Package leaflet: Information for the user

GOBIVAZ 100 mg solution for injection in pre-filled syringe
golimumab

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

Your doctor will also give you a Patient Reminder Card, which contains important safety information you need to be aware of before and during your treatment with GOBIVAZ.

What is in this leaflet

1. What GOBIVAZ is and what it is used for

GOBIVAZ contains the active substance called golimumab.

GOBIVAZ belongs to a group of medicines called 'TNF blockers'. It is used **in adults** for the treatment
of the following inflammatory diseases:
- Rheumatoid arthritis
- Psoriatic arthritis
- Axial spondyloarthritis, including ankylosing spondylitis and non-radiographic axial spondyloarthritis
- Ulcerative colitis

GOBIVAZ works by blocking the action of a protein called 'tumour necrosis factor alpha' (TNF-α). This
protein is involved in inflammatory processes of the body, and blocking it can reduce the inflammation in your body.

Rheumatoid arthritis
Rheumatoid arthritis is an inflammatory disease of the joints. If you have active rheumatoid arthritis you will first be given other medicines. If you do not respond well enough to these medicines, you

may be given GOBIVAZ which you will take in combination with another medicine called methotrexate
to:

- Reduce the signs and symptoms of your disease.
- Slow down the damage to your bones and joints.
- Improve your physical function

Psoriatic arthritis
Psoriatic arthritis is an inflammatory disease of the joints, usually accompanied by psoriasis, an inflammatory disease of the skin. If you have active psoriatic arthritis you will first be given other medicines. If you do not respond well enough to these medicines, you may be given GOBIVAZ to:

- Reduce the signs and symptoms of your disease.
- Slow down the damage to your bones and joints.
- Improve your physical function

Ankylosing spondylitis and non-radiographic axial spondyloarthritis
Ankylosing spondylitis and non-radiographic axial spondyloarthritis are inflammatory diseases of the spine. If you have ankylosing spondylitis or non-radiographic axial spondyloarthritis, you will first be given other medicines. If you do not respond well enough to these medicines, you may be given GOBIVAZ to:

- Reduce the signs and symptoms of your disease.
- Improve your physical function.

Ulcerative colitis
Ulcerative colitis is an inflammatory disease of the bowel. If you have ulcerative colitis you will first be given other medicines. If you do not respond well enough to these medicines, you will be given GOBIVAZ to treat your disease.

2. What you need to know before you use GOBIVAZ

Do not use GOBIVAZ

- If you are allergic (hypersensitive) to golimumab or any of the other ingredients of this medicine (listed in Section 6).
- If you have tuberculosis (TB) or any other severe infection.
- If you have moderate or severe heart failure.

If you are not sure if any of the above applies to you, talk to your doctor, pharmacist or nurse before using GOBIVAZ.

Warnings and precautions
Talk to your doctor, pharmacist or nurse before using GOBIVAZ

Infections
Tell your doctor straight away if you already have or get any symptoms of infection, during or after your treatment with GOBIVAZ. Symptoms of infection include fever, cough, shortness of breath, flu-like symptoms, diarrhoea, wounds, dental problems or a burning feeling when urinating.

- You may get infections more easily while using GOBIVAZ.
- Infections may progress more rapidly and may be more severe. In addition, some previous infections may reappear.

Tuberculosis (TB)
Tell your doctor straight away if symptoms of TB appear during or after your treatment. Symptoms of TB include persistent cough, weight loss, tiredness, fever or night sweats.

Cases of TB have been reported in patients treated with GOBIVAZ, in rare occasions even in patients who have been treated with medicines for TB. Your doctor will test you to see if you have TB. Your doctor will record these tests on your Patient Reminder Card.

- It is very important that you tell your doctor if you have ever had TB, or if you have been in close contact with someone who has had or has TB.
- If your doctor feels that you are at risk of TB, you may be treated with medicines for TB before you begin using GOBIVAZ.

