PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

# Touieo Solution for Subcutaneous

Injection in SoloStar pen

Active ingredient: Each pre-filled SoloStar pen contains ml of insulin place Each SoloStar pen supplies 1-80 units, in 1-unit intervals

Read this leaflet carefully in its entirety before using the

medicine.
This leaflet contains concise information about the medicine.
If you have further questions, refer to the doctor, pharmacist or nurse. This medicine has been prescribed for you. Do not pass it on

to others. It may harm them even if it seems to you that their medical condition is similar.

#### 1 WHAT IS THE MEDICINE INTENDED FOR

Toujeo is a solution for injection that contains insulin glargine. Insulin glargine is a modified insulin and is very similar to human insulin. Toujeo 300 units/ml contains 3 times more insulin per ml than standard insulin (100 units/ml).

insulin per ml than standard insulin (100 units/ml). loujoe is used for teatment of diabetes is adults. Diabetes is a diacase in which the body does not produce enough insulin to control blood sugar. Diedo sugar steadily over a Jong period of time. It is used for once-daily doing. If necessary, you can change your injection time. This is because this medicine lowers your blood sugar over a long period of lime (see section 3).

### 2. BEFORE USING THE MEDICINE

#### Do not use the medicine:

If you are sensitive (allergic) to insulin glargine or to any of the other ingredients of this medicine (see section 6).

## Special warnings regarding use of the medicine

ralk with the doctor, pharmacist or nurse before commencuse of Toujeo.

Strictly follow the instructions regarding dosage, monitori (blood and urine tests), diet and physical activity (physical wo resercise), and injection technique that you received fire the doctor. pharmacist or nurse before commencing

## Be especially aware of the following issues

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I you write, Imma another hope, brand or manufacturer of Produtances Service to plogidazone despetier with insulin'.

I mazer use of the right insulin, Medication errors due to insulp between sulling, particularly between long-action of the long-acti

Skin changes at the injection site.

The injection site should be rotated to prevent skin changes, such as Jumps under the skin. The insulin may not work very well if you inject into a lumpy area (see "How should you use the medicine"). Contact your doctor if you are currently injecting into a lumpy area before you start injecting in a different area
Your doctor may tell you to check your blood sugar more closely
and to adjust your insulin dosage or the dosage of your other when to their your blood stage held and in you meet to perform urine 150 begrown the 150 stage held and if you need to perform urine 150 begrown urine 150 b antidiahetic medications

amulation includes.

Illineses and injuries
In the following situations, the management of your diabetes
may require extra care (for example, blood and urine tests):

- If you are ill or have a major injury - your blood sugar level
may increase (hyperglycemia).

may increase (hyperglycemia).

If you are not eating enough your blood sugar level may become too low (hypoglycemia).

In most cases, you will need to see a doctor. Contact a doctor as soon as you feel ill or are injured.

If you have type 1 diabetes (insulin-dependent diabetes), and you are ill or are suffering from an injury: do not stop your insulin

do not stop your insulin
 continue to consume enough carbohydrates

you have diabetes. Treatment with insulin may cause the body to produce antiboc to insulin (substances that act against insulin); however, only rare cases will a change in the insulin dosage be required.

Travel Before e traveling, talk with your doctor. You may need to talk

 Use Toujeo once a day, preferably at the same time every day.
 When needed, Toujeo can be injected up to 3 hours before or after the usual time that you inject it. the availability of your type of insulin in the country you are Use in the elderly (65 years and over)

visiting,
- supply of insulin, needles, and other items
- correct storage of insulin while traveling,
- timing of meals and of insulin use,

mining or meals and or insulin use,
 the possible effects of changing to different time zones,
 any health risks in the countries you will visit,
 what you should do in emergency situations, when you do not leel well or become iff.

Children and adolescents
This medicine is not intended for children and adolescents below 18 years of age.

## Other medicines and Toujeo

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, inform the doctor or pharmacist.

Some medicines can cause a change in your blood sugar level. It may be necessary to adjust your insulin dosage.

Before taking a medicine, ask the doctor if it can affect your blood sugar level and what action, if any, you need to take. You must also be careful when you stop taking another medicine.

It is particularly important to inform the doctor or pharmacist

#### Your blood sugar level may fall (hypoglycemia) if you take

- other medicine to treat diabetes.
- fluoxetine (for depression). sulfonamide antibiotics. fibrates (to lower high blood lipid levels).
- monoamine oxidase (MAO) inhibitors (for depression). ACE inhibitors (for heart diseases or high blood pressure

- Act imbitors (for near diseases or nigh blood pressure), medicines to relieve pain and lower fever, such as pentoxis/filine, proposyphene, salicylates (such as aspirin), pentamidine (for certain infections caused by parasites). This may cause too Jow a blood sugar level, which can sometimes be followed by too high a blood sugar level.

