

Applicant/PHCR:	Ranbaxy Pharmaceuticals (Pty) Ltd
Product proprietary name:	SEMAGARD
Dosage form and strength:	Solution for injection, 2 mg / 1,5 mL and 4 mg / 3 mL (1,34 mg / mL) Semaglutide
Date of amendment:	30 June 2026

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

SEMAGARD

1,34 mg/ml solution for injection in pre-filled pen

Semaglutide

Contains propylene glycol 14 mg/ml

Read all of this leaflet carefully before you start using SEMAGARD

- 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.
- SEMAGARD 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 SEMAGARD is and what it is used for
2. What you need to know before you use SEMAGARD
3. How to use SEMAGARD
4. Possible side effects
5. How to store SEMAGARD
6. Contents of the pack and other information

1. What SEMAGARD is and what it is used for

SEMAGARD contains the active substance semaglutide.

SEMAGARD is used to lower blood sugar (glucose) in adults with type 2 diabetes:

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- on its own if your blood sugar is not controlled well enough by diet and exercise alone, or
- with other medicines for diabetes – when they are not enough to control your blood sugar levels. These other medicines may include: oral antidiabetics (such as metformin, thiazolidinedione medicines (TZDs), sulfonylurea medicines, SGLT2 inhibitors) or insulin.

It is important that you keep following your diet and lifestyle advice received from your healthcare professional while using SEMAGARD.

2. What you need to know before you use SEMAGARD

SEMAGARD should not be administered:

- if you are hypersensitive allergic to semaglutide or any of the other ingredients of SEMAGARD (listed in section 6).
- if you or any of your family have ever had a type of thyroid cancer called medullary thyroid carcinoma (MTC), or if you have an endocrine system condition called Multiple Endocrine Neoplasia syndrome type 2 (MEN 2).
- if you are pregnant.
- if you are breastfeeding your baby.

Women who may become pregnant should use effective contraception while taking SEMAGARD.

Warnings and precautions

Tell your doctor or health care provider before using this medicine:

SEMAGARD is not an insulin and should not be used:

- if you are allergic to semaglutide or any of the ingredients listed in Section 6.
- if you have type 1 diabetes – your body does not produce any insulin;



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- if you have diabetic ketoacidosis – a complication of diabetes that happens when the body is not able to break down glucose because there is not enough insulin.

- *Severe and on-going stomach pain which could be due to acute pancreatitis.*

If you have severe and on-going pain in the stomach area – see a doctor straight away as this could be a sign of acute pancreatitis (inflamed pancreas).

- *Dehydration*

During treatment with SEMAGARD, you may experience feeling sick (nausea) or being sick (vomiting), and diarrhoea. These side effects can cause dehydration (loss of fluids). It is therefore important to drink plenty of fluids to prevent dehydration. Talk to your doctor if you have any questions or concerns.

- *Diabetic eye disease (retinopathy)*

Fast improvements in blood sugar control may lead to a temporary worsening of diabetic eye disease. This may require treatment or lead to a loss of vision. You should inform your doctor if you have diabetic eye disease (retinopathy) or if you experience eye problems during treatment with SEMAGARD.

- if you notice lumps in your neck difficulty swallowing, shortness of breath or change in your voice it may be due to a problem developing in your thyroid gland. Consult your doctor if you feel a lump developing.

- *Sudden changes to your eyesight*

If you notice a sudden loss of vision or rapidly worsening eyesight during treatment with this medicine, immediately contact your doctor for advice. This may be caused by a very rare side effect called non-arteritic anterior ischaemic optic neuropathy (NAION) (See section 4: Serious side effects). Your doctor may refer you for an eye examination and you may have to stop treatment with this medicine.

- *Children and adolescents*

SEMAGARD is not recommended in children and adolescents under 18 years as the safety and efficacy in this age group have not yet been established.

- *Patients with delayed stomach emptying (gastroparesis)*



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If you have slow (delayed) stomach emptying (called gastroparesis), use of SEMAGARD may lead to serious or severe gastrointestinal adverse events. Talk to your doctor before using SEMAGARD.

Other medicines and SEMAGARD

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

Tell your healthcare professional if you are using medicines containing any of the following:

- sulfonylurea;
- insulin.

Combining these medicines with SEMAGARD might increase the risk of getting low blood sugar (hypoglycaemia). Please see section 4 for the warning signs of low blood sugar. Your doctor may tell you to test your blood sugar levels. This will help your doctor decide if the dose of the sulfonylurea or insulin needs to be changed to reduce the risk of low blood sugar.

In particular, tell your doctor, pharmacist or nurse if you are using medicines containing any of the following:

- Warfarin or other similar medicines taken by mouth to reduce blood clotting (oral anticoagulants).

You may need frequent blood tests to check how quickly your blood clots.

Using SEMAGARD with food and drink:

SEMAGARD may be taken with or without meals.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

SEMAGARD should not be used during pregnancy and for at least two months before a planned pregnancy because it is not known if it may affect your unborn child.



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If you could become pregnant while using SEMAGARD, you should use effective contraception.

Do not use SEMAGARD if you are breast-feeding. This is because SEMAGARD may pass into breast milk.

Driving and using machines

Low blood sugar (hypoglycaemia) may affect your ability to concentrate. Avoid driving or using machines if you get any signs of low blood sugar. See section 4 for the warning signs of low blood sugar. Talk to your doctor for further information.

It is not always possible to predict to what extent SEMAGARD may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which SEMAGARD affects them.

SEMAGARD contains dibasic sodium phosphate and sodium hydroxide.

Sodium content:

This medicine contains less than 1 mmol sodium (23 mg) (m/v) per dose, i.e. essentially 'sodium-free'.

Propylene glycol

This medicine contains 14 mg/ml of propylene glycol, which is equivalent to 21 mg/pen in the 2 mg/1,5 ml and 42 mg/pen in the 4 mg/3 mL strength.

Propylene glycol in this medicine can have the same effects as drinking alcohol and may increase the likelihood of side effects. Use only if recommended by a doctor. Your doctor may carry out extra checks while you are taking this medicine.



