

Product:	Actraphane HM (ge)	Strength & Dosage form	100 IU/ml human insulin	Reg. no.:	W287
Applicant:	Novo Nordisk (Pty) Ltd	Mod. 1 section no.:	1.3.2 PIL	Date corrected	20 Aug 2021

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APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S3**

PRODUCT NAME

Actraphane[®] HM (ge); 100 IU/ml; Suspension for Injection

Read all of this leaflet carefully before you start using Actraphane[®] HM (ge)

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- Actraphane[®] HM (ge) has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What ACTRAPHANE[®] HM (ge) is and what it is used for
2. What you need to know before you use ACTRAPHANE[®] HM (ge)
3. How to use ACTRAPHANE[®] HM (ge)
4. Possible side effects
5. How to store ACTRAPHANE[®] HM (ge)
6. Contents of the pack and other information

1. What ACTRAPHANE[®] HM (ge) is and what it is used for

ACTRAPHANE[®] HM (ge) is a recombinant human insulin, a mixture of fast acting insulin and long acting insulin. This means that it will start to lower your blood sugar about ½ hour after you take it and the effect will last for approximately 24 hours.

Actraphane[®] HM (ge) is used to treat diabetes.

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2. What you need to know before you use ACTRAPHANE® HM (ge)

Do not use ACTRAPHANE® HM (ge):

- In insulin infusion pumps
- If you are allergic (hypersensitive) to human insulin or any of the other ingredients in Actraphane® HM (ge)
- If you suspect hypoglycaemia (low blood sugar) is starting
- Vial: If the protective cap is loose or missing. If it is not in perfect condition when you get the vial, return the vial to your supplier.
- Penfill: If the cartridge or the device containing cartridge is dropped, damaged or crushed.
- FlexPen®: If FlexPen® is dropped, damaged or crushed
- If it has not been stored correctly or has been frozen
- If the resuspended insulin does not appear uniformly white and cloudy.

Tell your doctor or health care provider before using Actraphane® HM (ge)

Before using Actraphane® HM (ge)

- Check the label to make sure it is the right type of insulin.
- Remove the protective cap.

Warnings and precautions

Take special care with ACTRAPHANE® HM (ge):

- If you have trouble with your kidneys or liver, or with your adrenal, pituitary or thyroid gland
- If you are ill: carry on taking your insulin and consult your doctor

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- If you drink alcohol, watch for signs of a hypo i.e. low blood sugar and never drink alcohol on an empty stomach
- If you exercise more than usual or if you want to change your diet, as this may affect your blood sugar level
- If you are travelling abroad, travel over time zones may affect your insulin needs and the timing of your injections. Consult your doctor if you are planning such travel.

Other medicines and ACTRAPHANE® HM (ge)

Always tell your health care provider if you are using any other medicine. (This includes all complementary or traditional medicines).

Some medicines affect the way your glucose works in your body and this may influence your insulin dose.

Some medicines affect your blood sugar level, and this may mean that your insulin dose has to change. Listed below are the most common medicines which may affect your insulin treatment. In particular, you should tell your doctor if you are using any medicine mentioned below that may affect your blood sugar level.

If you take any of the below medicines your insulin requirements may be decreased

(Your blood sugar level may fall - hypoglycaemia):

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- Other medicines for the treatment of diabetes
- Monoamine oxidase inhibitors (MAOI) (used to treat depression)
- Beta-blockers (used to treat high blood pressure)
- Angiotensin converting enzyme (ACE) inhibitors (used to treat certain heart conditions or high blood pressure)
- Salicylates (used to relieve pain and lower fever)
- Sulfonamides (used to treat infections)
- Alcohol

If you take any of the below medicines your insulin requirements may be increased

(Your blood sugar level may rise – hyperglycaemia):

- Oral contraceptives (birth control pills)
- Thiazides (used to treat high blood pressure or excessive fluid retention)
- Glucocorticoids (such as 'cortisone' used to treat inflammation)
- Thyroid hormone (used to treat thyroid gland disorders)
- Sympathomimetics (such as salbutamol or terbutaline used to treat asthma)
- Growth hormone (medicine for stimulation of skeletal and somatic growth and pronounced influence on the body's metabolic processes)
- Danazol (medicine acting on ovulation).

