PACKAGE LEAFLET: INFORMATION FOR THE USER

HYPURIN® PORCINE RANGE OF INSULIN INJECTION



Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist or diabetic nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or diabetic nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Hypurin is and what it is used for
2. What you need to know before you use Hypurin
3. How to use Hypurin
4. Possible side effects
5. How to store Hypurin
6. Contents of the pack and other information

1. What Hypurin is and what it is used for

The name of your medicine is Hypurin Porcine Insulin. Hypurin Porcine is the brand name for a range of highly purified porcine (pig) insulin injections.
Hypurin Porcine Neutral is a sterile, clear solution of porcine insulin (100 international units/ml). It is short acting.
Hypurin Porcine Isophane is a sterile, white suspension of porcine insulin (100 international units/ml) with protamine sulfate and zinc chloride in water. It is longer acting than Hypurin Porcine Neutral.
Hypurin Porcine 30/70 Mix is a sterile, white suspension of porcine neutral and isophane insulins (100 international units/ml). It is intermediate acting.

What Hypurin is used for
Hypurin contains insulin which is a natural hormone, made by a gland called the pancreas. Insulin plays a key role in the way the body uses carbohydrate, fat and protein.
Hypurin Porcine is used for the treatment of insulin-dependent diabetes mellitus. In this type of diabetes, your pancreas does not make enough insulin to control the level of sugar in your blood. It can be treated by controlling your diet and taking insulin. Hypurin Porcine has been prescribed for you as a substitute for your own insulin.

2. What you need to know before you use Hypurin

Do not use Hypurin
- if you have symptoms of hypoglycaemia (low blood sugar or 'hypo' – see the section on hypoglycaemia in section 4 'Possible side effects')
- if you are allergic to insulin or any of the other ingredients of this medicine (listed in section 6)

If any of the above applies to you, should not inject Hypurin.

Talk to your doctor before taking this medicine if you are taking pioglitazone, as your risk of heart failure may be increased.

Hypurin Porcine Insulin in cartridges is only suitable for injection just under the skin using a reusable pen. Speak to your doctor if you need to inject your insulin by another method.

Skin changes at the injection site:
The injection site should be rotated to prevent skin changes such as lumps under the skin. The insulin may not work very well if you inject into a lumpy area (see How to use Hypurin). Contact your doctor if you are currently injecting into a lumpy area before you start injecting in a different area. Your doctor may tell you to check your blood sugar more closely, and to adjust your insulin or your other antidiabetic medications dose.

Other medicines and Hypurin
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
This includes medicines you may have bought yourself without a prescription.
Taking another medicine while you are using insulin can affect how it or the other medicine works.

Medicines that can affect the way insulin works are;
- Steroids, both corticosteroids, used to treat a range of allergic conditions, and anabolic steroids, used to treat various metabolic disorders.
- Levothyroxine, used for an underactive thyroid gland.
- Anti-inflammatory drugs such as aspirin and NSAIDs such as ibuprofen.
- Cyclophosphamide, used to treat a wide range of tumours.
- Isoniazid, used to treat tuberculosis (TB).
- Some drugs used to treat high blood pressure such as beta blockers, ACE inhibitors, nifedipine, clonidine or guanethidine.
- Some drugs such as adrenaline, which are used to treat shock
- Some drugs used to treat mental illness such as chlorpromazine, amitriptyline, fluoxetine and MAOIs such as phenelzine
- Thiazide diuretics or loop diuretics, used to control excess water.
- Oral contraceptives (birth control pills)
- Octreotide, an anti-hormone preparation.
- Antimalarial drugs, such as chloroquine or quinine.
- Diazoxide, used to treat high blood pressure or low blood sugar.
- Disopyramide or quinidine, used to treat an irregular heartbeat.
- Fenfluramine, used to treat obesity.
- Fibrates or gemfibrozil, used to regulate lipids.
- Mebendazole, used to treat threadworm.
- Oxytetracycline, an antibiotic.
- Pentoxifylline, used to treat leg ulcers and problems with blood circulation in the legs.
- Testosterone.

Alcohol and smoking can also affect the way insulin works. If you have any doubts about your medicine then discuss things more fully with your doctor, pharmacist or diabetes nurse.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before using this medicine.
Particularly careful control of your diabetes and prevention of hypoglycaemia is important for your health and the health of your baby.

Insulin requirements should be assessed frequently by an experienced diabetes physician during pregnancy, after delivery and whilst breast-feeding.

Driving and using machines
Your ability to concentrate or react may be reduced if you have hypoglycaemia. This might put yourself and others at risk when you are driving a car or operating machinery. You should contact your doctor about the advisability of driving if you have:
- frequent episodes of hypoglycaemia
- reduced or lack of warning signs of hypoglycaemia.

Important information about some of the ingredients of Hypurin
Zinc, protamine and the preservatives m-cresol and phenol may cause allergic reactions.