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The other ingredients are: disodium phosphate dihydrate, propylene glycol, phenol (as preservative), sodium hydroxide, hydrochloric acid and water for injections.

3. How to use SEMAGARD

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

Always use SEMAGARD exactly as your doctor or pharmacist has told you. Check with your doctor, pharmacist or nurse if you are not sure.

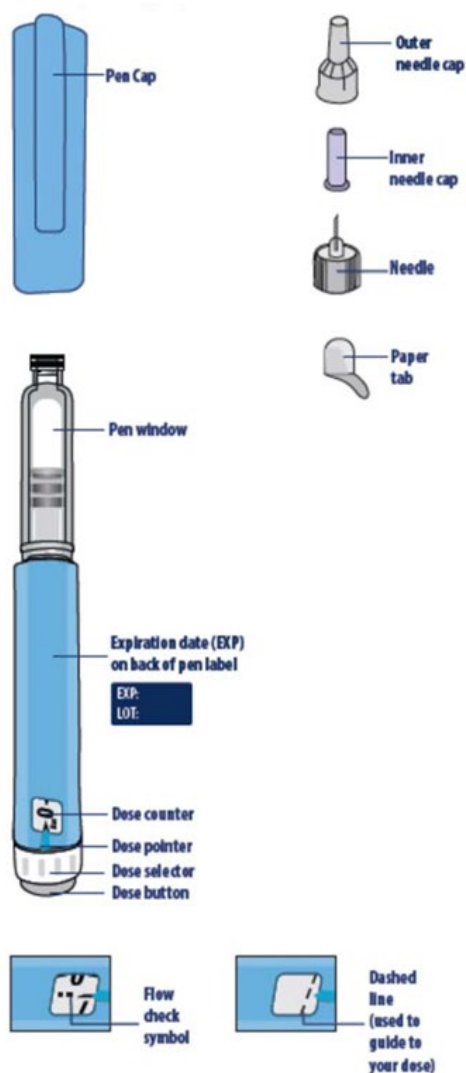
Instructions on how to use SEMAGARD 0,25 mg, 0,5 mg/dose solution for injection in pre-filled pen	
- Read these instructions carefully before using your SEMAGARD injection pen. - Do not use your pen without proper training from your healthcare provider. Make sure that you know how to inject with the pen before you start your treatment. - Do not share your SEMAGARD injection pen with other people, even if the needle has been changed. You may give other people a serious infection, or get a serious infection from them.	SEMAGARD injection pen and BD Ultra Fine™ needle (example)



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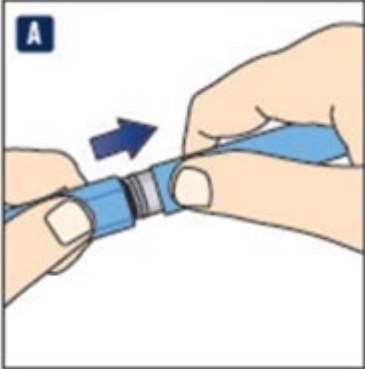
⚠ If you are blind or have poor eyesight and cannot read the dose counter on the pen, do not use this pen without help. Get help from a person with good eyesight who is trained to use the SEMAGARD injection pen.

- Start by checking your pen to make sure that it contains the SEMAGARD injection, then look at the pictures below to get to know the different parts of your pen and needle.
- Your pen is a prefilled, single-patient-use, dial-a-dose pen. It contains 2 mg of semaglutide, and you can select doses of 0,25 mg or 0,5 mg. Your pen is made to be used with BD Ultra-Fine™ disposable needles up to a length of 8 mm.
- Always use a new needle for each injection. Supplies you will need to



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give your SEMAGARD injection: • SEMAGARD injection pen • a new BD Ultra Fine™ needle • 1 alcohol swab • 1 gauze pad or cotton ball • 1 sharps disposal container for throwing away used SEMAGARD injection pens and needles. See “Disposing of used SEMAGARD injection pens and needles” at the end of these instructions.	
Step 1. Prepare your pen with a new needle	
• Wash your hands with soap and water. • Check the name and coloured label of your pen, to make sure that it contains SEMAGARD injection. This is especially important if you take more than one type of medicine. • Pull off the pen cap.	

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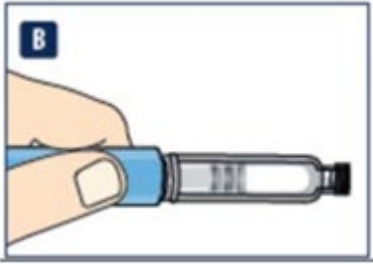
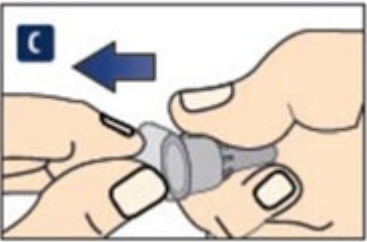
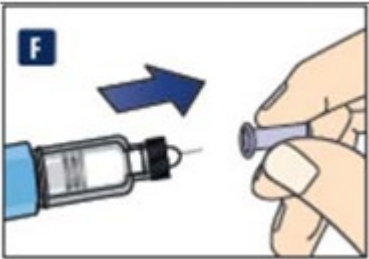
SEMAGARD

Dosage form and strength:

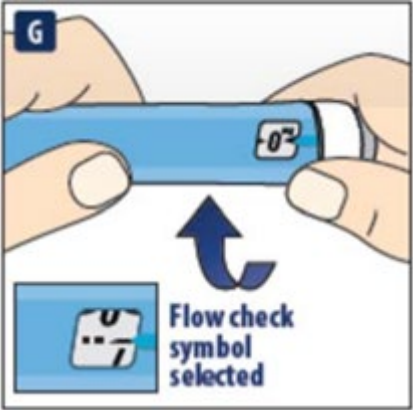
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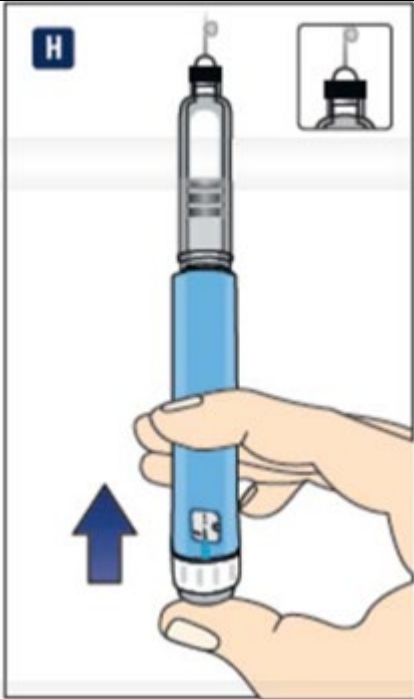
Check that the SEMAGARD injection medicine in your pen is clear and colourless. Look through the pen window. If SEMAGARD injection looks cloudy or contains particles, do not use the pen.	
Take a new needle, and tear off the paper tab. Do not attach a new needle to your pen until you are ready to give your injection.	
Push the needle straight onto the pen. Turn until it is on tight.	
Pull off the outer needle cap. Do not throw it away. You will need it after the injection, to safely remove the needle from the pen.	
Pull off the inner needle cap and throw it away. A drop of solution may appear at the needle tip. This is normal, but you must still check the semaglutide injection flow, if you use a new pen for the first time.	

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⚠ Always use a new needle for each injection. This will reduce the risk of contamination, infection, leakage of semaglutide injection, and blocked needles leading to the wrong dose. Do not reuse or share your needles with other people. You may give other people a serious infection, or get a serious infection from them. Never use a bent or damaged needle.	
Step 2. Check the semaglutide injection flow with each new pen	
- Check the semaglutide injection flow before your first injection with each new pen. If your SEMAGARD injection pen is already in use, go to Step 3 “Select your dose”. - Turn the dose selector until the dose counter shows the flow check symbol (→).	

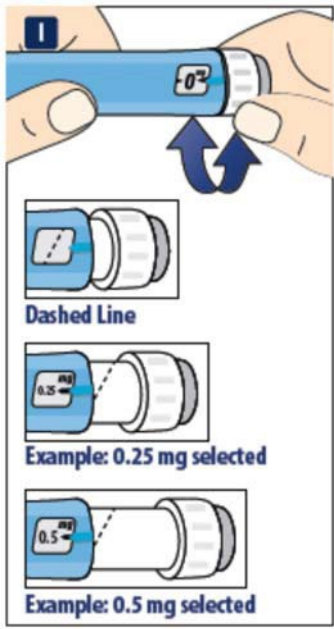
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- Hold the pen with the needle pointing up. Press and hold in the dose button until the dose counter shows 0. The 0 must line up with the dose pointer. A drop of SEMAGARD injection will appear at the needle tip. - If no drop appears, repeat Step 2 above as shown in Figure G and Figure H up to 6 times. If there is still no drop, change the needle and repeat Step 2 as shown in Figure G and Figure H one more time. Dispose of the pen if a drop of SEMAGARD injection still does not appear.	
⚠ Always make sure that a drop appears at the needle tip before you use a new pen for the first time. This makes sure that semaglutide injection flows. If no drop appears, you will not inject any SEMAGARD injection, even though the dose counter may move. This may mean that there is a blocked or damaged needle. A small drop may remain at the needle tip, but it will not be injected. Ensure that you check the SEMAGARD injection flow before your first injection with each	
Step 3.	

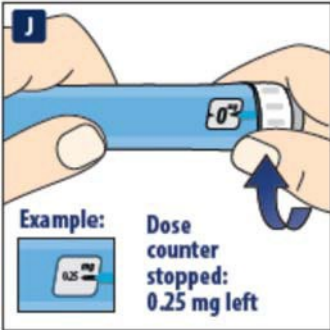


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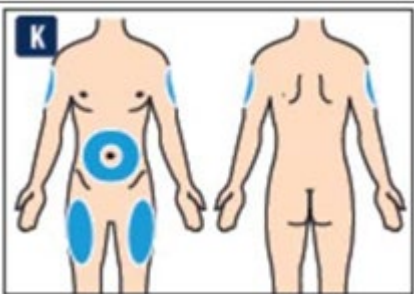
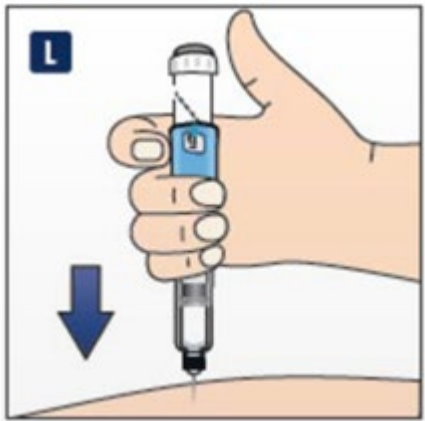
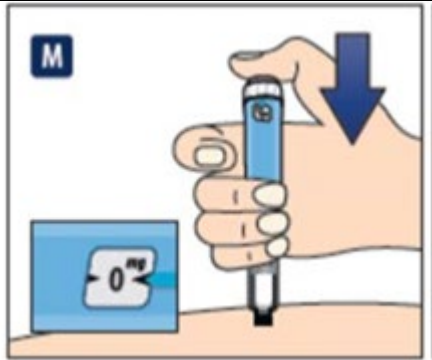
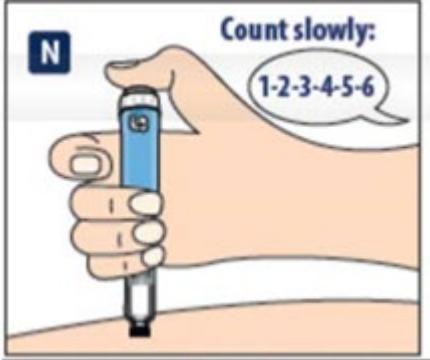
Select your dose	
Turn the dose selector until the dose counter shows your dose (0,25 mg or 0,5 mg). The dashed line in the dose counter (:) will guide you to your dose. Make sure you know the dose of semaglutide injection you should use. If you select the wrong dose, you can turn the dose selector forward or backwards to the correct dose.	
⚠ Always use the dose counter and the dose pointer to see how many mg you select. You will hear a “click” every time you turn the dose selector. Do not set the dose by counting the number of clicks you hear. Do not count the pen clicks. Only doses of 0,25 mg or 0,5 mg can be selected with the dose selector. The selected dose must line up exactly with the dose pointer to make sure that you get a correct dose. The dose selector changes the dose. Only the dose counter and dose pointer will show how many mg you select for each dose. You can select 0,25 mg or 0,5 mg for each dose. When your pen contains less than 0,5 mg or 0,25 mg, the dose counter stops before 0,5 mg or 0,25 mg is shown. The dose selector clicks differently when turned forward or backward.	