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Octreotide (used for treatment of acromegaly, a rare hormonal disorder that usually occurs in middle-aged adults, caused by the pituitary gland producing excess growth hormone) may either increase or decrease your blood sugar level.

Combination of Actraphane HM (ge) with pioglitazone

Pioglitazone (class of oral antidiabetic medicines used for the treatment of type 2 diabetes mellitus). Some patients with long-standing type 2 diabetes mellitus and heart disease or previous stroke who are treated with pioglitazone in combination with insulin may develop heart failure. Inform your doctor as soon as possible if you experience signs of heart failure such as unusual shortness of breath or rapid increase in weight or localised swelling (oedema).

ACTRAPHANE® HM (ge) with food and drink and alcohol

If you are drinking alcohol your need for insulin may change as your blood sugar level may either rise or fall. Careful monitoring is recommended.

Pregnancy and breast-feeding

If you are pregnant, planning a pregnancy or breastfeeding your baby whilst using Actraphane HM (ge), please consult your doctor, pharmacist or other healthcare provider for advice.

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There are no restrictions on the treatment of diabetes with Actraphane® HM (ge) during lactation. Insulin treatment of the nursing mother presents no risk to the baby. However the dosage, diet or both may need to be monitored more frequently.

Driving and using machines

If you drive or use tools or machine, watch out for signs of low blood sugar called hypoglycaemia (hypo). Your ability to concentrate or to react will be less when your blood sugar level is low (i.e. during a hypo). Never drive or use machinery if you feel symptoms of low blood sugar (a hypo) coming on. Discuss with your doctor whether you can drive or use machines at all, if you have a lot of hypos (low blood sugar) or if you find it hard to recognize hypos (low blood sugar).

ACTRAPHANE HM (ge) contains sodium

Actraphane HM (ge) contains less than 1 mmol sodium (23 mg) per dose, i.e. Actraphane HM (ge) essentially 'sodium-free'.

3. How to use ACTRAPHANE® HM (ge)

Do not share medicines prescribed for you with any other person.

Always use your ACTRAPHANE HM (ge) exactly as your doctor or pharmacist has told you.

Check with your doctor or pharmacist if you are not sure.

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Make sure you eat a meal or snack containing carbohydrates within 30 minutes of the injection to avoid low blood sugar.

Do not change your insulin unless your doctor tells you to. 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.

It is recommended that you measure your blood sugar regularly.

How and where to inject

Actraphane[®] HM (ge) is for injection under the skin (subcutaneously) only.

Never inject your insulin directly into a vein or muscle. Always vary the sites you inject within the same region, to reduce the risk of developing lumps or skin pitting. The best places to give yourself an injection are:

- The front of your waist (abdomen),
- The front of your thighs and upper arms.

Your insulin will work more quickly if you inject it around the waist.

If you inject more ACTRAPHANE[®] HM (ge) than you should

If you inject too much Actraphane[®] HM (ge) your blood sugar gets too low (hypoglycaemia).

See *Summary of serious and very common side effects in section 4.*

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In the event of overdosage, please consult your doctor or pharmacist.

If neither is available, seek help at the nearest hospital or poison control center.

If you forget to inject ACTRAPHANE® HM (ge)

If you forget to inject your insulin, your blood sugar may get too high (hyperglycaemia). See warning signs of hyperglycaemia under "*If you stop using Actraphane HM (ge)*".

Do not take a double dose to make up for forgotten individual doses.

If you stop using ACTRAPHANE® HM (ge)

You must never stop using your Actraphane HM (ge) without talking with your doctor who will tell you what needs to be done, discontinuation of treatment may lead to hyperglycaemia especially in type 1 diabetes. This could lead to very high blood sugar (severe hyperglycaemia) and ketoacidosis.

The warning signs of hyperglycaemia 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

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condition called diabetic ketoacidosis. If you do not treat it, this could lead to diabetic coma and eventually death.