Hepatitis B virus (HBV)

- Tell your doctor if you are a carrier or if you have or have had HBV before you are given GOBIVAZ.
  Tell your doctor if you think you might be at risk of contracting HBV.
- Your doctor should test you for HBV.
- Treatment with TNF blockers such as GOBIVAZ may result in reactivation of HBV in
- patients who carry this virus, which can be life-threatening in some cases.

Invasive fungal infections

If you have lived in or travelled to an area where infections caused by specific type of fungi that can affect the lungs or other parts of the body (called histoplasmosis, coccidioidomycosis, or blastomycosis), are common, tell your doctor straight away. Ask your doctor if you don't know if these fungal infections are common in the area in which you have lived or travelled.

<u>Cancer and lymphoma</u>

Tell your doctor if you have ever been diagnosed with lymphoma (a type of blood cancer) or any other cancer before you use GOBIVAZ.

- If you use GOBIVAZ or other TNF blockers, your risk for developing lymphoma or another cancer may increase.
- Patients with severe rheumatoid arthritis and other inflammatory diseases, who have had the disease for a long time, may be at higher than average risk of developing lymphoma.
- There have been cases of cancers, including unusual types, in children and teenage patients taking TNF-blocking agents, which sometimes resulted in death.
- On rare occasions, a specific and severe type of lymphoma called hepatosplenic T-cell
- lymphoma has been observed in patients taking other TNF-blockers. Most of these patients were adolescent or young adult males. This type of cancer has usually resulted in death. Almost all of these patients had also received medicines known as azathioprine or 6-mercaptopurine.
  Tell your doctor if you are taking azathioprine or 6-mercaptopurine with GOBIVAZ.
- Patients with severe persistent asthma, chronic obstructive pulmonary disease (COPD), or are heavy smokers may be at increased risk for cancer with GOBIVAZ treatment. If you have severe persistent asthma, COPD or are a heavy smoker, you should discuss with your doctor whether treatment with a TNF blocker is appropriate for you.
- Some patients treated with golimumab have developed certain kinds of skin cancer. If any changes in the appearance of the skin or growths on the skin occur during or after therapy, tell your doctor.

<u>Heart failure</u>

Tell your doctor straight away if you get new or worsening symptoms of heart failure. symptoms of heart failure include shortness of breath or swelling of your feet.

- New and worsening congestive heart failure has been reported with TNF blockers, including GOBIVAZ. Some of these patients died.
- If you have mild heart failure and you are being treated with GOBIVAZ, you must be closely monitored by your doctor.

<u>Nervous system disease</u>

Tell your doctor straight away if you have ever been diagnosed with or develop symptoms of a

demyelinating disease such as multiple sclerosis. Symptoms may include changes in your vision, weakness in your arms or legs or numbness or tingling in any part of your body. Your doctor will decide if you should receive GOBIVAZ.

Operations or dental procedures

- Talk to your doctor if you are going to have any operations or dental procedures.
- Tell your surgeon or dentist performing the procedure that you are having treatment with GOBIVAZ by showing them your Patient Reminder Card.

Autoimmune disease

Tell your doctor if you develop symptoms of a disease called lupus. Symptoms include persistent rash, fever, joint pain and tiredness.

- On rare occasions, people treated with TNF blockers have developed lupus.

Blood disease

In some patients the body may fail to produce enough of the blood cells that help your body fight infections or help you to stop bleeding. If you develop a fever that does not go away, bruise or bleed very easily or look very pale, call your doctor right away. Your doctor may decide to stop treatment.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before using GOBIVAZ.

Vaccinations

Talk to your doctor if you have had, or are due to have a vaccine.

- You should not receive certain (live) vaccines while using GOBIVAZ.
- Certain vaccinations may cause infections. If you received GOBIVAZ while you were pregnant, your baby may be at higher risk for getting such an infection for up to approximately six months after the last dose you received during pregnancy. It is important that you tell your baby's doctors and other health care professionals about your GOBIVAZ use so they can decide when your baby should receive any vaccine.