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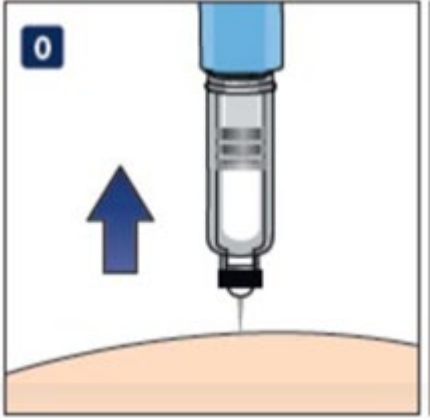
How much SEMAGARD injection is left?	
- To see how much SEMAGARD injection is left in your pen, use the dose counter: Turn the dose selector until the dose counter stops. - If it shows 0,5, at least 0,5 mg is left in your pen. If the dose counter stops before 0,5 mg, there is not enough semaglutide injection left for a full dose of 0,5 mg. - If it stops at 0,25, then 0,25 mg is left in your pen. If the dose counter stops before 0,25 mg, there is not enough SEMAGARD injection left for a full dose of 0,25 mg. If there is not enough SEMAGARD injection left in your pen for a full dose, do not use it. Use a new SEMAGARD injection pen.	 Example: Dose counter stopped: 0.25 mg left
Step 4. Inject your dose	

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Choose your injection site and wipe the skin with an alcohol swab. Let the injection site dry before you inject your dose (See Figure K).	
- Insert the needle into your skin as your healthcare provider has shown you. - Make sure you can see the dose counter. Do not cover it with your fingers. This could stop the injection.	
Press and hold down the dose button until the dose counter shows 0. The 0 must line up with the dose pointer. You may hear or feel clicking sound during injection.	
Keep the needle in your skin after the dose counter has returned to 0 and count slowly to 6. If the needle is removed earlier, you may see a stream of semaglutide injection coming from the needle tip. If this happens, the full dose will not be	

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delivered.	
Remove the needle from your skin. If blood appears at the injection site, press lightly with a gauze pad or cotton ball. Do not rub the area.	
⚠ Always watch the dose counter to make sure you have injected your complete dose. Hold the dose button down until the dose counter shows 0. How to identify a blocked or damaged needle? - If 0 does not appear in the dose counter after continuously pressing the dose button, you may have used a blocked or damaged needle. - If this happens you have not received any SEMAGARD injection even though the dose counter has moved from the original dose that you have set.	
How to handle a blocked needle? Change the needle as described in Step 5, and repeat all steps starting with Step 1: “Prepare your pen with a new needle”. Never touch the dose counter when you inject. This can stop the injection. You may see a drop of semaglutide injection at the needle tip after injecting. This is normal and does not affect your dose.	
Step 5. After your injection	



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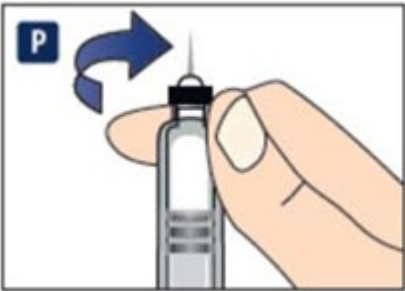
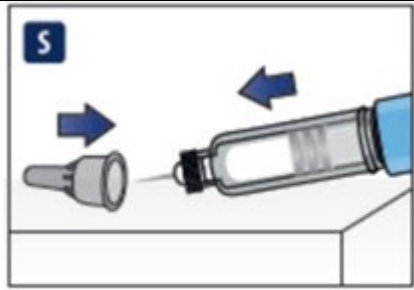
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Carefully remove the needle from the pen. Do not put the needle caps back on the needle to avoid needle stick injuries.	
Place the needle in a sharps disposal container right away to reduce the risk of needle stick injuries. See “Disposing of used semaglutide injection pens and needles” below for more information about how to dispose of used pens and needles the right way.	
Put the pen cap on your pen after each use to protect SEMAGARD injection from light.	
If you do not have a sharps disposal container, follow a one-handed needle recapping method. Carefully slip the needle into the outer needle cap. Dispose of the needle in a sharp's disposal container as soon as possible.	

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⚠ Never try to put the inner needle cap back on the needle. You may stick yourself with the needle. Always remove the needle from your pen. This will reduce the risk of contamination, infection, leakage of SEMAGARD injection or blocked needles leading to the wrong dose. If the needle is blocked, you will not inject any semaglutide injection.

Always dispose of the needle after each injection.

Disposing of used semaglutide injection pens and needles:

- Put your used SEMAGARD injection pen and needle in a sharp's disposal container right away after use.
- If you do not have a sharps disposal container, you may use a household container that is:
 - made of a heavy-duty plastic
 - can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out
 - upright and stable during use
 - leak-resistant
 - properly labelled to warn of hazardous waste inside the container
- When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharp's disposal container. There may be state or local laws about how you should throw away used needles and syringes.
- Do not dispose of your used sharps disposal container in your household trash unless your community guidelines permit this. Do not recycle your used sharps disposal container.
- Safely dispose of SEMAGARD injection that is out of date or no longer needed.

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Important

- Caregivers must be very careful when handling used needles to prevent accidental needle stick injuries and prevent passing (transmission) of infection.
- Never use a syringe to withdraw semaglutide injection from your pen.
- Always carry an extra pen and new needles with you, in case of loss or damage.
- Always keep your pen and needles out of reach of others, especially children.
- Always keep your pen with you. Do not leave it in a car or other place where it can get too hot or too cold.

