling and itching at the injection site, rash, shortness of breath, fast
- you are experiencing hypoglycaemia (low blood sugar).

pulse or sweating

- your Hypurin Neutral is no longer clear or has solid pieces in it
- your Hypurin Isophane is no longer a cloudy white suspension after shaking or has solid pieces in it
- the packaging is torn or shows signs of tampering or the product does not look right
- 6. the expiry date (EXP) printed on the pack has passed

### Before you start to use it

### Tell your doctor if:

- 1. you have any allergies to any other medicines or any other substances such as foods, preservatives or dyes
- 2. you have or have had any medical conditions, especially the following:
  - · liver problems
  - · kidney problems
  - adrenal, pituitary or thyroid problems
  - · heart problems
- you are pregnant or intend to become pregnant. Insulin requirements may change during pregnancy.
- 4. you are breast feeding or plan to breast feed
- 5. Also tell your doctor if:
  - you ever drink alcohol
  - you do not eat regular meals
  - you do a lot of exercise
  - you are ill or feeling unwell.

Alcohol, diet, exercise and your general health all strongly affect the control of your diabetes.

Discuss these things with your doctor.

### Taking other medicines

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

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Some medicines may affect the way **Hypurin** works. These include:

- alcohol
- · oral contraceptives
- thyroid hormones
- some medicines used to treat depression eq. MAOI's
- medicines that affect your metabolism eq. corticosteroids
- some medicines used to treat arthritis, pain and inflammation eg. aspirin or other salicylates
- some medicines used to treat tuberculosis eg. isoniazid
- some medicines used to treat cancer eg. cyclophosphamide
- some medicines used to treat high blood pressure and angina eg. beta-blockers
- diuretics, also known as fluid tablets eg. thiazides
- some medicines used to treat mental illness or psychotic disorders eg. chlorpromazine
- some asthma medicines, cough and cold preparations containing sympathomimetic agents eg. salbutamol, adrenaline

You may need different amounts of your medicine or you may need to take different medicines. Your doctor or pharmacist has more information on medicines to be careful with or avoid while using **Hypurin**.

### How to use Hypurin

Follow all directions given to you by your doctor or pharmacist.
They may differ from the information contained in this leaflet.

### How much to use

Your doctor will determine how much **Hypurin** you need to use each day. The dose you require will depend on the severity of your diabetes.

Insulin requirements may increase at times (for example, during infection, puberty, pregnancy or emotional upsets) and unless the dosage is adjusted, symptoms of hyperglycaemia may appear. Your doctor may tell you to mix the shorter acting **Hypurin Neutral** with a proportion of the longer acting **Hypurin Isophane**.

Be very careful if you change the type of insulin you use particularly if you have been using another commercially available brand. You may need to use more or less than before.

### How to use it

Hypurin should be injected under the skin in the upper arms, thighs, buttocks or abdomen.

Hypurin Isophane should not be given intravenously.

Hypurin Neutral may be given intramuscularly or if a very rapid effect is required, intravenously.

Vary the injection area so that you do not use the same site more than about once a month. Do not massage the injection site.

Only use syringes designed for use with 100 U insulins.

#### Filling the syringe

- 1. Wash your hands thoroughly.
- Wipe the rubber seal of the vial with an alcohol swab.
- 3. If using **Hypurin Isophane** gently shake the vial.
- Draw air into the syringe equal to the amount of insulin to be injected.
- 5. Push the needle through the rubber seal and inject air into the vial.
- Invert the vial and syringe taking care that the tip of the needle remains below the surface of the liquid and slowly withdraw the plunger until the syringe contains more insulin than required.
- Return the plunger to the correct mark to expel any air bubbles. The rubber stopper seals itself as the needle is withdrawn.

#### Mixing insulins

Never mix one type of insulin with another unless your doctor tells you to.

If your doctor has told you to mix Hypurin Neutral with Hypurin Isophane proceed as follows:

- 1. Wash your hands.
- 2. Wipe the rubber seal of the **Isophane** vial with an alcohol swab.
- Inject air, equivalent to the amount of insulin to be removed, into the vial containing the **Hypurin Isophane** but do not withdraw the dose yet.
- Similarly, inject air into the vial containing the Hypurin Neutral insulin and withdraw the dose in the usual way.
- Re-insert the needle into the vial of **Hypurin Isophane** and withdraw the amount required into the same syringe.
- 6. Inject the insulin immediately.

### Giving the injection

- 1. Any of the following sites may be used: upper arm, buttocks, upper thighs, lower abdomen.
- Pinch up the skin and thrust the needle at an angle between 45° and 90° so that the tip lies just beneath the skin.
- 3. Check that the needle has not entered a blood vessel by gently pulling back the plunger a little if blood appears in the syringe, make the injection elsewhere.
- 4. Release the skin, push the plunger home to empty the syringe and pull the needle out.
- Press gently but firmly on the injection site for a few seconds with your finger afterwards but do not massage the site.

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#### When to use it

Your doctor will tell you when to use your **Hypurin**.

### How long to use it

# Continue using Hypurin for as long as your doctor recommends.

Make sure you keep enough **Hypurin** to last over weekends and holidays. It is important to keep using your medicine even if you feel well.