Therapeutic infectious agents

Talk to your doctor if you have recently received or are scheduled to receive treatment with a therapeutic infectious agent (such as BCG instillation used for the treatment of cancer).

Allergic reactions

Tell your doctor straight away if you develop symptoms of an allergic reaction after your treatment with GOBIVAZ. Symptoms of an allergic reaction may include swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing, skin rash, hives, swelling of the hands, feet or ankles.

- Some of these reactions may be serious or, rarely, life-threatening.
- Some of these reactions occurred after the first administration of GOBIVAZ

Children and adolescents

GOBIVAZ 100 mg is not recommended for children and adolescents (younger than 18 years).

Other medicines and GOBIVAZ

- Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines, including any other medicines to treat rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, non-radiographic axial spondyloarthritis, or ulcerative colitis.
- You should not take GOBIVAZ with medicines containing the active substance anakinra or abatacept. These medicines are used for the treatment of rheumatic diseases.
- Tell your doctor or pharmacist if you are taking any other medicines that affect your immune System.
  You should not receive certain (live) vaccines while using GOBIVAZ.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before using GOBIVAZ.

Pregnancy and breast-feeding
Talk to your doctor before using GOBIVAZ if:

- You are pregnant or are planning to become pregnant while using GOBIVAZ. There is limited information about the effects of this medicine in pregnant women. If you are being treated with GOBIVAZ, you must avoid becoming pregnant by using adequate contraception during your treatment and for at least 6 months after the last GOBIVAZ injection. GOBIVAZ should only be used during pregnancy if it is clearly necessary for you.
- Before starting breast-feeding, your last treatment with GOBIVAZ must be at least 6 months ago.
  You must stop breast-feeding if you are to be given GOBIVAZ.
- If you received GOBIVAZ during your pregnancy, your baby may have a higher risk for getting an infection. It is important that you tell your baby's doctors and other health care professionals about your GOBIVAZ use before the baby receives any vaccine (for more information see section on vaccination).

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines
GOBIVAZ has minor influence on your ability to drive and use tools or machines. Dizziness may however occur after you take GOBIVAZ. If this happens, do not drive or use any tools or machines.

GOBIVAZ contains sorbitol
Sorbitol intolerance
This medicine contains 41 mg sorbitol in each pre-filled syringe

3. How to use GOBIVAZ

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

How much GOBIVAZ is given
Rheumatoid arthritis, psoriatic arthritis, and axial spondyloarthritis, including ankylosing spondylitis and non-radiographic axial spondyloarthritis:

- The recommended dose is 50 mg given once a month, on the same date each month.
- Talk to your doctor before taking your fourth dose. Your doctor will determine if you should continue GOBIVAZ treatment.
  - If you weigh more than 100 kg, the dose might be increased to 100 mg (the content of 1 pre-filled syringe) given once a month, on the same date each month.

Ulcerative colitis

- The table below shows how you will usually use this medicine.

Initial treatment	A starting dose of 200 mg (the contents of 2 pre-filled syringes) followed by 100 mg (the contents of 1 pre-filled syringe) 2 weeks later.
Maintenance treatment	• In patients weighing less than 80 kg, 50 mg (the 50 mg pre-filled pen or pre-filled syringe must be used to administer this dose) 4 weeks after your last treatment, then every 4 weeks thereafter. Your doctor may decide to prescribe 100 mg (the contents of 1 pre-filled syringe), depending on how well GOBIVAZ works for you. • In patients weighing 80 kg or more, 100 mg (the contents of

	1 pre-filled syringe) 4 weeks after your last treatment, then every 4 weeks thereafter.

How GOBIVAZ is given

- GOBIVAZ is given by injection under the skin (subcutaneously).
- At the start, your doctor or nurse may inject GOBIVAZ. However, you and your doctor may decide that you may inject GOBIVAZ yourself. In this case you will get training on how to inject GOBIVAZ yourself.

Talk to your doctor if you have any questions about giving yourself an injection. You will find detailed "Instructions for Use" at the end of this leaflet.