Caring for your pen

- Do not drop your pen or knock it against hard surfaces. If you drop it or suspect a problem, attach a new needle and check the semaglutide injection flow before you inject.
- Do not try to repair your pen or pull it apart.
- Do not try to refill your pen. Once empty, it must be disposed of.
- Do not expose your pen to dust, dirt or liquid.
- Do not wash, soak, or lubricate your pen. If necessary, clean it with mild detergent on a moistened cloth.
- Do not inject SEMAGARD which has been frozen or exposed to direct sunlight. If you do that, you might not get the intended effect of this medicine.

Instructions on how to use SEMAGARD 1 mg/dose solution for injection in pre-filled pen	
Read these instructions carefully before using your SEMAGARD injection pen.	SEMAGARD injection pen and BD Ultra Fine™ needle (example)



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- Do not use your pen without proper training from your healthcare provider. Make sure that you know how to give yourself an injection with the pen before you start your treatment.
- Do not share your SEMAGARD injection pen with other people, even if the needle has been changed. You may give other people a serious infection, or get a serious infection from them.

⚠ If you are blind or have poor eyesight and cannot read the dose counter on the pen, do not use this pen without help. Get help from a person with good eyesight who is trained to use the SEMAGARD injection pen.

- Start by checking your pen to make sure that it contains SEMAGARD

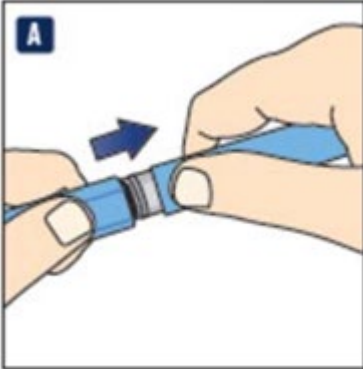
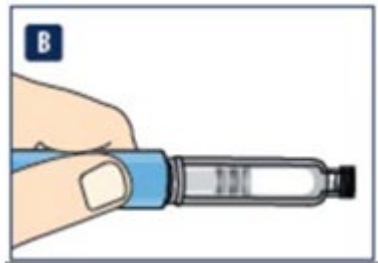
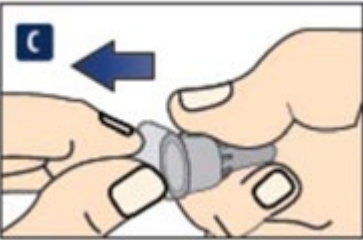
The diagram illustrates the components and usage of the SEMAGARD injection pen. It includes a Pen Cap, Outer needle cap, Inner needle cap, Needle, and Paper tab. The main pen assembly shows the Pen window, Expiration date (EXP) on back of pen label, Dose counter, Dose pointer, Dose selector, and Dose button. Two inset diagrams show the Flow check symbol and a Dashed line (used to guide to your dose).

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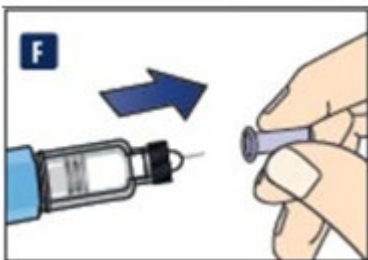
injection, then look at the pictures below to get to know the different parts of your pen and needle.

- Your pen is a prefilled, single-patient-use, dial-a-dose pen. It contains 4 mg of semaglutide, and you can select doses of 1 mg. Your pen is made to be used with BD Ultra- Fine™ disposable needles up to a length of 8 mm.
- Always use a new needle for each injection. Supplies you will need to give your SEMAGARD injection:
 - SEMAGARD injection pen 1 mg dose
 - a new BD Ultra Fine™ needle
 - 1 alcohol swab
 - 1 gauze pad or cotton ball
 - 1 sharps disposal container for throwing away used SEMAGARD Injection pens and needles.

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Product proprietary name:	SEMAGARD
Dosage form and strength:	Solution for injection, 2 mg / 1,5 mL and 4 mg / 3 mL (1,34 mg / mL) Semaglutide
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See “Disposing of used SEMAGARD injection pens and needles” at the end of these instructions.	
Step 1. Prepare your pen with a new needle	
- Wash your hands with soap and water. - Check the name and coloured label of your pen, to make sure that it contains semaglutide injection. This is especially important if you take more than 1 type of medicine. - Pull off the pen cap.	
Check that the SEMAGARD injection medicine in your pen is clear and colourless. Look through the pen window. If SEMAGARD injection looks cloudy or contains particles, do not use the pen.	
Take a new needle, and tear off the paper tab. Do not attach a new needle to your pen until you are ready to give your injection.	

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Push the needle straight onto the pen. Turn until it is on tight.	
Pull off the outer needle cap. Do not throw it away.	
Pull off the inner needle cap and throw it away. A drop of solution injection may appear at the needle tip. This is normal, but you must still check the semaglutide injection flow, if you use a new pen for the first time.	
⚠ Always use a new needle for each injection. This will reduce the risk of contamination, infection, leakage of semaglutide injection, and blocked needles leading to the wrong dose. Do not reuse or share your needles with other people. You may give other people a serious infection, or get a serious infection from them. Never use a bent or damaged needle.	
Step 2. Check the semaglutide flow with each new pen	



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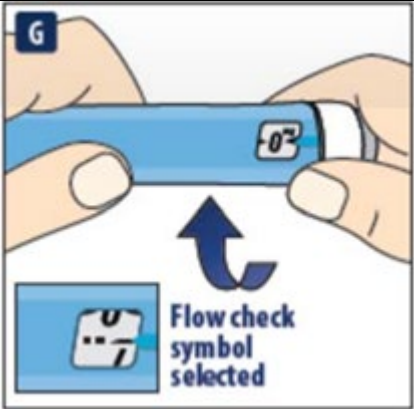
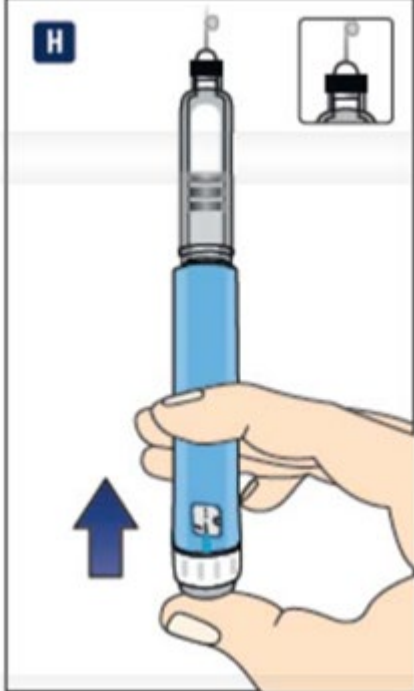
SEMAGARD