3. How to use Hypurin

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

What dose is needed?
There is no 'standard' dose of insulin. Each person with diabetes has their own dose calculated according to their needs. Your doctor will decide which dose is best for you and which insulin to use.
Always follow your doctor's instructions exactly and also follow any special instructions or warnings that appear on the label that the pharmacist has put on the package.

Dosage adjustments
Patients with disease of the liver, kidneys, adrenal, pituitary or thyroid glands, or coeliac disease (symptoms may include severe diarrhoea and unintentional weight loss) may need lower doses.
This dose may alter during illness (including infection and surgery), injury, emotional stress, during puberty, around the time of a menstrual period, and during pregnancy and after delivery. Lactating women may also require dosage adjustments. It may also change with your diet and lifestyle, particularly if you are exercising more.

Patients transferred to Hypurin Porcine Insulins from other types of insulin may require dosage adjustments. Newly diagnosed diabetic patients may require dosage adjustments during the first weeks, months or years of treatment.

If you do not understand or are in any doubt ask your doctor, pharmacist or diabetes nurse.

Advice and checks to be made when using Hypurin Porcine Insulin
- You must keep a close watch on your blood sugar by testing your glucose levels regularly in your blood or urine
- Your urine should be tested for ketones at regular intervals.
- Be aware that insulin resistance can occur, particularly in patients who have lipid disorders (usually this will be diagnosed by blood tests), hypertension (high blood pressure) or heart disease. Stress can also contribute to insulin resistance.
- If your doctor has asked you to increase the frequency or dose of your insulin treatment in order to improve your sugar levels, you may at some point lose some of the warning symptoms that usually occur when your blood sugar is falling too low (hypoglycaemia). These symptoms include shakiness, pounding heartbeat, sweating and feeling anxious.
- You may also lose some of the warning symptoms of hypoglycaemia if you have had repeated attacks of hypoglycaemia, if control of your blood sugar is greatly improved, if you have a long history of diabetes, or if you are also taking certain other medicines, such as beta blockers (used to treat high blood pressure and angina) or clonidine (used to treat high blood pressure).
- If you are elderly, you may have more severe episodes of hypoglycaemia and some of the warning symptoms may change, be weaker or be missing.
- Be aware that activities such as taking a hot bath, sunbathing, or using a sunbed or sauna can increase the rate at which insulin is absorbed and increase the risk of hypoglycaemia.

Injection sites
Recommended injection sites include the upper arms, thighs, buttocks and lower abdomen. It may be preferable to use those areas that are less visible. Each time you inject your insulin you should use a different spot in the same general area. Change to a different injection area each week.

Hypurin Porcine Insulin in cartridges is only suitable for injecting just under the skin using a reusable pen. Speak to your doctor if you need to inject your insulin by another method.

Hypurin Porcine Isophane or Hypurin Porcine 30/70 Mix should not be injected into a vein.
Hypurin Porcine Neutral may be injected into a vein, **but only by a doctor in an emergency.**

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

- Check that the cartridge in the carton has the same label as on the carton and that different types of Hypurin Porcine have not been mixed up.
- Do not use Hypurin Porcine that has been frozen or contains lumps that do not disappear on mixing.
- Wash and dry your hands.
- If you are using a new cartridge of Hypurin Porcine Isophane or Hypurin Porcine 30/70 Mix or one that has been used before but now looks clear, roll the cartridge down, with a "bell ringing" action at least ten times until the insulin appears white and cloudy. The cartridge contains a glass bead to help mix the suspension.
- Hypurin Porcine Neutral does not need to be mixed. It should be a clear, colourless solution and not contain any particles.
- Put the cartridge into the pen following the pen manufacturer's written instructions.
- Before using the pen to inject Hypurin Porcine Isophane or Hypurin Porcine 30/7 Mix, the insulin must be mixed again by turning the pen up and down at least ten times on each occasion.
- Always check that your pen is working before each injection by performing an 'air shot'. Hold the pen vertically, needle up. Dial two units, press the release button and check for a drop of insulin at the end of the needle (repeat until insulin is seen).
- Dial your dose to the number of units required. You are now ready to inject your insulin.
- Pinch up the skin at the injection site. Inject the Hypurin Porcine Insulin under the skin as you have been taught, keeping the pen in place for a count of five seconds. Release the pinched up skin and remove the pen. Remove the needle from the pen. There is no need to massage the area.
- Your doctor may prescribe more than one type of Hypurin Porcine cartridge injection for you. A separate pen must be used for each type of insulin.