If you use more GOBIVAZ than you should

If you have used or been given too much GOBIVAZ (either by injecting too much on a single occasion, or by using it too often), talk to your doctor or pharmacist straight away. Always take the outer carton and this leaflet with you, even if it is empty.

If you forget to use GOBIVAZ

If you forget to use GOBIVAZ on your planned date, inject the forgotten dose as soon as you remember.

Do not use a double dose to make up for a forgotten dose.

When to inject your next dose:

- If you are less than 2 weeks late, inject the forgotten dose as soon as you remember and stay on your original schedule.
- If you are more than 2 weeks late, inject the forgotten dose as soon as you remember and talk to your doctor or pharmacist to ask when you need to take the next dose.

If you are not sure what to do, talk to your doctor or pharmacist.

If you stop using GOBIVAZ

If you are considering stopping GOBIVAZ, talk to your doctor or pharmacist first.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Some patients may experience serious side effects and may require treatment. The risk of certain side effects is greater with the 100 mg dose compared with the 50 mg dose. Side effects may appear up to several months after the last injection.

Tell your doctor straight away if you notice any of the following serious side effects of GOBIVAZ which include:

- **allergic reactions which may be serious, or rarely, life-threatening (rare).** Symptoms of an allergic reaction may include swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing, skin rash, hives, swelling of the hands, feet or ankles. Some of these reactions occurred after the first administration of GOBIVAZ.
- **serious infections (including TB, bacterial infections including serious blood infections and pneumonia, severe fungal infections and other opportunistic infections) (common).** Symptoms of an infection can include fever, tiredness, (persistent) cough, shortness of breath, flu-like symptoms, weight loss, night sweats, diarrhoea, wounds, dental problems and a burning feeling when urinating.
- **reactivation of hepatitis B virus if you are a carrier or have had hepatitis B before (rare).**

Symptoms can include yellowing of the skin and eyes, dark brown-coloured urine, right-sided abdominal pain, fever, feeling sick, being sick, and feeling very tired.

- **nervous system disease such as multiple sclerosis (rare).** Symptoms of nervous system disease can include changes in your vision, weakness in your arms or legs, numbness or tingling in any part of your body.
- **cancer of the lymph nodes (lymphoma) (rare).** Symptoms of lymphoma can include swelling of the lymph nodes, weight loss, or fever.
- **heart failure (rare).** Symptoms of heart failure can include shortness of breath or swelling of your feet.
- **signs of immune system disorders called:**
  - **lupus (rare).** Symptoms can include joint pain or a rash on cheeks or arms that is sensitive to the sun.
  - **sarcoidosis (rare).** Symptoms can include a persistent cough, being short of breath, chest pain, fever, swelling of your lymph nodes, weight loss, skin rashes, and blurred vision.
- **swelling of small blood vessels (vasculitis) (rare).** Symptoms can include fever, headache, weight loss, night sweats, rash, and nerve problems such as numbness and tingling.
- **skin cancer (uncommon).** Symptoms of skin cancer can include changes in the appearance of your skin or growths on your skin.
- **blood disease (common). Symptoms** of blood disease can include a fever that does not go away, bruising or bleeding very easily or looking very pale.
- **blood cancer (leukaemia) (rare).** Symptoms of leukaemia can include fever, feeling tired, frequent infections, easy bruising, and night sweats.

Tell your doctor straight away if you notice any of the above symptoms.

The following additional side effects have been observed with GOBIVAZ

Very common side effects (may affect more than 1 in 10 people):

- Upper respiratory tract infections, sore throat or hoarseness, runny nose

Common side effects (may affect up to 1 in 10 people):

- Abnormal liver tests (increased liver enzymes) found during blood tests done by your doctor
- Feeling dizzy
- Headache
- Feeling numb or having a tingling feeling
- Superficial fungal infections
- Abscess
- Bacterial infections (such as cellulitis)
- Low red blood cell counts
- Low white blood cell counts
- Positive blood lupus test
- Allergic reactions
- Indigestion
- Stomach pain
- Feeling sick (nausea)
- Flu
- Bronchitis
- Sinus infection
- Cold sores
- High blood pressure
- Fever
- Asthma, shortness of breath, wheezing
- Stomach and bowel disorders which include inflammation of the stomach lining and colon which may cause fever
- Pain and ulcers in the mouth
- Injection site reactions (including redness, hardness, pain, bruising, itching, tingling and