Dosage form and strength:

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• Check the semaglutide injection flow before your first injection with each new pen. If your SEMAGARD injection pen is already in use, go to Step 3 “Select your dose”. • Turn the dose selector until the dose counter shows the flow check symbol (—).	 Figure G shows a hand holding the SEMAGARD injection pen. The dose selector is turned until the flow check symbol (—) is visible on the dose counter. An inset shows a close-up of the dose counter with the flow check symbol selected. A blue arrow points to the symbol, and the text 'Flow check symbol selected' is written next to it.
• Hold the pen with the needle pointing up. Press and hold in the dose button until the dose counter shows 0. The 0 must line up with the dose pointer. A drop of SEMAGARD injection will appear at the needle tip. • If no drop appears, repeat Step 2 above as shown in Figure G and Figure H up to 6 times. If there is still no drop, change the needle and repeat Step 2 as shown in Figure G and Figure H 1 more time. Do not use the pen if a drop of SEMAGARD injection still does not appear.	 Figure H shows a hand holding the SEMAGARD injection pen with the needle pointing up. The dose button is being pressed. An inset shows a close-up of the dose button being pressed. A blue arrow points to the button.

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⚠ Always make sure that a drop appears at the needle tip before you use a new pen for the first time. This makes sure that semaglutide injection flows. If no drop appears, you will not inject any SEMAGARD injection, even though the dose counter may move. This may mean that there is a blocked or damaged needle.

A small drop may remain at the needle tip, but it will not be injected.

Only check the SEMAGARD flow before your first injection with each new pen.

Step 3.

Select your dose

Turn the dose selector until the dose counter stops and shows your 1 mg dose.

The dashed line in the dose counter (!) will guide you to 1 mg.

⚠ Always use the dose counter and the dose pointer to see that 1 mg has been selected.

- You will hear a “click” every time you turn the dose selector. Do not set the dose by counting the number of clicks you hear.**

Only doses of 1 mg can be selected with the dose selector. 1 mg must line up exactly with the dose pointer to make sure that you get a correct dose.

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The dose selector changes the dose. Only the dose counter and dose pointer will show that 1 mg has been selected.

You can select 1 mg for each dose. When your pen contains less than 1 mg, the dose counter stops before 1 mg is shown.

The dose selector clicks differently when turned forward or backward. Do not count the pen clicks.

How much SEMAGARD injection is left?

- To see how much SEMAGARD is left in your pen, use the dose counter:
Turn the dose selector until the dose counter stops.
 - If it shows 1, at least 1 mg is left in your pen. If the dose counter stops before 1 mg, there is not enough SEMAGARD injection left for a full dose of 1 mg.
- If there is not enough SEMAGARD injection left in your pen for a full dose, do not use it. Use a new SEMAGARD injection pen.



Step 4.

Inject your dose

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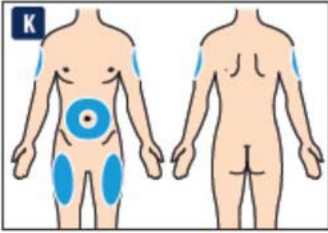
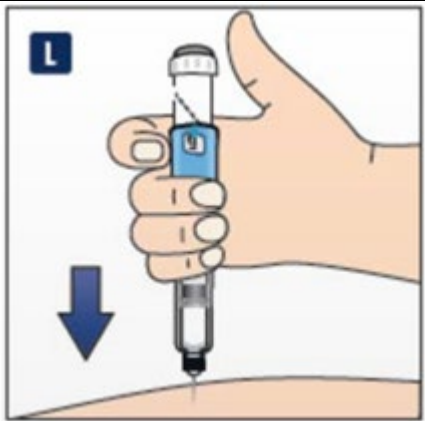
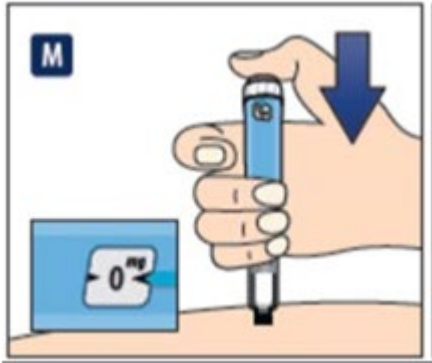
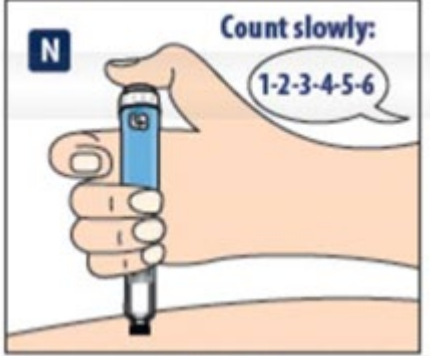
SEMAGARD

Dosage form and strength:

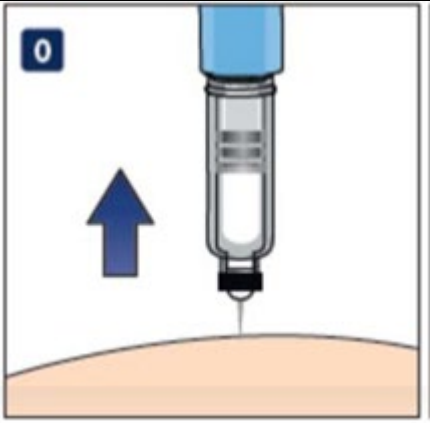
Solution for injection, 2 mg / 1,5 mL and 4 mg / 3 mL
(1,34 mg / mL) Semaglutide