4. Possible side effects

ACTRAPHANE® HM (ge) can cause side effects.

Not all side effects reported for ACTRAPHANE® HM (ge) are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using ACTRAPHANE® HM (ge), please consult your health care provider for advice.

Summary of serious and very frequent side effects

Low blood sugar (hypoglycaemia) is a very frequent side effect.

Low blood sugar may occur if you:

- Inject too much insulin.
- Eat too little or miss a meal.
- Exercise more than usual.
- Drink alcohol,

Signs of low blood sugar:

Cold sweat; cool pale skin; headache; rapid heartbeat; feeling sick; feeling very hungry; temporary changes in vision; drowsiness; unusual tiredness and weakness; nervousness or tremor; feeling anxious; feeling confused; difficulty in concentrating.

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Severe low blood sugar can lead to unconsciousness. If prolonged severe low blood sugar is not treated, it can cause brain damage (temporary or permanent) and even death. 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 sugar snack as soon as you are conscious. If you do not respond to glucagon treatment, you will have to be treated in a hospital.

What to do if you experience low blood sugar:

- If you experience low blood sugar, eat glucose tablets or another high sugar snack (e.g. sweets, biscuits, fruit juice). Measure your blood sugar if possible and rest.

Always carry glucose tablets or high sugar snacks with you, just in case.

- When the symptoms of low blood sugar have disappeared or when your blood sugar level is stabilised, continue insulin treatment as usual.

- If you have such low blood sugar that it makes you pass out,

if you have had the need for an injection of glucagon, or if you have experienced many

incidents of low blood sugar, talk to a doctor. The amount or timing of insulin, food or

exercise may need to be adjusted. Tell relevant people that you have diabetes and what the

consequences may be, including the risk of passing out (becoming unconscious) due to low

blood sugar. Let them know that if you pass out, they must turn you on your side and get

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medical help straight away. They must not give you any food or drink, because you may choke.

Serious allergic reaction to Actraphane[®] HM (ge) or one of its ingredients (called a systemic allergic reaction) is a very rare side effect, but it can potentially be life threatening.

Tell your doctor immediately or go to the casualty department at your nearest hospital:

- If signs of allergy spread to other parts of your body.
- If you suddenly feel unwell, and you: start sweating; start being sick (vomiting); have difficulty in breathing; have a rapid heartbeat; feel dizzy.

This is a very serious side effects. If you have had it, you may have had a serious reaction to Actraphane[®] HM (ge).

Tell your doctor if you notice any of the following side effects:

Less frequent side effects:

Eye disorders:

- Diabetic retinopathy (eye disease related to diabetes which can lead to loss of vision)

If you have diabetic retinopathy and your blood sugar level improves very fast, the retinopathy may get worse. Ask your doctor about this.

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Skin and subcutaneous disorders

- Changes at the injection site (lipodystrophy)

The fatty tissue under the skin at the injection site may shrink (lipoatrophy) or thicken (lipohypertrophy). Lumps under the skin may also be caused by build-up of a protein called amyloid (cutaneous amyloidosis; how often this occurs is not known). The insulin may not work very well if you inject into a lumpy, shrunken or thickened area.

Changing the site with each injection may help to reduce the risk of developing such skin changes. If you notice your skin pitting or thickening at the injection site, tell your doctor and other healthcare professionals. These reactions can become more severe, or they may change the absorption of your insulin if you inject in such a site.

- Immune system disorders
- Signs of allergy

Reactions (redness, swelling, itching) at the injection site may occur (local allergic reactions). These usually disappear after a week of taking Actraphane HM (ge). If they do not disappear, see your doctor.

- Nervous system disorders
- Painful neuropathy (pain due to nerve damage)
- If your blood sugar level improves very fast, you may get nerve related pain, this is called acute neuropathy and is usually transient.
- General disorders and administration site conditions

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- Swollen joints

When you start taking Actraphane HM (ge), water retention may cause swelling around your ankles and other joints, usually this soon disappears

Other side effects reported are:

- Vision problems

When you first start Actraphane HM (ge) treatment, it may disturb your vision, but the disturbance is usually temporary.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reporting Form”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of Actraphane® HM (ge)

5. How to store ACTRAPHANE® HM (ge)

Store all medicines out of reach of children.

