1. What Hypurin® is and what it is used for

Hypurin® is a sterile, white suspension of bovine insulin (100 international units/ml) mixed withprotamine sulphate and zinc chloride in water. It is longer acting than Hypurin Bovine Neutral.

Hypurin Bovine Lente is a sterile, white suspension of bovine insulin (100 international units/ml) with zinc chloride in water. It is very long acting.

Hypurin Bovine Protamine Zinc is a sterile, white suspension of bovine insulin (100 international units/ml) mixed withprotamine sulphate and zinc chloride in water. It is very long acting.

Hypurin Lente is prepared by adding protamine sulphate and zinc chloride in water. The name of your medicine is Hypurin Bovine insulin. Hypurin Bovine is the brand name for a range of highly purified bovine insulin (porcine) insulin injections.

Hypurin Bovine Neutral is a sterile, clear, solution of bovine insulin (100 international units/ml). It is short acting.

Hypurin Bovine Symphon is a sterile, white suspension ofbovine insulin (100 international units/ml) withprotamine sulphate and zinc chloride in water. It is longer acting than Hypurin Bovine Neutral.

Hypurin Bovine Lente is a sterile, white suspension of bovine insulin (100 international units/ml) with zinc chloride in water. It is very long acting.

Hypurin Bovine Protamine Zinc is a sterile, white suspension of bovine insulin (100 international units/ml) mixed withprotamine sulphate and zinc chloride in water. It is very long acting.

2. Before you receive Hypurin®

You should not inject Hypurin® insulin if:

• you have symptoms of hypersensitivity (e.g. blood sugar or sugar), or ‘hypo’ – see the section on hypoglycaemia in section 4.2.4.4. If any of the above applies to you, do not inject Hypurin®.

• you are pregnant or wish to become pregnant or start breast-feeding.

• you develop an allergic reaction to insulin or any of the other ingredients in Hypurin Bovine (see ‘What Hypurin® contains’ in section 6.1). Information on the ingredients in Hypurin Bovine can be found in section 6.1. Information on the ingredients in Hypurin Bovine can be found in section 6.1.

• you are pregnant or wish to become pregnant or start breast-feeding.

You should contact your doctor about the advisability of driving

• if you are pregnant or wish to become pregnant or start breast-feeding.

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• if you have:

• a cold, or are taking a hot bath,

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Injecting Hypurin
Your doctor or diabetes nurse will advise you on how to inject your insulin.

• Check that the vial in the carton has the same label as on the vial and that different types of Hypurin Bovine have not been mixed up.

• Do not use Hypurin Bovine that has been frozen or contains lumps that do not disappear on mixing.

• Wash and dry your hands.

• Clean the rubber plug on the vial, but do not remove it.

• If you use Hypurin Bovine Isophane, Hypurin Bovine Lente or Hypurin Bovine Protamine Zinc, roll the vial between your palms or invert it several times to mix the contents immediately before use.

• Hypurin Bovine Neutral does not need to be mixed. It should be a clear, colourless solution and not contain any lumps.

• Before withdrawing your insulin from the vial, draw air into the syringe equal to the amount of insulin to be drawn up. Push the needle through the rubber plug of the vial and inject the air into the vial. This will make it easier for you to withdraw the insulin.

• Leaving the needle in the vial, turn the vial upside down making sure the needle tip stays below the surface of the insulin. Slowly tilt the vial slightly with your fingers until you see your usual dose of insulin. Push the plunger back to your correct dose, expelling any air bubbles into the vial. Take the needle out of the vial. You are now ready to inject your insulin.

• Push up the skin at the injection site. Stick the needle in at right angles. Do not release the skin. Push the plunger down to empty the syringe keeping the needle in place for a count of five seconds. Release the plunger up and take the needle out. There is no need to massage the area.

• Once the vial is opened the insulin must only be used by the same patient.

If your doctor recommends it, Hypurin Bovine Neutral can be mixed with Hypurin Bovine Isophane or Hypurin Bovine Lente in this same syringe. If you need to do this, draw the Hypurin Bovine Neutral into the syringe before the Hypurin Bovine Isophane or Hypurin Bovine Lente. This should be demonstrated to you before you attempt to do it yourself.

Use the injection immediately.

Hypurin Bovine Neutral should not be mixed together.

4. POSSIBLE SIDE EFFECTS

Like all medicines, there may be side effects in some patients when treatment is first started or if there is a change in the type of insulin used.

These include:

• Hypoglycaemia (see section “Treating hypoglycaemia”).

• Swelling (injection site).

• Localized itching or swelling around the area of injection.

• Sensitivity reactions of warmth or burning at the site of injection.

• Pain in the area of injection.

• Localized itching in the area used for injection (iodophorylate).

• Pain caused by nerve damage.

• Severe itching or rash.

• Low levels of potassium, which can cause muscle weakness, palpitations, abnormal heart rhythm (hypokalaemia).

• Muscle pain.

• Nausea.

• Headache. The following side effects may occur:

• Allergic reactions and generalised swelling (severe). The use of ephedrine or adrenaline may be needed.

