Insuman® Comb 50

100 IU/ml

suspension for injection in a cartridge

Insulin Human

1. WHAT INSUMAN COMB 50 IS AND WHAT IT IS USED FOR

Insuman Comb 50 is a fluid (suspension) for injection in a cartridge. It contains inulin.

Insuman Comb 50 is an insulin preparation designed for use in an injection device of the Optipen series.

1.3 How to use Insuman Comb 50

1.3.1 Dosage

In each cartridge, you will find 100IU (International Units) of Insuman Comb 50, expressed as Human Insulin.

1.3.2 Method of administration

2. BEFORE YOU USE INSUMAN COMB 50

Do not use Insuman Comb 50 if you are allergic (hypersensitive) to insulin or any of the other ingredients of Insuman Comb 50.

3. HOW TO USE INSUMAN COMB 50

3.1 Dosage

Based on your lifestyle and the results of your blood sugar (glucose) tests, your doctor will tell you:

• determine how much Insuman Comb 50 you will need per day,
• tell you whether you need to carry out urine tests,
• tell you when you may need to inject a higher or lower dose of Insuman Comb 50. If the pen does not function well, you can draw the insulin from the cartridge into an injection syringe. Therefore, keep injection

3.2 Method of administration

Insuman Comb 50 is injected under the skin from 20 to 30 minutes before a meal.

3.3 Details of use

4. POSSIBLE SIDE EFFECTS

Side effects reported commonly [Seem in less than 1 in 10 but more than 1 in 100 patients]

• Odema

Insulin treatment may cause temporary build-up of water in the body with swelling in the calves and ankles.

• Injection reactions

Side effects reported uncommonly [Seem in less than 1 in 100 but more than 1 in 10 000 patients]

• Severe allergic reaction with low blood pressure (shock)

• Injection-site urticaria (itchy rash)

• Systemic allergic reactions

Associated symptoms may include large-scale (general) body swelling and itching all over the body, severe swelling of skin or mucous membranes (angioedema), shortness of breath, a fall in blood pressure with rapid heart beat and sweating.

• Eye reactions

A marked change or improvement in your vision when your blood sugar control can disturb your vision temporarily. If you have photophobia (susceptibility of an eye disease related to diabetes) severe hyperglycaemia may cause temporary loss of vision.

• Skin changes at the injection site

If you inject your insulin too often at the same skin site, fatty tissue under the skin at the injection site may become thicker. In insulin that you inject in such a site may not work very well. Changing the injection site or rotation may help to prevent such skin changes.

• Skin and allergic reactions

Other mild reactions at the injection site include:

a) skin irritation
b) itching

4. POSSIBLE SIDE EFFECTS

Like all medicines, Insuman Comb 50 can cause side effects although not everybody gets them.

At this stage, Insulation therapy, the most frequent side effect is hypoglycaemia (low blood sugar). This may lead to a heart attack or brain damage and may be life-threatening. For further information, see ‘Managing low blood sugar or high blood sugar, see the box at the end of this leaflet.

Severe allergic reactions to insulin may present with anaphylaxis. Such reactions to insulin or to the excipients can cause large-scale reactions (rash and itching all over the body), severe swelling of skin or mucous membranes (angioedema), shortness of breath, a fall in blood pressure with rapid heart beat and sweating.

3.3.1 Controlling your insulin dosage

If you have type 1 diabetes (insulin dependent diabetes mellitus), do not stop taking insulin and continue to get enough food.

If you have type 2 diabetes, you may need to talk about:

• your insulin requirements, and the amount of other medicines to treat diabetes change,
• any drug interactions you may have with your insulin, or the amount of other medicines you are taking,
• how your dosage of insulin needs to be altered.

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1.3.2 Method of administration

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3. HOW TO USE INSUMAN COMB 50

3.1 Dosage

Based on your lifestyle and the results of your blood sugar (glucose) tests, your doctor will tell you:

• determine how much Insuman Comb 50 you will need per day,
• tell you when to check your blood sugar level, and what action, if any, needs to be taken.

3.3 Details of use

4. POSSIBLE SIDE EFFECTS

Side effects reported commonly [Seem in less than 1 in 10 but more than 1 in 100 patients]

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Inulin treatment can cause the body to produce antibodies to insulin (substances that act against insulin). This can very rarely, this will require a change to your insulin dosage.

Tell your doctor or pharmacist if you notice any of the side effects listed above or any other unwanted or unexpected effects. To prevent serious reactions, speak to a doctor immediately if a side effect is severe, occurs suddenly or gets worse rapidly.

5. HOW TO STORE INSUMAN COMB 50

Keep out of the reach and sight of children. Do not use Insuman Comb 50 after the expiry date which is stated on the carton and on the label of the cartridge. The expiry date refers to the last day of that month.

- Store in a refrigerator (2 °C – 8 °C). Do not freeze. Do not put Insuman Comb 50 next to the freezer compartment or a freezer pack. Keep the cartridge in the outer carton in order to protect from light.

- Cartridges in-use (in the insulin pen) or carried as a spare may be stored for a maximum of 4 weeks not above 25 °C away from direct heat (for example next to a heating unit) or direct light (direct sunlight or next to a lamp). The cartridge in-use must not be stored in a refrigerator. Do not use the cartridge after this time period.

- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required.

- These measures will help to protect the environment.

6. FURTHER INFORMATION

What Insuman Comb 50 contains

- The active substance is insulin human.
- One ml of Insuman Comb 50 contains 100 IU (International Units) of the active substance insulin human. 50 % of the insulin is dissolved in water; the other 50 % is present as tiny crystals of insulin.
- The other ingredients are: potassium chloride, sodium dihydrogen phosphate, metacresol, phenol, zinc chloride, sodium dihydrogen phosphate dihydrate, gelatin, sodium hydroxide, hydrochloric acid (for pH adjustment) and water for injection.

What Insuman Comb 50 looks like and contents of the pack

After mixing, Insuman Comb 50 is a uniformly milky fluid (suspension for injection), with no clumps, particles or flocculation visible.

Insuman Comb 50 is supplied in cartridges containing 3 ml suspension. (300 IU). Packs of 3, 4, 5, 6, 9 and 10 cartridges of 3 ml are available. Not all pack sizes may be marketed.