Do not freeze.

Keep out of sunlight.

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Before opening:

Actraphane HM (ge) FlexPen[®], Penfill[®] and vials not in use to be stored between 2 °C and 8 °C (in a refrigerator) for 30 months.

During use or when carried as a spare:

Actraphane[®] HM (ge) FlexPen[®], Penfill and vial in use may be kept at room temperature (maximum 25 °C) for one month.

They must not be exposed to sunlight or temperatures above 37 °C.

Do not store FlexPen[®] and Penfill in use in the refrigerator.

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

Actraphane[®] HM (ge) which does not become completely homogeneous (uniform) when agitated should not be used.

Do not use this medicine after the expiry date, which is stated on the vial label and carton after 'EXP'. The expiry date refers to the last day of that month.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage system (e.g toilets).

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7. Contents of the pack and other information

What ACTRAPHANE® HM (ge) contains

The active ingredient is human insulin. Actraphane® HM (ge) is a mixture consisting of 30% soluble human insulin and 70% isophane human insulin. Each ml of biphasic bio-synthetic human insulin contains a sterile suspension of 100 units of genetically engineered monocomponent insulin preserved with 0,15 % m-cresol and 0,065 % phenol.

The other ingredients are:

Zinc chloride, glycerol, sodium phosphate dihydrate, sodium hydroxide, hydrochloric acid, protamine sulphate and water for injection.

What ACTRAPHANE® HM (ge) looks like and contents of the pack

White suspension for injection which on standing deposits a white sediment and leaves a colourless or almost colourless supernatant liquid. The sediment is readily re-suspended on gentle shaking.

Actraphane® HM (ge) is presented as:

- Vial: 10 ml vial made of glass (type 1). The vial is closed with a rubber closure and packed in a carton (1 x 10 ml).

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- Penfill®: 3 ml cartridge is made of glass (Type 1), containing a bromobutyl rubber plunger and a bromobutyl/polyisoprene rubber stopper. The cartridge contains a glass ball to facilitate re-suspension. 5 x 3 ml Penfill® are packed in a carton.
- FlexPen®: FlexPen® is a pre-filled (multidose disposable pen) in which a Penfill cartridge of 3 ml is inserted. The cartridge is made of glass (Type 1), containing a bromobutyl rubber plunger and a bromobutyl/polyisoprene rubber stopper. The cartridge contains a glass ball to facilitate re-suspension. 5 x 3 ml FlexPen® packed in a carton.

Snap-off caps:

The Actraphane® HM (ge) vials are packed and shipped with a protective, colour coded, tamper-proof plastic cap. In order to withdraw insulin from a new vial, the cap must be removed. If the cap is not securely fastened to a newly purchased vial, return the vial to the pharmacy.

Holder of certificate of registration

Novo Nordisk (Pty) Ltd

150 Rivonia Road

10 Marion Street Office Park

Building C1

Sandton, Johannesburg

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Appendix 1

10 ml vial instructions for use

Note:

Check the name and coloured label of your vial to make sure that the vial you are preparing injection contains the correct type of insulin. If you administer the wrong type of insulin, your blood sugar level may get too high or too low.

How to inject Actraphane® HM (ge) 10 ml vial

- ▶ **Make sure you have the correct syringe** with the corresponding unit scale for insulin injections.
- ▶ **Follow the instructions** given by your healthcare professional.
- ▶ **Just before injecting this insulin**, roll the vial between your hands until the liquid is uniformly white and cloudy. Resuspending is easier if the insulin has reached room temperature.
 - Clean the skin.
 - Wipe the rubber disc on the vial with alcohol.
 - Draw the piston of the syringe out to a distance corresponding to the quantity of insulin required.
 - Gently agitate the vial of insulin.
 - Then pierce the rubber disc with the needle, then push the piston home, and turn the vial upside down.

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- Draw the required amount of insulin into the syringe.
- Avoid air in the syringe and needle by working the piston slightly up and down.