# If you use too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, if you think that you or anyone else may have used too much Hypurin. Do this even if there are no signs of discomfort or poisoning.

If you use too much **Hyupurin** you may experience symptoms of hypoglycaemia due to the level of sugar in the blood becoming too low.

At the first signs of hypoglycaemia, raise your blood sugar quickly by eating some jelly beans, sugar or honey, a sugar containing soft drink or glucose tablets.

# While you are using Hypurin

### Things you must do

If you become pregnant while using Hypurin, tell your doctor.

If you are about to start using any new medicines, tell your doctor and pharmacist that you are using Hypurin.

Tell all doctors, dentists, and pharmacists who treat you that you are using Hypurin.

Make sure you, your friends, family and work colleagues can recognise the symptoms of hypoglycaemia and hyperglycaemia and know how to treat them.

If you experience any of the symptoms of *hypoglycaemia*, you need to raise your blood glucose urgently. You can do this by taking one of the following:

- 5-7 jelly beans
- 3 teaspoons of sugar or honey
- ½ can of ordinary (non-diet) soft drink
- 2-3 concentrated glucose tablets

Unless you are within 10 to 15 minutes of your next meal or snack, follow up with extra carbohydrates eg plain biscuits, fruit or milk - when over the initial symptoms. Taking this extra carbohydrate will prevent a second drop in your blood glucose level.

If your blood glucose is not properly controlled, you may experience *hypoglycaemia* (low blood glucose) or *hyperglycaemia* (high blood glucose).

## Hypoglycaemia – what to look for

Low blood glucose can occur suddenly. Signs may include:

- · weakness, trembling or shaking
- sweating
- lightheadedness, dizziness, drowsiness or lack of concentration
- · tearfulness or crying
- irritability
- hunger, headache
- numbness around the lips and tongue.
- blurred vision

If not treated promptly, these may progress to:

- loss of co-ordination
- · slurred speech
- confusion
- · loss of consciousness or fitting.

The risk of hypoglycaemia is increased in the following situations:

- too much **Hypurin**
- delayed meal or snack
- · too little food
- too much or unexpected exercise.

# Hyperglycaemia – what to look for

Signs of high blood glucose may include:

- · lethargy or tiredness
- headache
- thirst
- · passing large amounts of urine

If you experience any of the signs of high blood glucose (hyperglycaemia), contact your doctor immediately.

The risk of hyperglycaemia is increased in the following situations:

- undiagnosed or uncontrolled diabetes
- illness, infection or stress
- too little Hypurin
- certain other medicines
- · too little exercise
- eating more carbohydrate than normal.

### Things you must not do

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

Do not skip meals while using Hypurin.

### Things to be careful of

If you have to be alert, for example, when driving, be especially careful not to let your blood glucose levels fall too low. Low blood glucose levels may slow your reaction time and affect your ability to drive or operate machinery. Drinking alcohol can make this worse.

If you are travelling, it is a good idea to:

- wear some form of identification showing you have diabetes
- carry some form of sugar to treat hypoglycaemia if it occurs, for example, sugar sachets or jelly beans
- carry emergency food rations in case of a delay, for example, dried fruit, biscuits or muesli bars
- keep **Hypurin** readily available.

## Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Hypurin.

Like other medicines **Hypurin** can cause some unwanted side effects. 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.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you experience any of the following and they worry you:

- signs of hypoglycaemia (low blood sugar)
- local allergy redness, swelling and itching at the injection site
- lipodystrophy lumps or depressions form below the surface of the skin. This can occur if you inject insulin too often at the same injection site.

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

- swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing
- symptoms of lactic acidosis (too much acid in the blood) which may include loss of appetite, unexplained weight loss, nausea,

- vomiting, stomach pain, trouble breathing, feeling weak, tired or uncomfortable, unusual muscle pain, slow heart beat
- rash, sores, redness or itching of the skin/itchy hives-like rash or spots

### **After using Hypurin**

### Storage

Keep your Hypurin in the fridge between 2 - 8 degrees C.

Do not freeze Hypurin.

Do not leave Hypurin near heat or in the sun.

All medicines should be kept where young children cannot reach them.

#### metdcresol

- phenol
- glycerol
- water for injections

### Supplier

Aspen Pharmacare Australia Pty Ltd 34-36 Chandos Street St.Leonards NSW 2065 Australia

Australian Registration Numbers:

Hypurin Neutral: AUST R 27750

Hypurin Isophane: AUST R 27803

® = Registered Trademark

Date of preparation: October 2001.

### **Product description**

### What it looks like

**Hypurin Neutral** is a clear colourless solution which is available in 10mL multi-dose vials with a red flip off top.

**Hypurin Isophane** is a milky white suspension which is available in 10mL multi-dose vials with a blue flip off top.

### Ingredients

**Hypurin Neutral** contains 100 units of insulin per mL. It also contains:

- hydrochloric acid or phosphoric acid or sodium hydroxide
- metacresol
- phenol
- glycerol
- · water for injections

**Hypurin Isophane** contains 100 units of insulin per mL. It also contains:

- hydrochloric acid or phosphoric acid or sodium hydroxide
- protamine sulphate
- · zinc chloride
- · sodium phosphate

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