

RA Labelling & Graphics

Insert: 295x125-002
Current 3.0

I10 - Vials

Use in carton with laserprint
Colour: PMS 280C**PACKAGE LEAFLET:
INFORMATION FOR THE USER****Mixtard® 30****100 IU/ml suspension for injection in a vial**
Insulin human (rDNA)**Read all of this leaflet carefully before you start using your insulin.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, diabetes nurse or your pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, diabetes nurse or your pharmacist.

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

Mixtard® is human insulin to treat diabetes. Mixtard is a mixture of fast-acting insulin and long-acting insulin. This means that it will start to lower your blood sugar about half an hour after you take it, and the effect will last for approximately 24 hours.

2. Before you use Mixtard®**Do not use Mixtard**

- ▶ **If you are allergic (hypersensitive)** to this insulin product, metacresol or any of the other ingredients (see *7 Further information*). Look out for the signs of allergy in *5 Possible side effects*
- ▶ **If you feel a hypo** coming on (a hypo is short for a hypoglycaemic reaction and is a symptom of low blood sugar). See *4 What to do in an emergency* for more about hypos.

Take special care with Mixtard

- ▶ **If you have trouble** with your kidneys or liver, or with your adrenal, pituitary or thyroid glands
- ▶ **If you are drinking alcohol:** watch for signs of a hypo and never drink alcohol on an empty stomach
- ▶ **If you are exercising** more than usual or if you want to change your usual diet
- ▶ **If you are ill:** carry on taking your insulin
- ▶ **If you are going abroad:** travelling over time zones may affect your insulin needs and the timing of your injections.

Using other medicines

Many medicines affect the way glucose works in your body and they may influence your insulin dose. Listed below are the most common medicines which may affect your insulin treatment. Talk to your doctor or pharmacist if you take or have recently taken any other medicines, even those not prescribed. **Your need for insulin may change** if you also take: oral antidiabetic products; monoamine oxidase inhibitors (MAOI); beta-blockers; ACE-inhibitors; acetylsalicylic acid; anabolic steroids; sulphonamides; oral contraceptives;

thiazides; glucocorticoids; thyroid hormone therapy; beta-sympathomimetics; growth hormone; danazol; octreotide or lanreotide.

Pregnancy and breast-feeding
If you are pregnant, planning a pregnancy or breast-feeding: please contact your doctor for advice.

Driving and using machines

If you drive or use tools or machines: watch out for signs of a hypo. Your ability to concentrate or to react will be less during a hypo. Never drive or use machinery if you feel a hypo coming on. Discuss with your doctor whether you can drive or use machines at all, if you have a lot of hypos or if you find it hard to recognise hypos.

3. How to use Mixtard®

Talk about your insulin needs with your doctor and diabetes nurse. Follow their advice carefully. This leaflet is a general guide. If your doctor has switched you from one type or brand of insulin to another, your dose may have to be adjusted by your doctor. Eat a meal or snack containing carbohydrates within 30 minutes of the injection. It is recommended that you measure your blood glucose regularly.

Before using Mixtard

- ▶ **Check the label to make sure** it is the right type of insulin
- ▶ **Disinfect the rubber membrane** with a medicinal swab.

Do not use Mixtard

- ▶ **In insulin infusion pumps**
- ▶ **If the protective cap is loose or missing.**

Each vial has a protective, tamper-proof plastic cap. If it isn't in perfect condition when you get the vial, return the vial to your supplier

- ▶ **If it hasn't been stored correctly** or been frozen (see *6 How to store Mixtard*)
- ▶ **If it's not uniformly white and cloudy** when it's resuspended.

How to use this insulin

Mixtard is for injection under the skin (subcutaneously). Never inject your insulin directly into a vein or muscle. Always vary the sites you inject, to avoid lumps (see *5 Possible side effects*). The best places to give yourself an injection are: the front of your waist (abdomen); your buttocks; the front of your thighs or upper arms. Your insulin will work more quickly if you inject it around the waist. Mixtard vials are for use with insulin syringes with the corresponding unit scale.

Just before injecting this insulin

1. Roll the vial between your hands until the liquid is uniformly white and cloudy. Resuspending is easier if the insulin has reached room temperature
2. Draw air into the syringe, in the same amount as the dose of insulin you need
3. Inject the air into the vial: push the needle through the rubber stopper and press the plunger
4. Turn the vial and syringe upside down
5. Draw the right dose of insulin into the syringe
6. Pull the needle out of the vial
7. Make sure there is no air left in the syringe: point the needle upwards and push the air out
8. Check you have the right dose
9. Inject straight away.

Inject the insulin

- ▶ **Inject the insulin** under the skin. Use the injection technique advised by your doctor or diabetes nurse
- ▶ **Keep the needle under your skin** for at least 6 seconds to make sure that the full dose has been delivered.

4. What to do in an emergency**If you get a hypo**

A hypo means your blood sugar level is too low.

The warning signs of a hypo may come on suddenly and can include: cold sweat; cool pale skin; headache; rapid heart beat; feeling sick; feeling very hungry; temporary changes in vision; drowsiness; unusual tiredness and weakness; nervousness or tremor; feeling anxious; feeling confused; difficulty in concentrating.