Use the injection technique advised by your healthcare professional.

- Make the injection at a suitable depth under the skin (subcutaneously). It is important that the injection is made with a syringe which is marked for use with an insulin preparation containing 100 units per ml. Failure to use the correct syringe, can lead to dosage errors.

► **Keep the needle under your skin** for at least 6 seconds to make sure that the

full dose has been delivered.

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Appendix 2

Use of Penfill®

Note:

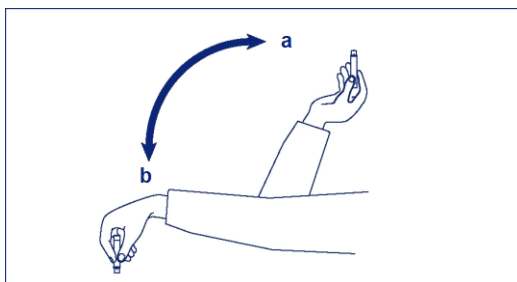
Check the name and coloured label of your vial to make sure that the vial you are preparing injection contains the correct type of insulin. If you administer the wrong type of insulin, your blood sugar level may get too high or too low.

Resuspending the insulin

Resuspending is easier when the insulin has reached room temperature.

Before you put the Penfill® cartridge into the insulin delivery system, move it up and down between positions **a** and **b** and back (see the picture) so that the glass ball moves from one end of the cartridge to the other at least 20 times.

Repeat this movement at least 10 times before each injection. The movement must always be repeated until the liquid appears uniformly white and cloudy. Complete the other stages of injection without delay.



Check there are at least 12 units of insulin left in the cartridge to allow even resuspending.

If there are less than 12 units left, use a new one.

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How to inject this insulin

- ▶ **Inject the insulin** under the skin. Use the injection technique advised by your doctor or nurse and as described in your delivery system manual.

- ▶ **Keep the needle under your skin** for at least 6 seconds. Keep the push button fully depressed until the needle has been withdrawn. This will ensure correct delivery and limit possible flow of blood into the needle or insulin reservoir.

- ▶ **After each injection** be sure to remove and discard the needle and store Actraphane[®] HM (ge) without the needle attached. Otherwise the liquid may leak out which can cause inaccurate dosing.

Do not refill Actraphane[®] Penfill[®].

Penfill[®] cartridges are designed to be used with Novo Nordisk insulin delivery systems and NovoFine[®] or NovoTwist[®] needles.

If you are treated with Actraphane[®] Penfill[®] and another insulin Penfill[®] cartridge, you should use two insulin delivery systems, one for each type of insulin.

As a precautionary measure, always carry a spare insulin delivery device in case your Penfill[®] is lost or damaged.

Delivery of dosage using NovoPen:

- ▶ Use the injection technique advised by the healthcare practitioner.

- ▶ With NovoPen it is possible to select a dose larger than the number of units remaining in the Penfill. For your convenience the cartridge holder has marks which show the approximate dose remaining in the Penfill.

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- ▶ Do not dial up more than what is available.
- ▶ Do not initiate injection if the rubber piston can be seen in the small inspection windows as the glass ball needs room to resuspend the insulin.
- ▶ When a dosage greater than the insulin remaining in the cartridge is required, the following options can be exercised:
 - i) The dosage remaining in the current Penfill can be administered. A new Penfill is then inserted according to the manufacturer's instructions, and the balance of the required dosage is administered from the new Penfill

or

 - ii) The current Penfill can be discarded. A new Penfill is then inserted according to the manufacturer's instructions and the full dosage is administered from the new Penfill.
To avoid possible transmission of disease, Penfill is for single person use only.

