

Actrapid® HM Penfill®

Neutral Insulin Injection
Biosynthetic Human Insulin
1.5 ml

100 iu/ml

Actrapid® HM Penfill® 1.5 ml cartridges are specially designed for use with NovoPen®, NovoPen® II, NovoPen® 1.5 insulin delivery systems and NovoFine® needles. Novo Nordisk A/S cannot be held responsible for malfunctions occurring as a consequence of using Penfill 1.5 ml in combination with products that do not meet the same specifications or quality standards as NovoPen, NovoPen II, NovoPen 1.5 insulin delivery systems and NovoFine needles. Actrapid®, NovoPen®, Penfill® and NovoFine® are trademarks owned by Novo Nordisk A/S, Denmark.

Product Information

Actrapid HM Penfill is a neutral solution of biosynthetic human insulin. Biosynthetic human insulin is manufactured by recombinant DNA technology using yeast cells as the production organism. It is characterized by being identical to human insulin and of monocomponent purity. *Action profile after subcutaneous injection* (approximate figures): onset ½ hour, maximum effect: between 1 st and 3 rd hour, duration of action: 8 hours.

Indication

Diabetes mellitus.

catheters, Actrapid HM Penfill is not recommended for use in insulin pumps.

Precautions

An insulin reaction (hypoglycaemia) may occur if you take too much insulin, miss meals or exercise more than usual. The first symptoms of an insulin reaction can come on suddenly and may include a cold sweat, rapid heart beat, nervousness or shakiness. These symptoms may be abolished by immediately taking sugar or a sugar sweetened product. Therefore, always carry a few sugar lumps or sweets with you. A few patients have reported that after being transferred to human insulin, the early warning symptoms for hypoglycaemia were less pronounced than they were with animal-source insulin. Your relatives and close work-mates should know that you are a diabetic and how to help if you get a severe insulin reaction. They must be aware that an unconscious person should not be given anything to eat or drink (as choking is possible), but should be turned on his side and medical assistance sought immediately. Recovery from unconsciousness may be hastened by the injection of glucagon, which can be given by a relative or friend who has been instructed in its use. If glucagon is used, sugar or glucose should be given by mouth as soon as consciousness has been regained. In the event of an insulin overdose, in addition to glucagon, glucose may be given intravenously by your doctor. Consult your doctor if you have experienced repeated insulin reactions, or one leading to unconsciousness, since a change in insulin dosage may be necessary. If severe hypoglycaemia is not treated, it can cause temporary or permanent brain damage, and death.

Dosage and Administration

Follow the instructions from your doctor concerning type of insulin, dose and time of injection. Make sure that you have got the type and strength of insulin prescribed by your doctor.

When a switch is made from mixed species (porcine/bovine) or bovine insulin a dosage adjustment may be required dependent upon dosage, purity, species and formulation of the insulin(s) currently administered.

Variations in glycaemic control may occur and adjustments in therapy should be made under the guidance of your doctor. For patients currently controlled on porcine monocomponent or other highly purified human or porcine insulins, no dosage change is anticipated other than the routine adjustments made in order to maintain stable diabetic control. Do not change dosage or preparation except on your doctor's advice.

Treatment with Actrapid HM Penfill may be supplemented by longer acting insulin in accordance with your doctor's advice.

Follow carefully the directions for use of NovoPen insulin pen-devices.

Actrapid HM Penfill is for subcutaneous, intramuscular or intravenous injection.

Before use check that the Penfill cartridge is intact (e.g. no fissures). Do not use Penfill if any damage is seen, or if the rubber piston is visible above the white bar code band.

To avoid possible transmission of disease, Penfill cartridge is for single person use only.

After injection the needle should remain under the skin for at least 6 seconds. Keep the push button fully depressed until after the needle has been withdrawn from the skin. This will ensure correct delivery and limit possible flow of blood or other body fluids into the needle or insulin reservoir. The Penfill cartridge should not be emptied beyond the coloured band; the width of the band corresponds to 6 units of insulin.

Actrapid HM Penfill must not be refilled.

Due to risk of precipitation in some pump

Diabetic ketoacidosis means a condition in which the blood sugar is usually very high. This is a very serious condition, which may develop if you take less insulin than you need. This may be due to increased insulin demand during illness or infection, neglect of diet, omission of insulin doses or the injection of a smaller insulin dose than that prescribed by your doctor. A developing ketoacidosis will be revealed by urine tests which show large amounts of sugar and ketones. The symptoms of thirst, large urine volumes, loss of appetite, fatigue, dry skin and deep and rapid breathing come on gradually, usually over a period of some hours or days. If you recognize these symptoms, consult your doctor immediately. If such symptoms are not treated, they can cause diabetic coma and death.

Interactions

A number of drugs are known to influence insulin requirement. Therefore, if you are taking any other medication, please consult your doctor.

Storage

Penfill cartridges not in use should be stored in their carton between 2° and 8°C, preferably in a refrigerator (not too near the freezing compartment).

Penfill can be used in NovoPen or carried with you as a spare for up to one month. They must not be exposed to sunlight or extreme temperatures. Do not store Penfill in use in a refrigerator. Keep out of reach of children.

Note

Actrapid HM Penfill should not be used if not water-clear and colourless.

Never use insulin after expiry date.

If you are treated with Actrapid HM Penfill and another insulin in Penfill cartridge, two pen-devices should be used, one for each type of insulin.

On the label of the Penfill 1.5 ml cartridge there is a coloured band that is unique to the specific insulin preparation. When the cartridge is



mounted in NovoPen, NovoPen II or NovoPen 1.5 the coloured band is visible through a window in the cartridge holder. Before each injection make sure that you are using the right insulin preparation

NOVO PEN 1.5