• Hypersensitivity (anaphylactic) reaction.

Hypoglycaemia means low blood sugar. The symptoms of hypoglycaemia are:

• Pale face, sweating, palpitations, rapid heartbeat, heart disease (symptoms may include chest pain and shortness of breath).

• Hunger.

• Cramps.

• Dizziness or feeling faint.

• Weakness, drowsiness, yawning, fatigue, reduced consciousness.

• Alteration in behaviour, aggression, confusion, irritability, anxiety, nervousness, restlessness, excitement, moodiness.

• Difficulty in feeding, difficulties in concentration.

• Itch.

• Vision and/or double vision, blurred speech.

• Tingling or numbness of the nose, mouth, fingers, or eyelids.

• Headache, excess fluid in the brain (symptoms may include headache, loss of co-ordination), brain damage (symptoms may include forgetfulness, learning difficulties).

Why might hypoglycaemia occur?

Hypoglycaemia may occur for the following reasons (or occasionally for no apparent reason):

• Error in or postponing a meal or eating less than the correct dietary allowance.

• Taking more exercise than usual.

• Incorrect mixing of the wrong doses of insulin.

• Acute hepatic alcohol intake — ‘long drinking’.

Hypertension can have serious consequences. It is important to recognise the symptoms of uncontrolled hypertension early.

Treating hypoglycaemia

Always carry glucose tablets or sugar lumps, Euro, and take them with you whenever you go.

• If you feel faint, take the quick-acting glucose tablets or sugar lumps with you as soon as you can.

• If you are not, take the quick-acting glucose tablets or sugar lumps with you as soon as you can.

• If you feel that you have eaten or drunk too much food or drink with sugar in it, you should begin to feel better almost immediately.

• You should feel better in ten minutes if you take the glucose tablets or sugar lumps.

• If the ‘hypo’ happens shortly before a meal or snack, take the above actions as soon as you can.

• If you do not feel better, take the quick-acting glucose tablets or sugar lumps with you as soon as you can.

• If you mix up Hypurin® Bovine Neutral and Hypurin® Bovine Lente it should be a clear, colourless solution and not contain any lumps.

• If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the table. If you think you have received too much Hypurin, contact your doctor or pharmacist or nurse.

• However, occasional difficulty in breathing (symptoms may include chest pain and shortness of breath).

• Rash, thickening or pitting of the skin in the areas used for injection.

• Swelling (oedema) in the type of insulin used.

• Patients when treatment is first started or if there is a change in the type of insulin used.

• Hypoglycaemia (“hypo” or insulin reaction) symptoms such as sweating, trembling, nervousness, excitement and irritability which could lead to collapse and coma.

5. HOW TO STORE HYPURIN®

How to store your medicine will depend on the reach and sight of children.

• Keep your Hypurin® Bovine side should be stored in a refrigerator between 2°C - 8°C. If once in use, the cartridge may be kept at room temperature up to 25°C for 28 days after which it should be discarded.

• Do not use your medicine if the expiry date on the label has passed or if the insulin has been frozen. The expiry date is stated on the carton.

• Keep out of reach of children.

• Medicines should not be disposed of as waste or household rubbish. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. WHAT HYPURIN® BOVINE CONTAINS

Hypurin Bovine Neutral is a sterile, clear solution of bovine insulin (100 international units/ml), 0.01% sodium metabisulphite, phenol, glycerol and sodium phosphate.

Hypurin Bovine Isophane is a sterile, white suspension of bovine insulin (100 international units/ml) with protamine zinc and zinc chloride in water. It also contains sodium metabisulphite, phenol, glycerol and sodium phosphate.

Hypurin Bovine Lente is a sterile, white suspension of bovine insulin (100 international units/ml) with zinc oxide in water. It also contains sodium chloride, sodium acetate and parahydroxybenzoate.

Hypurin Bovine Protamine Zinc is a sterile, white suspension of bovine insulin (100 international units/ml) mixed with protamine sulphate and zinc chloride in water. It also contains phenol, glycerol and sodium phosphate.

What Hypurin Bovine looks like and contents of the pack

Hypurin Bovine is available in glass vials, which contain 3ml of medicine, no longer required. These measures will help to protect the environment.

Hypurin Bovine Neutral and Hypurin Bovine Isophane are also available in glass cartridges which contain 3ml of medicine or suspension for use in pen injectors.

Other formats:

• To listen or to request a copy of this leaflet in Braille, large print or audio please call, free of charge:

  0800 198 5000 (UK Only)

• Please be ready to give the following information:

  - Name of medicine
  - Date of birth
  - Gender
  - National insurance number
  - Date of diagnosis

This is a service provided by the Royal National Institute of Blind People.

Marketing Authorisation Holder and Manufacturer Marketing Authorisation Holder Wockhardt UK Limited, Ash Road North, Wrexham, LL13 9UF, UK.

Manufacturer
CP Pharmaceuticals Ltd, Ash Road North, Wrexham, LL13 9UF, UK.

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Measure bar should be 150mm at 100% scale