- irritation)
- Hair loss
- Rash and itching of the skin
- Difficulty sleeping
- Depression
- Feeling weak
- Bone fractures
- Chest discomfort

Uncommon side effects (may affect up to 1 in 100 people):

- Kidney infection
- Cancers, including skin cancer and non-cancerous growths or lumps, including skin moles
- Skin blisters
- Severe infection throughout the body (sepsis), sometimes including low blood pressure (septic shock)
- Psoriasis (including on the palms of your hand and/or the soles of your feet and/or in the form of skin blisters)
- Low platelet count
- Combined low platelet, red, and white blood cell count
- Thyroid disorders
- Increase in blood sugar levels
- Increase in blood cholesterol levels
- Balance disorders
- Vision disturbances
- Inflamed eye (conjunctivitis)
- Eye allergy
- Sensation of heart beating irregularly
- Narrowing of the blood vessels in the heart
- Blood clots
- Flushing
- Constipation
- Chronic inflammatory condition of the lungs
- Acid reflux
- Gall stones
- Liver disorders
- Breast disorders
- Menstrual disorders

Rare side effects (may affect up to 1 in 1,000 people):

- Failure of the bone marrow to produce blood cells
- Severely decreased number of white blood cells
- Infection of the joints or the tissue around them
- Impaired healing
- Inflammation of blood vessels in internal organs
- Leukaemia
- Melanoma (a type of skin cancer)
- Merkel cell carcinoma (a type of skin cancer)
- Lichenoid reactions (itchy reddish-purple skin rash and/or threadlike white-grey lines on mucous membranes)
- Scaly, peeling skin
- Immune disorders that could affect the lungs, skin and lymph nodes (most commonly presenting
- as sarcoidosis)
- Pain and discolouration in the fingers or toes

- Taste disturbances
- Bladder disorders
- Kidney disorders
- Inflammation of the blood vessels in your skin which results in rash

Side effects of which the frequency is not known:
- A rare blood cancer affecting mostly young people (hepatosplenic T-cell lymphoma)
- Kaposi's sarcoma, a rare cancer related to infection with human herpes virus 8. Kaposi's sarcoma most commonly appears as purple lesions on the skin
- Worsening of a condition called dermatomyositis (seen as a skin rash accompanying muscle weakness)

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store GOBIVAZ

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the label and the carton after "EXP". The expiry date refers to the last day of that month.
- Store in a refrigerator (2°C-8°C). Do not freeze.
- Keep the pre-filled syringe in the outer carton in order to protect it from light.
- This medicine can also be stored out of the refrigerator at temperatures up to a maximum of 25°C for a single period of up to 30 days, but not beyond the original expiry date printed on the carton. Write the new expiry date on the carton including day/month/year (no more than 30 days after the medicine is removed from the refrigerator). Do not return this medicine to refrigerator if it has reached room temperature. Discard this medicine if not used by the new expiry date or the expiry date printed on the carton, whichever is earlier.
- Do not use this medicine if you notice that the liquid is not a clear to light yellow colour, cloudy, or contains foreign particles.
- Do not throw away any medicines via wastewater or household waste. Ask your doctor or pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What GOBIVAZ contains
The active substance is golimumab. One 1 mL pre-filled syringe contains 100 mg of golimumab.
The other ingredients are sorbitol, L-histidine, L-histidine monohydrochloride monohydrate, poloxamer 188 and water for injections. For more information on sorbitol, see Section 2.

What GOBIVAZ looks like and contents of the pack
GOBIVAZ is supplied as solution for injection in a single-use pre-filled syringe. GOBIVAZ is available in packs containing 1 pre-filled syringe and multipacks containing 3 (3 packs of 1) pre-filled syringes. Not all pack sizes may be marketed.

