Do not use Insuman Basal

If you are allergic (hypersensitive) to insulin or any of the other ingredients of Insuman Basal.

Do not inject Insuman Basal into a vein containing another medicine. Do not use insulin pumps or other injection pumps — special insulin preparations are available for use in such devices.

Take special care with Insuman Basal

Follow the instructions for dosage, monitoring (blood and urine tests), diet and physical activity (physical exercise and exercise) as discussed with your doctor.

Special patient groups

If you have liver or kidney problems or if you are elderly, speak to your doctor as you may need a lower dose.

Travel

Before travelling, consult your doctor. You may need to talk about:

- the availability of your insulin in the countries you are visiting;
- supplies of insulin, injection syringes etc.;
- correct storage of your insulin while travelling;
- timing of meals and insulin administration while travelling;
- the possible effects of changing to different time zones;
- possible new health risks in the countries you will be visiting;
- what you should do in emergency situations when you feel unwell or become ill.

In illnesses and injuries

In the following situations, the management of your diabetes may require a lot of care:

- if you are ill or have a major injury then your blood sugar level may increase (hyperglycaemia);
- if you are not eating enough, your blood sugar level may become too low (hypoglycaemia);
- in most cases you will need a doctor. Make sure that you contact a doctor early.

If you have type 1 diabetes (insulin dependent diabetes mellitus) you do not stop insulin and continue to get enough carbohydrates. Always tell people who are caring for you or treating you that you require insulin.

Using other medicines

Some medicines cause changes in the blood sugar level (fluence, increase or both depending on the situation). In each case, it may be necessary to adjust your insulin dosage to avoid low blood sugar levels that are too low or too high.

Be careful when you start or stop taking another medicine.

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including any obtained without a prescription. Before taking a medicine ask your doctor if it can affect your blood sugar level, and what action, if any, you need to take.

Medicines that may cause your blood sugar level to fall (hypoglycaemia)

- angiotensin inhibitors (used to treat heart conditions or high blood pressure);
- disopramide (used to treat heart conditions);
- fluoxetine (used to treat depression);
- pentoxifylline, propafenone, salicylates (such as aspirin, used to relieve pain and lower fever);
- statin drugs.

Medicines that may cause your blood sugar level to rise (hyperglycaemia)

- angiotensin inhibitors (such as ‘captopril’, used to treat hypertension);
- danazol (medication acting on ovulation);
- diuretics (used to treat high blood pressure);
- drugs used to treat high blood pressure or excessive fluid retention;
- glucagon (gastrocrin hormone used to treat severe hypoglycaemia);
- icarosid (used to treat tuberculosis);
- oestrogens and progestogens (such as in the contraceptive pill or hormone replacement therapy);
- psychotropic drugs (such as tricyclic antidepressants);
- urate-inhibiting drugs used to treat gout;
- zopiclone (used to treat insomnia);
- zolpidem.

Your blood sugar level may either rise or fall if you take:

- beta-blockers (used to treat high blood pressure);
- clonidine (used to treat high blood pressure);
- corticosteroids (used to treat psychiatric disorders);
- metformin (used to treat hyperglycaemia).

Your blood sugar level may either rise or fall if you inject:

- insulin (used to treat diabetes);
- clonidine (used to treat high blood pressure);
- corticosteroids (used to treat psychiatric disorders).

Pentamidine (used to treat infections such as chlamydia or syphilis) may increase your blood sugar level. If you are not sure whether you are taking one of these medicines ask your doctor or pharmacist.

Using Insuman Basal with food and drink

Your blood sugar levels may either rise or fall if you drink alcohol.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

Inform your doctor if you are planning to become pregnant or if you are already pregnant.

In the following situations, the management of your diabetes may require a lot of care:

- if you have hyperglycaemia (high blood sugar), severe complications may occur;
- if you have a forgotten dose.

Medicines that may cause your blood sugar level to rise (hyperglycaemia)

- angiotensin inhibitors (used to treat hypertension);
- danazol (medication acting on ovulation);
- diuretics (used to treat high blood pressure);
- drugs used to treat high blood pressure or excessive fluid retention;
- glucagon (gastrocrin hormone used to treat severe hypoglycaemia);
- icarosid (used to treat tuberculosis);
- oestrogens and progestogens (such as in the contraceptive pill or hormone replacement therapy);
- psychotropic drugs (such as tricyclic antidepressants);
- urate-inhibiting drugs used to treat gout;
- zopiclone (used to treat insomnia);
- zolpidem.

Important information about some of the ingredients of Insuman Basal

The medicinal product contains less than 1 mmol (23 mg) sodium per dose, i.e. it is essentially ‘sodium-free’.

3. HOW TO USE INSUMAN BASAL

Doseage

Based on your life-style and the results of your blood glucose (sugar) tests, your doctor will

- determine how much Insuman Basal per day you should inject;
- tell you when to check your blood sugar level, and whether you need to carry out urine tests;
- tell you when you may need to inject a higher or lower dose of Insuman Basal.

Many factors may influence your blood sugar level. You should know these factors so that you are able to react correctly to changes in your blood sugar level and to prevent it from becoming too high or too low. See the box at the end of this leaflet for further information.

Frequency of administration

Inject Insuman Basal regularly during the skin 45 to 60 minutes before a meal.

Method of administration

Do not inject into a vein. Your doctor will show you in which area of your body you should inject your insulin. If you are injecting into the skin, do not inject one of the injections within the particular area of skin that you are using.

How to handle the vials

Insuman Basal contains 100 IU insulin per ml. Only injection syringes designed for this insulin may be used. The injection syringes must not contain any other medicines or traces of medication. Before the first withdrawal of insulin you must remove the safety-tilt-off lid on the insulin bottle. Mix the insulin well immediately before each injection. This is best done by rolling the vial tilted between the palms of your hands. Do not shake the vial vigorously as this could damage the insulin, which may cause temporary loss of effectiveness.

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

4. POSSIBLE SIDE EFFECTS

Side effects reported commonly (seen in less than 1 in 10 but more than 1 in 100 patients;

- Oedema
Inulin treatment may cause temporary swelling of fingers, toes, ankles or other parts of the body.

- Injection site reactions

Side effects reported uncommonly (seen in less than 1 in 100 but more than 1 in 1000 patients)

- Severe reaction with low blood pressure (shock)

- Injection site urticaria (itchy rash)

- Other side effects include

  - Systemic reactions

- Other mild reactions at the injection site (such as bruising, irritation), usually no pain at the injection site, itching, injection site swelling or injection site infection

- Skin and allergic reactions

- Other minor reactions may happen quite rarely (less than once in 100 patients)

- Tell your doctor or pharmacist if you notice any of the side effects listed above or any unexpected or unexpected effects. To prevent serious reactions, speak to a doctor immediately if the blood sugar level becomes too low. Your ability to concentrate or react may be reduced.

- Tell your doctor or pharmacist if you notice any of the side effects listed above or any unexpected effects. To prevent serious reactions, speak to a doctor immediately if the blood sugar level becomes too low. Your ability to concentrate or react may be reduced.
HYPERGLYCAEMIA AND HYPOGLYCAEMIA
Always carry some sugar (at least 20 grams) with you.
CARRY SOME INFORMATION WITH YOU TO SHOW YOU ARE DIABETIC.

Always carry some sugar (at least 20 grams) with you.