If you think you have received too much Hypurin
If you think you have received too much Hypurin, contact your doctor or diabetes nurse immediately. Symptoms of an overdose include weakness, sweating, trembling, nervousness, excitement and irritability which, if untreated, could lead to collapse and coma.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.
These include:

- Hypoglycaemia (see section "Treating hypoglycaemia" below)
- swelling (oedema)
- redness, itching or swelling around the area of injection
- stinging, or sensations of warmth or burning at the site of injection
- thickening or pitting of the skin in the areas used for injection (lipodystrophy)
- rash
- pain caused by nerve damage
- shortness of breath or wheezing
- low levels of potassium, which can cause muscle weakness, twitching or abnormal heart rhythm (hypokalaemia)
- weight gain
- nausea.

Rarely the following side effects may occur:

- allergic reactions and generalised swelling (oedema).
- severe allergic reactions that cause difficulty in breathing or dizziness.

Hypoglycaemia ("hypo" or insulin reaction) symptoms
Hypoglycaemia means low blood sugar. The symptoms of a "hypo" are:

- pale face, sweating
- palpitations, rapid heartbeat, heart disease (symptoms may include chest pain and shortness of breath)
- hunger
- cramps
- deep breathing
- weakness, drowsiness, yawning, fatigue, reduced consciousness
- altered behaviour, aggression, confusion, irritability, anxiety, nervousness, restlessness, excitement, trembling.
- difficulty in finding words, difficulty in concentration
- fits
- blurred vision and/or double vision, slurred speech
- tingling or numbness of the nose, mouth, fingers, or toes, paralysis
- 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):

- missing or postponing a meal or eating less than the correct dietary allowance
- taking more exercise than usual
- injecting the wrong dose of insulin
- Episodic heavy alcohol intake – 'binge drinking'.

Untreated "hypos" can have serious consequences. It is important to recognise the symptoms and treat hypoglycaemia early.

Treating hypoglycaemia

- Always carry glucose tablets or sugar lumps with you wherever you go.
- At the first warning sign of hypoglycaemia, stop what you are doing and take five glucose tablets or three sugar lumps, preferably with water. You should begin to feel better almost immediately.
- If you do not feel better in ten minutes repeat the glucose tablets or sugar lumps.
- If the "hypo" happens shortly before a meal or snack, treat the "hypo" and have your meal as soon as you can.
- If a meal is not due, take the quick-acting glucose tablets or sugar lumps and follow them with some longer-acting carbohydrate food like a sandwich or biscuits.
- Because of the risk of a "hypo" you should carry an identification card or wear an identity bracelet or necklace carrying details of your name, address, doctor and insulin treatment. It is also important that relatives, friends and colleagues know that you have diabetes.

Skin changes at the injection site:
If you inject insulin too often at the same place, the fatty tissue may either shrink (lipoatrophy) or thicken (lipohypertrophy). Lumps under the skin may also be caused by build-up of a protein called amyloid (cutaneous amyloidosis). The insulin may not work very well if you inject into a lumpy area. Change the injection site with each injection to help prevent these skin changes.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Hypurin

Keep all cartridges, needles and pens out of the sight and reach of children.

- Do not use this medicine after the expiry date which is stated on the label and carton after 'EXP' or if the insulin has been frozen. The expiry date refers to the last day of that month.
- Hypurin Porcine cartridges should be stored in a refrigerator between 2°C - 8°C. Once in use, the cartridge can be kept at room temperature (up to 25°C) for 28 days after which it should be discarded.
- The cartridge should be changed once the plunger has reached the coloured band at the bottom of the cartridge. The empty cartridge should be disposed of immediately. Do not attempt to refill it. Fit a new needle to your pen every time you inject your insulin; do not leave a used needle on your pen between injections as this can cause the cartridge to leak and become non-sterile. Do not share needles.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Hypurin Porcine Contains
Hypurin Porcine Neutral is a sterile, clear solution of porcine insulin (100 international units/ml).
It also contains m-cresol, phenol, glycerol and sodium phosphate.
Hypurin Porcine Isophane is a sterile, white suspension of porcine insulin (100 international units/ml) with protamine sulfate and zinc chloride in water. It also contains m-cresol, phenol, glycerol and sodium phosphate.
Hypurin Porcine 30/70 Mix is a sterile, white suspension of porcine neutral and isophane insulins (100 international units/ml). It also contains m-cresol, phenol, glycerol and sodium phosphate.

What Hypurin Porcine looks like and contents of the pack
Hypurin Porcine is available in packs of five glass cartridges, which contain 3ml of solution or suspension for use in pen injectors and glass vials, which contain 10ml of solution or suspension.

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

0800 198 5000 (UK only)

Please be ready to give the following information:

Product name	Reference number
Hypurin® Porcine Neutral 100 IU/ml Insulin Injection	29831/0124
Hypurin® Porcine Isophane 100 IU/ml Insulin Injection	29831/0122
Hypurin® Porcine 30/70 Mix 100 IU/ml Insulin Injection	29831/0119

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

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

This leaflet was last revised in 06/2020

WOCKHARDT