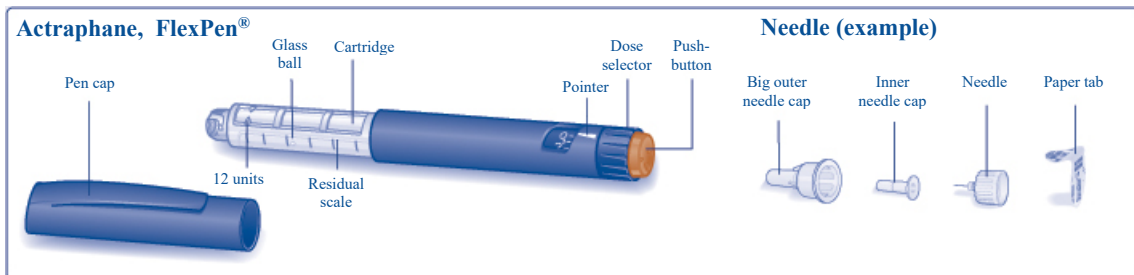
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Appendix 3

Instructions on how to use Actraphane® HM (ge) suspension for injection in FlexPen®

Read the following instructions carefully before using your Actraphane® HM (ge) FlexPen®. If you do not follow the instructions carefully, you may get too little or too much insulin, which can lead to too high or too low blood sugar level.

Your Actraphane® HM (ge) FlexPen® is a pre-filled dial-a-dose insulin pen. You can select doses from 1 to 60 units in increments of 1 unit. The FlexPen® is designed to be used with NovoFine® or NovoTwist® disposable needles up to a length of 8 mm. As a precautionary measure, always carry a spare insulin delivery device in case your Actraphane® FlexPen® is lost or damaged.



Caring for your pen

Your Actraphane® HM (ge) FlexPen® must be handled with care.

If it is dropped, damaged or crushed, there is a risk of insulin leakage. This may cause inaccurate dosing, which can lead to too high or too low blood sugar level.

You can clean the exterior of your Actraphane® HM (ge) FlexPen® by wiping it with a medicinal swab. Do not soak it, wash or lubricate it as it may damage the pen.

Do not refill your Actraphane® HM (ge) FlexPen®.

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Preparing your Actraphane® HM (ge) FlexPen®

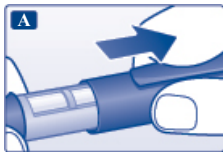
A

Check the name and coloured label of your pen to make sure that it contains the correct type of insulin. This is especially important if you take more than one type of insulin. If you take the wrong type of insulin, your blood sugar level may get too high or too low.

Every time you use a new pen

Let the insulin reach room temperature before you use it. This makes it easier to resuspend.

Pull off the pen cap (see A).



B

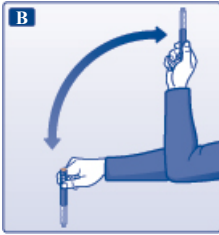
Before your first injection with a new pen, you must resuspend the insulin:

Move the pen up and down twenty times between the two positions as shown, so the glass ball moves from one end of the cartridge to the other. Repeat until the liquid appears uniformly white and cloudy.

For every following injection, move the pen up and down between the two positions at least 10 times until the liquid appears uniformly white and cloudy.

Always make sure that you have resuspended the insulin prior to each injection. This reduces the risk of too high or too low blood sugar level. After you have resuspended the insulin, complete all the following steps of injection without delay.

Product:	Actraphane HM (ge)	Strength & Dosage form	100 IU/ml human insulin	Reg. no.:	W287
Applicant:	Novo Nordisk (Pty) Ltd	Mod. 1 section no.:	1.3.2 PIL	Date corrected	20 Aug 2021



⚠ Always check there are at least 12 units of insulin left in the cartridge to allow resuspension. If there are less than 12 units left, use a new pen.

Attaching a needle

C

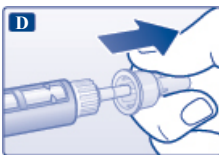
Remove the paper tab from a new disposable needle.

Screw the needle straight and tightly onto your Actraphane[®] HM (ge) FlexPen[®].



D

Pull off the big outer needle cap and keep it for later.

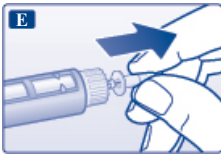


E

Pull off the inner needle cap and dispose of it.

Never try to put the inner needle cap back on the needle. You may stick yourself with the needle.

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⚠ Always use a new needle for each injection. This reduces the risk of contamination, infection, leakage of insulin, blocked needles and inaccurate dosing.