If you get any of these signs, eat glucose tablets or a high sugar snack (sweets, biscuits, fruit juice), then rest.

Don't take any insulin if you feel a hypo coming on.

Carry glucose tablets, sweets, biscuits or fruit juice with you, just in case.

Tell your relatives, friends and close colleagues that if you pass out (become unconscious), they must: turn you on your side and seek medical advice straight away. They must not give you any food or drink as it could choke you.

- ▶ **If severe hypoglycaemia** is not treated, it can cause brain damage (temporary or permanent) and even death



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- **If you have a hypo** that makes you pass out, or a lot of hypos, talk to your doctor. The amount or timing of insulin, food or exercise may need to be adjusted.

Using glucagon

You may recover more quickly from unconsciousness with an injection of the hormone glucagon by someone who knows how to use it. If you are given glucagon you will need glucose or a sugary snack as soon as you are conscious. If you do not respond to glucagon treatment, you will have to be treated in a hospital. Seek medical advice after an injection of glucagon; you need to find the reason for your hypo to avoid getting more.

Causes of a hypo

You get a hypo if your blood sugar gets too low. This might happen:

- If you take too much insulin
- If you eat too little or miss a meal
- If you exercise more than usual.

If your blood sugar gets too high

Your blood sugar may get too high (this is called hyperglycaemia).

The warning signs appear gradually. They include: increased urination; feeling thirsty; losing your appetite; feeling sick (nausea or vomiting); feeling drowsy or tired; flushed, dry skin; dry mouth and a fruity (acetone) smell of the breath.

If you get any of these signs, test your blood sugar level and test your urine for ketones if you can. Then seek medical advice straight away.

These may be signs of a very serious condition called diabetic ketoacidosis. If you don't treat it, this could lead to diabetic coma and death.

Causes of hyperglycaemia

- Having forgotten to take your insulin
- Repeatedly taking less insulin than you need
- An infection or a fever
- Eating more than usual
- Less exercise than usual.

5. Possible side effects

Like all medicines, Mixtard can cause side effects, although not everybody gets them. Mixtard may cause hypoglycaemia (low blood sugar). See the advice in 4 *What to do in an emergency*.

Side effects reported uncommonly

(in less than 1 patient in 100)

Changes at the injection site

(Lipodystrophy). If you inject yourself too often at the same site, fatty tissue under the skin at this site may shrink (lipoatrophy) or thicken (lipohypertrophy). Changing the site with each injection may help to prevent such skin changes. If you notice your skin pitting or thickening at the injection site, tell your doctor or diabetes nurse because these reactions can become more severe, or they may change the absorption of your insulin if you inject in such a site.

Signs of allergy. Reactions (redness, swelling, itching) at the injection site may occur (local allergic reactions). These usually disappear after a few weeks of taking your insulin. If they do not disappear, see your doctor.

Seek medical advice immediately:

- if signs of allergy spread to other parts of the body, or
- if you suddenly feel unwell and you start

sweating; start being sick (vomiting); have difficulty in breathing; have a rapid heart beat; feel dizzy; feel like fainting.

You may have a very rare serious allergic reaction to Mixtard or one of its ingredients (called a systemic allergic reaction). See also warning in 2 *Before you use Mixtard*.

Diabetic retinopathy (eye background changes). If you have diabetic retinopathy and your blood glucose levels improve very fast, the retinopathy may get worse. Ask your doctor about this.

Swollen joints. When you start taking insulin, water retention may cause swelling around your ankles and other joints. This soon disappears.

Painful neuropathy (nerve related pain). If your blood glucose levels improve very fast it may cause a burning, tingling or electric pain. This is called acute painful neuropathy and it usually disappears. If it does not disappear, see your doctor.

Side effects reported very rarely (in less than 1 patient in 10,000)

Vision problems. When you first start your treatment, it may disturb your vision, but the reaction usually disappears.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, diabetes nurse or pharmacist.

6. How to store Mixtard®

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

The vials that are not being used are to be stored in a refrigerator (2°C - 8°C). Do not store them in or too near the freezer section or cooling element. Do not freeze. Keep the vials in the original package.

The vials that are being used or about to be used are not to be kept in a refrigerator. After removing the vial from the refrigerator it is recommended to let it reach room temperature before resuspending the insulin as instructed for the first time use. See 3 *How to use Mixtard*. You can carry them with you and keep them at room temperature (not above 25°C) for up to 6 weeks.

Always keep the vial in the outer carton when you're not using it in order to protect it from light.

Mixtard must be protected from excessive heat and sunlight.

Mixtard 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.

7. Further information

What Mixtard 30 contains

- **The active substance** is insulin human made by recombinant biotechnology (30% as soluble insulin and 70% as isophane insulin). 1 ml contains 100 IU of insulin human. 1 vial contains 10 ml equivalent to 1000 IU
- **The other ingredients** are zinc chloride, glycerol, metacresol, phenol, disodium phosphate dihydrate, sodium hydroxide, hydrochloric acid, protamine sulphate and water for injections.

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