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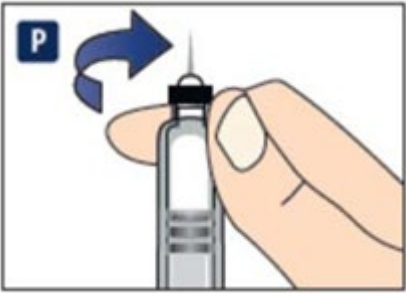
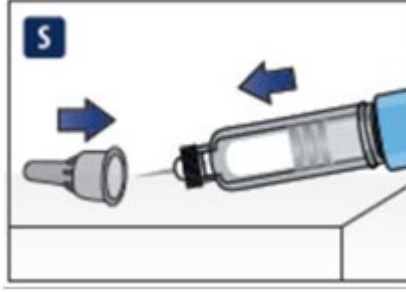
Choose your injection site and wipe the skin with an alcohol swab. Let the injection site dry before you inject your dose (See Figure K).	
• Insert the needle into your skin as your healthcare provider has shown you. • Make sure you can see the dose counter. Do not cover it with your fingers. This could stop the injection.	
• Press and hold down the dose button until the dose counter shows 0. The 0 must line up with the dose pointer. You may hear or feel clicking sound during injection.	
• Keep the needle in your skin after the dose counter has returned to 0 and count slowly to 6. If the needle is removed earlier, you may see a stream of semaglutide injection coming from the needle tip. If this happens, the full dose will not be delivered.	

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Remove the needle from your skin. If blood appears at the injection site, press lightly with a gauze pad or cotton ball. Do not rub the area.	
⚠ Always watch the dose counter to make sure you have injected your complete dose. Hold the dose button down until the dose counter shows 0. How to identify a blocked or damaged needle? - If 0 does not appear in the dose counter after continuously pressing the dose button, you may have used a blocked or damaged needle. - If this happens you have not received any semaglutide injection even though the dose counter has moved from the original dose that you have set.	
How to handle a blocked needle? Change the needle as described in Step 5, and repeat all steps starting with Step 1: “Prepare your pen with a new needle”. Never touch the dose counter when you inject. This can stop the injection. You may see a drop of semaglutide injection at the needle tip after injecting. This is normal and does not affect your dose.	
Step 5. After your injection	



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Carefully remove the needle from the pen. Do not put the needle caps back on the needle to avoid needle sticks.	
Place the needle in a sharps disposal container right away to reduce the risk of needle sticks. See “Disposing of used semaglutide injection pens and needles” below for more information about how to dispose of used pens and needles the right way.	
Put the pen cap on your pen after each use to protect semaglutide injection from light.	
If you do not have a sharps disposal container, follow a 1-handed needle recapping method. Carefully slip the needle into the outer needle cap. Dispose of the needle in a sharp’s disposal container as soon as possible.	

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⚠ Never try to put the inner needle cap back on the needle. You may stick yourself with the needle. Always remove the needle from your pen. This will reduce the risk of contamination, infection, leakage of semaglutide injection, and blocked needles leading to the wrong dose. If the needle is blocked, you will not inject any semaglutide injection.

Always dispose of the needle after each injection.

Disposing of used SEMAGARD pens and needles:

- Put your used semaglutide injection pen and needle in a sharp's disposal container right away after use.
- If you do not have a sharps disposal container, you may use a household container that is:
 - made of a heavy-duty plastic
 - can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out
 - upright and stable during use
 - leak-resistant
 - properly labelled to warn of hazardous waste inside the container
- When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharp's disposal container. There may be state or local laws about how you should throw away used needles and syringes.
- Do not dispose of your used sharps disposal container in your household trash unless your community guidelines permit this. Do not recycle your used sharps disposal container.
- Safely dispose of semaglutide injection that is out of date or no longer needed.

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Important

- **Caregivers must be very careful when handling used needles to prevent accidental needle stick injuries and prevent passing (transmission) of infection.**
- **Never use a syringe to withdraw semaglutide injection from your pen.**
- **Always carry an extra pen and new needles with you, in case of loss or damage.**
- **Always keep your pen and needles out of reach of others, especially children.**
- **Always keep your pen with you. Do not leave it in a car or other place where it can get too hot or too cold.**

Caring for your pen

- Do not drop your pen or knock it against hard surfaces. If you drop it or suspect a problem, attach a new needle and check the semaglutide injection flow before you inject.
- Do not try to repair your pen or pull it apart.
- Do not expose your pen to dust, dirt or liquid.
- Do not wash, soak, or lubricate your pen. If necessary, clean it with mild detergent on a moistened cloth.

How much to use

- When you first start using SEMAGARD, the starting dose is 0,25 mg once a week for four weeks.
- After four weeks you should increase your dose to 0,5 mg once a week. Talk to your doctor before increasing your dose.
- Your doctor may increase your dose to 1 mg once a week if your blood sugar is not controlled well enough with a dose of 0,5 mg once a week.



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- Do not change your dose unless your doctor has told you to do so.

How SEMAGARD is given

SEMAGARD is given as an injection under the skin (subcutaneous injection). Do not inject it into a vein or muscle.

- The best places to give the injection are the front of your thighs, the front of your waist (abdomen), or your upper arm.
- Before you use the pen for the first time, your doctor, pharmacist or other healthcare professional will show you how to use it.

Detailed instructions for use are at the end of this leaflet.

When to use SEMAGARD

- You should use SEMAGARD once a week on the same day each week if possible.
- You can administer the injection yourself at any time of the day – regardless of meals.
- To help you remember to inject SEMAGARD once a week only, it is recommended to note the chosen weekday (e.g., Wednesday) on the carton. You can also write the date on the carton every time you have injected SEMAGARD.
- If necessary, you can change the day of your weekly injection of SEMAGARD as long as it has been at least 2 days since your last injection of SEMAGARD.

If you inject more SEMAGARD than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

You may get side effects such as feeling sick (nausea) or being sick (vomiting), or diarrhoea.