⚠ Be careful not to bend or damage the needle before use.

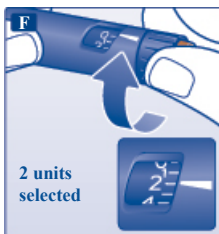
Checking the insulin flow

F

Prior to each injection, small amounts of air may collect in the cartridge during normal use.

To avoid injection of air and ensure proper dosing:

Turn the dose selector to select 2 units.



G

Hold your Actraphane® HM (ge) FlexPen® with the needle pointing upwards and tap the cartridge gently with your finger a few times to make any air bubbles collect at the top of the cartridge.



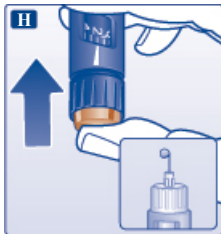
Product:	Actraphane HM (ge)	Strength & Dosage form	100 IU/ml human insulin	Reg. no.:	W287
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H


Keeping the needle upwards, press the push-button all the way in. The dose selector returns to 0.

A drop of insulin should appear at the needle tip. If not, change the needle and repeat the procedure no more than 6 times.

If a drop of insulin still does not appear, the pen is defective, and you must use a new one.



 Always make sure that a drop appears at the needle tip before you inject. This makes sure that the insulin flows. If no drop appears, you will not inject any insulin, even though the dose selector may move. This may indicate a blocked or damaged needle.

 Always check the flow before you inject. If you do not check the flow, you may get too little insulin or no insulin at all. This may lead to too high blood sugar level.

Selecting your dose

I

Check that the dose selector is set at 0.

Turn the dose selector to select the number of units you need to inject.

The dose can be corrected either up or down by turning the dose selector in either direction until the correct dose lines up with the pointer. When turning the dose selector, be careful not to push the push-button as insulin will come out.

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You cannot select a dose larger than the number of units left in the cartridge.



- ⚠ Always use the dose selector and the pointer to see how many units you have selected before injecting the insulin.
- ⚠ Do not count the pen clicks. If you select and inject the wrong dose, your blood sugar level may get too high or too low. Do not use the residual scale, it only shows approximately how much insulin is left in your pen.

Making the injection

J

Insert the needle into your skin. Use the injection technique shown by your doctor or nurse.

Inject the dose by pressing the push-button all the way in until 0 lines up with the pointer. Be careful only to push the push-button when injecting.

Turning the dose selector will not inject insulin.



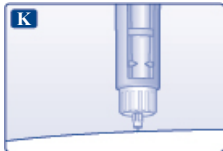
Product:	Actraphane HM (ge)	Strength & Dosage form	100 IU/ml human insulin	Reg. no.:	W287
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K

Keep the push-button fully depressed and let the needle remain under the skin for at least 6 seconds. This will make sure you get the full dose.

Withdraw the needle from the skin, then release the pressure on the push-button.

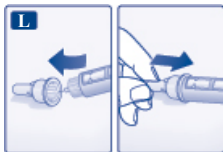
Always make sure that the dose selector returns to 0 after the injection. If the dose selector stops before it returns to 0, the full dose has not been delivered, which may result in too high blood sugar level.




L

Lead the needle into the big outer needle cap without touching it. When the needle is covered, carefully push the big outer needle cap completely on and then unscrew the needle.

Dispose of it carefully and put the pen cap back on.



 Always remove the needle after each injection and store your Actraphane[®] HM (ge) FlexPen[®] without the needle attached. This reduces the risk of contamination, infection, leakage of insulin, blocked needles and inaccurate dosing.

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Further important information

- ⚠ Caregivers must be very careful when handling used needles – to reduce the risk of needle sticks and cross-infection.
- ⚠ Dispose of your used Actraphane® HM (ge) FlexPen® carefully without the needle attached.
- ⚠ Never share your pen or your needles with other people. It might lead to cross-infection.
- ⚠ Never share your pen with other people. Your medicine might be harmful to their health.
- ⚠ Always keep your pen and needles out of sight and reach of others, especially children.