The solution is clear to slightly opalescent (having a pearl-like shine), colourless to light yellow and may contain a few small translucent or white particles of protein. Do not use GOBIVAZ if the solution is discoloured, cloudy or you can see foreign particles in it.

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This leaflet was last revised in September 2025.

INSTRUCTIONS FOR USE

If you would like to self inject Govibaz, you must be trained by a healthcare professional to prepare an injection and give it to yourself. If you have not been trained, please contact your doctor, nurse or pharmacist to schedule a training session.

In these instructions:
1. Preparing for use of the pre-filled syringe
2. Choosing and preparing the injection site
3. Injecting the medicine
4. After the injection

The diagram below (see figure 1) shows what the pre-filled syringe looks like.

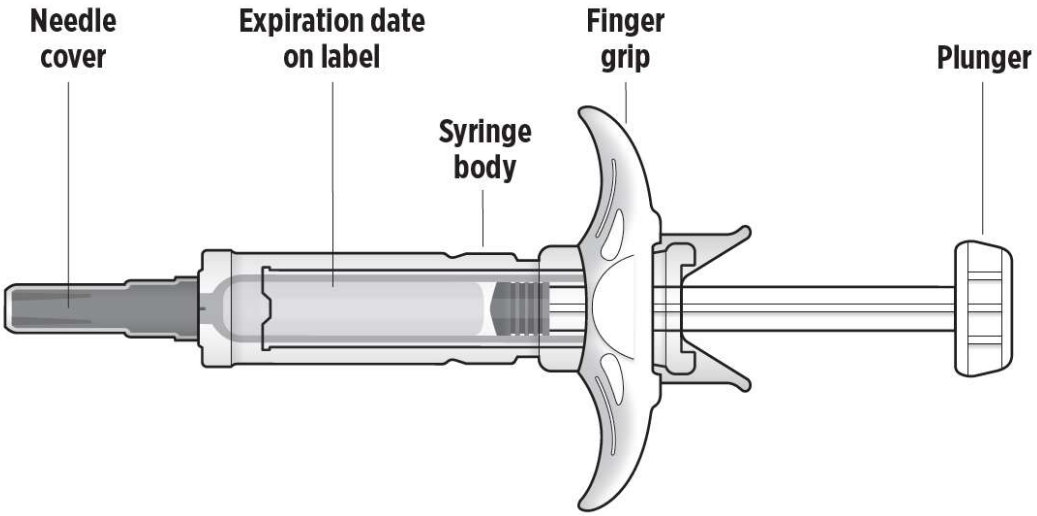

Figure 1

1. Preparing for use of the pre-filled syringe

Hold the pre-filled syringe by the body of the pre-filled syringe
- Do not hold by the plunger, or needle cover.
- Do not pull back on the plunger at any time.
- Do not shake the pre-filled syringe at any time.
- Do not remove the needle cover from the pre-filled syringe until instructed to do so.

Check the number of pre-filled syringes

Check the pre-filled syringes to make sure
- the number of pre-filled syringes and strength is correct
  - If your dose is 100 mg, you will get one 100 mg pre-filled syringes. If your dose is 200 mg, you will get two 100 mg pre-filled syringes and you will need to give yourself two injections. Choose different sites for these injections and give the injections one right after the other.

Check expiry date (see figure 2)
- Check the expiration date printed or written on the carton and blister.
- Check the expiration date (as indicated by "EXP") on the label in the body of the pre-filled syringe.
- Do not use the pre-filled syringe if the expiration date has passed. The printed expiration date refers to the last day of the month. Please contact your doctor or pharmacist for assistance.