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If you forget to inject SEMAGARD:

If you forgot to use a dose and:

- it is 5 days or less since you should have administered SEMAGARD injection, administer the injection as soon as you remember. Then inject your next dose as usual on your scheduled day.
- it is more than 5 days since you should have used SEMAGARD, skip the missed dose. Then inject your next dose as usual on your scheduled day.

Do not take an extra dose or increase the dose to make up for a missed dose.

If you stop using SEMAGARD:

Do not stop using SEMAGARD without talking to your doctor. If you stop using it, your blood sugar levels may increase.

4. Possible side effects

SEMAGARD can have side effects.

Not all side effects reported for SEMAGARD are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using SEMAGARD, please consult your healthcare provider for advice.

If any of the following happens, stop using SEMAGARD and tell your doctor immediately or go to the casualty department at your nearest hospital.

Serious side effects

Less frequent



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- Severe allergic reactions (anaphylactic reactions, angioedema). You should seek immediate medical help and inform your doctor straight away if you get symptoms such as breathing problems, swelling of face, lips, tongue and/or throat with difficulty swallowing and a fast heartbeat.
- Inflamed pancreas (acute pancreatitis) which could cause severe pain in the stomach and back which does not go away. You should see a doctor immediately if you experience such symptoms.
- A medical condition of the eye called non-arteritic anterior ischaemic optic neuropathy (NAION), which may cause loss of vision to one of your eyes without any pain. You should immediately contact your doctor if you notice sudden or gradually worsening eyesight (see section 2: “Sudden changes to your eyesight”).

These are all very serious side effects. If you have them, you may have had a serious reaction to SEMAGARD. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Other side effects

Frequent

- feeling sick (nausea)
- diarrhoea
- low blood sugar (hypoglycaemia) when SEMAGARD is used with a sulfonylurea or insulin.

The warning signs of low blood sugar may come on suddenly. They can include: cold sweat, cool pale skin, headache, fast heartbeat, feeling sick (nausea) or very hungry, changes in vision, feeling sleepy or weak, feeling nervous, anxious or confused, difficulty concentrating or shaking.

Your doctor will tell you how to treat low blood sugar and what to do if you notice these warning signs.

- being sick (vomiting)
- indigestion



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- inflamed stomach ('gastritis') – the signs include stomach ache, feeling sick (nausea) or being sick (vomiting)
- reflux or heartburn – also called 'gastro-esophageal reflux disease' (GERD)
- stomach pain
- bloating of the stomach
- constipation
- burping
- gall stones with severe pain in right upper abdomen
- feeling dizzy
- feeling tired
- weight loss
- less appetite
- gas (flatulence)
- increase of pancreatic enzymes (such as lipase and amylase)
- complications of diabetic eye disease (retinopathy).
- Headache.

Less frequent

- Severe allergic reactions (anaphylactic reactions, angioedema). You should seek immediate medical help and inform your doctor straight away if you get symptoms such as breathing problems, swelling of face, lips, tongue and/or throat with difficulty swallowing and a fast heartbeat.
- change in the way food or drink tastes
- fast pulse
- injection site reactions – such as bruising, pain, irritation, itching and rash.
- A delay in the emptying of the stomach.



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Side effects with unknown frequency

- Angioedema (swelling under the skin surface due to allergic reaction generally occurs around the eyes, lips and tongue)
- Change in skin sensation
- Bowel obstruction. A severe form of constipation with additional symptoms such as stomach ache, bloating, vomiting etc. These are all very serious side effects. If you have them, you may have had a serious reaction to SEMAGARD. You may need urgent medical attention or hospitalisation.

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

Reporting of side effects

If you get side effects, talk to you doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. Suspected adverse reactions can also be reported directly to the HCR via email: pharmacovigilance.africasme@sunpharma.com or tel: +27(0) 12 643 2000. By reporting side effects, you can help provide more information on the safety of SEMAGARD.



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5. How to store SEMAGARD

- Store all medicines out of reach of children.
- Do not use after the expiry date stated on the pen label and carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

Prior to first use, SEMAGARD should be stored in a refrigerator between 2 °C to 8 °C.

Do not store in the freezer or directly adjacent to the refrigerator cooling element. Do not freeze SEMAGARD and do not use SEMAGARD if it has been frozen.

After first use of SEMAGARD, the pen can be stored for 56 days at controlled room temperature (15 °C to 30 °C) or in a refrigerator (2 °C to 8 °C). Do not freeze. Keep the pen cap on when not in use.

SEMAGARD should be protected from excessive heat and sunlight

6. Contents of the pack and other information

What SEMAGARD contains

SEMAGARD contains the active substance is semaglutide.

One ml solution for injection contains 1,34 mg semaglutide.

SEMAGARD 0,25 mg and 0,5 mg/dose pen:

Each pre-filled pen contains 2 mg semaglutide in 1,5 ml solution

SEMAGARD 1 mg/dose pen:

Each pre-filled pen contains 4 mg semaglutide in 3 ml solution

The other ingredients are dibasic sodium phosphate, hydrochloric acid, phenol, propylene glycol, sodium hydroxide, water for injection.



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What SEMAGARD looks like and contents of the pack

A clear, colourless solution, free from visible particulate matter, filled in plunger stoppered glass cartridge assembled in pre-filled, disposable, single patient-use pen with blue body sub assembly, gray button and white dose set knob and blue cap.

3 mL colourless USP type I glass cartridges with a 10 mm grey bromobutyl rubber plunger stopper and a combination seal (cream inner and gray outer).

One filled and sealed cartridge of SEMAGARD, 2 mg /1,5mL and 4 mg/ 3mL (1,34 mg/mL), packed in one transparent cartridge holder and assembled with the help of body subassembly (blue body with grey button and white dose knob) and blue cap for pen injector.

Pack sizes:

SEMAGARD 0,25 mg, 0,5 mg / dose pen:

1 x 1,5 ml pre-filled pen including 6 disposable needles.

SEMAGARD 1 mg/dose pen:

1 x 3 ml pre-filled pen including 4 disposable needles.

Holder of Certificate of Registration

RANBAXY PHARMACEUTICALS (PTY) LTD

14 Lautre Road

Stormill Ext.1

Roodepoort

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South Africa
Tel: +27(0) 12 643 2000

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