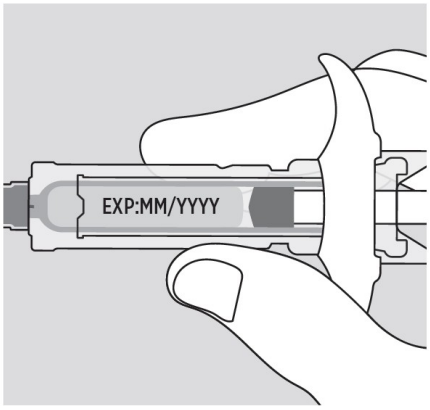

Figure 2

Wait 30 minutes to allow pre-filled syringe to reach room temperature

- To ensure proper injection, allow the pre-filled syringe to sit at room temperature outside the box for 30 minutes, out of the reach of children.

Do not warm the pre-filled syringe in any other way (for example, do not warm it in a microwave or in hot water).
Do not remove the pre-filled syringe's needle cover while allowing it to reach room temperature.

Get the rest of your equipment ready

While you are waiting you can get the rest of your equipment ready, including an alcohol swab, a cotton ball or gauze and a sharps container.

Check the liquid in the pre-filled syringe

- Hold the pre-filled syringe by its body with the covered needle pointing downward.
- Look at the liquid through the viewing window of the pre-filled syringe and make sure that it is clear to slightly opalescent (having a pearl-like shine) and colourless to light yellow. The solution can be used if it contains a few small translucent or white particles of protein.
- If you cannot see the liquid through the viewing window, hold the pre-filled syringe by its body and rotate the needle cover to line up the liquid to the viewing window (see figure 2).

Do not use the pre-filled syringe if the liquid is the wrong colour, cloudy, or contains larger particles. If this happens, talk to your doctor or pharmacist.

2. Choosing and preparing the injection site (see figure 3)

- You usually inject the medicine into the front of the middle thighs.
- You can also use the lower stomach (abdomen) below the belly button, except for approximately the 5 cm area directly underneath the belly button.
- Do not inject into areas where the skin is tender, bruised, red, scaly, hard or has scars or stretch marks.
- If multiple injections are required for a single administration, the injections should be administered at different sites on the body.

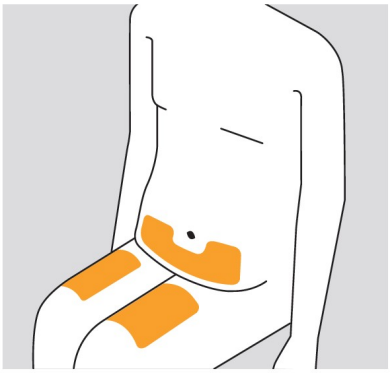

Figure 3

Injection site selection for caregivers (see figure 4)

- If a caregiver is giving you the injection, they can also use the outer area of the upper arms.
- Again, all sites mentioned can be used regardless of your body type or size.

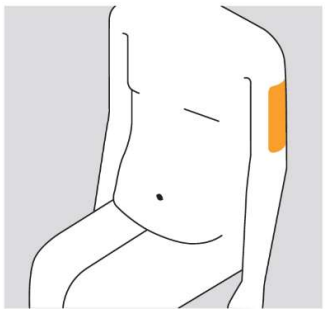

Figure 4

Preparing injection site

- Wash your hands thoroughly with soap and warm water.
- Wipe the injection site with an alcohol swab.
- Allow the skin to dry before injecting. Do not fan or blow on the clean area.

Do not touch this area again before giving the injection.

3. Injecting the medicine

The needle cover should not be removed until you are ready to inject the medicine. The medicine should be injected within 5 minutes after the needle cover has been removed.

Do not touch the plunger during needle cover removal.

Remove the needle cover (see figure 5)

- When you are ready to inject, hold the body of the pre-filled syringe with one hand.
- Pull the needle cover straight off and throw it away after your injection. Do not touch the plunger while you do this.
- You may notice an air bubble in the pre-filled syringe or a drop of liquid at the end of the needle. These are both normal and do not need to be removed.
- Inject the dose promptly after removing the needle cover.

Do not touch the needle or allow it to touch any surface.
Do not use the pre-filled syringe if it is dropped without the needle cover in place. If this happens, please contact your doctor or pharmacist.

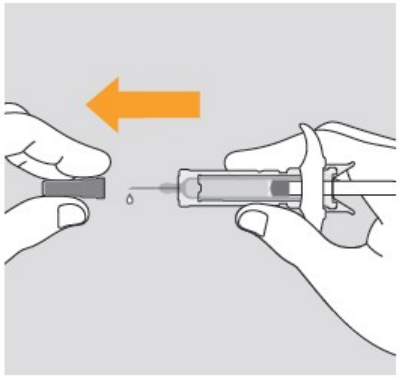

Figure 5

Position the pre-filled syringe to inject

- Hold the body of the pre-filled syringe with one hand between the middle and index fingers and place the thumb on top of the plunger head and use the other hand to gently pinch the area of skin that you previously cleaned. Hold firmly. Do not pull back on the plunger at any time.

Inject the medicine

- Place the needle at approximately a 45-degree angle to the pinched skin. In a single and swift motion, insert the needle through the skin as far as it will go (see figure 6).

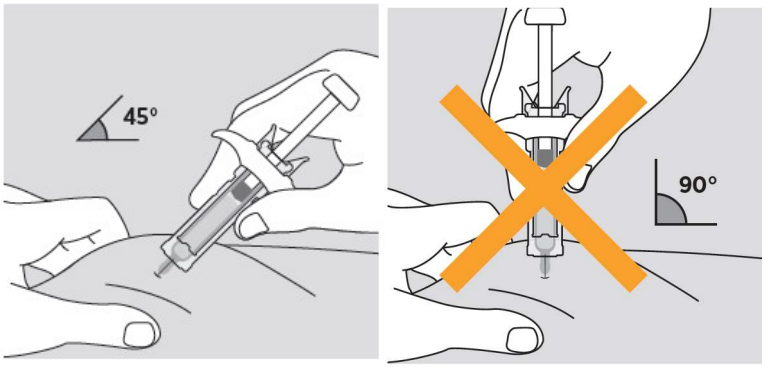

Figure 6

- Release pinch and reposition hand. Use your free hand to grasp the body of the pre-filled syringe. Place thumb from the opposite hand on the plunger and press the plunger all the way down until it stops. (see figure 7).

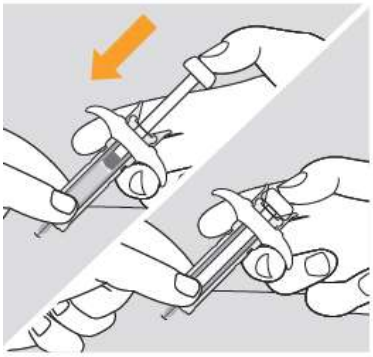

Figure 7

- Release pressure from plunger, the safety guard will cover the needle and lock into place, removing the needle from your skin. (see figure 8).

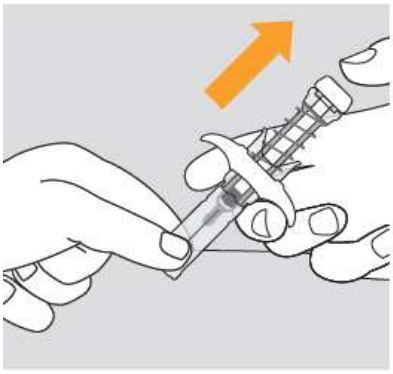

Figure 8

4. After the injection

Use a cotton ball or gauze

- There may be a small amount of blood or liquid at the injection site. This is normal.
- You can press a cotton ball or gauze over the injection site and hold for 10 seconds.
- You may cover the injection site with a small adhesive bandage, if necessary.
- Do not rub your skin.

Throw the pre-filled syringe away (see figure 9)

- Place your pre-filled syringe in a sharps container straight away. Make sure you dispose of the bin as instructed by your doctor or nurse.

Do not attempt to recap the needle.

Do not ever re-use a pre-filled syringe, for your safety and health and for the safety of others.

If you feel that something has gone wrong with the injection or if you are not sure, talk to your doctor or pharmacist.

Figure 9