Your blood sugar level may rise (hyperglycemia) if you take:
- corticosteroids (such as "cortisone", for inflammation).
- danazol (for endometriosis).

- diazoxide (for high blood pressi
- somatronin (growth hormone)

Blood sugar level may either rise or fall if you take

- beta-blockers or clonidine (for high blood pressu

- lithium salts (for mental health problems).

- Inhium sids for mental health products, Beat-balvers. Bit bother sympatholytic medicines (such as Gondine, saunethidne, and resegnate- for high Blood pressure), any make it hard for occapione the warring signs of our blood sympate. In the product of the such products of the such pro- ting the such products of the such products of the such pro- ting standing signs of your Blood signs being bell by be of insufficient to copie with this such as one patients with long-standing signs of such blood signs being bell by the such as unusual shortness of breath, rapid weight gain or localed swelling clean, effort the decider as soon as possible. If you are not sure whether your text belling sign of these medicines, the out the research of the such products of the such products the such as the such products of the such as the such products of the such products the such products

Use of the medicine with alcohol Your blood sugar level may rise or fall if you drink alcohol. Y should check your blood sugar level more often than usual.

your doctor or pharmacist before taking any medi Inform your doctor if you are pregnant, think you are pregnant, are planning to become pregnant or are breastfeeding.

are planning to become pregnant or are breastfeeding. four insulin dosage may change during pregnancy and aft giving birth. Strict control of your diabetes and prevention rypoglycemia are particularly important for your baby's health if you are breastfeeding, consult your doctor, as you may requi-a change in your insulin dosage and diet.

a triange in your insolin coolege and user.

Driving and using machines

Sugar levels that are too low or too high or eyesight problems
can affect your ability to drive or operate machinery.

Your ability to concentrate may be affected. This can be
dangerous to you and to others.

oangerous to you and to others.
Consult the doctor regarding driving if:
• your blood sugar level is often too low.
• you find it hard to recognize when your blood sugar is too low.

Important information regarding some of the ingredients of Toujeo

or rouse: This medicine contains less than 1 mmol (23 mg) sodium ions per ml; this means it is essentially "sodium-free".

Always use the medicine exactly according to the doctor's instructions. Check with the doctor, nurse or pharmacist if you are uncertain.

Although Toujeo contains the same active ingredient as insulin glargine 100 units/ml, do not switch between the medicines switching from one insulin treatment to another requires a medical prescription, medical supervision and monitoring of sugar levels. For further information, consult the doctor.

The Toujeo SoloStar pen can provide a dose of 1 to 80 units per injection, at intervals of 1 unit. injection, a tintervals of 1 unit.
The dose window of the Solostar pen shows the number of Toujoo units to be injected. Do not recalculate the dose.
Based on your fliestyle, results of your blood sugar tests and your previous insulin use, the doctor will fell you:
- when much Toujoo you need each day and at what time,
- when to check your blood sugar level and if you need to

3. HOW SHOULD YOU USE THE MEDICINE?

Flexibility in time of administration

If you have kidney or liver problems

How to inject

is changed

Do not use Toujeo

hypoglycemia.

an insulin numr

If you are 65 years of age or older, talk to your doctor as you may need a lower dosage.

If you have kidney or liver problems, talk to your doctor as you may need a lower dosage.

Before injecting
• Carefully read the instructions for use included in this leaflet

- sarenumy read the instructions for use included in this leaflet.
If you do not follow all of these instructions, you may receive
too much or too little insulin.
 Perform a safety test as described in Step 3 of the Instructions
for Use. If you do not perform one, you may not receive your
ful dose. If this cours, increase the frequency of thecking your
blood sigar level and you might need to administer additional
insulin. See also section 2.

ow to inject
Toujeo is injected under the skin (subrutaneous - SC).
Inject Toujeo into the front of the thighs, upper arms or in t
front of the waist (abdomen).
Change the place within the area you inject each day to lov
the risk of shrinking or thickening of the skin (see section

To prevent possible transmission of diseases, do not use the

Always use a new sterile needle for each injection. Do not reuse needles. Reuse of needles increases the risk of their blockage and of you getting too much or too little insulin.

in a vein. This will change its activity and may cause

in an insulin pump.
 if there are particles in the insulin. The solution should be clear, clothess and with a water-like texture.
 Never use a syringe to remove Tougot from your Solostar pen, as it may cause a severe overdose. See section 2.
 Do not use the Solostar pen if it is dramaged, was not stored properly, does not work properly, or if you notice there is an unexpected worsening of control of your blood sugar levels.

sulin pen for more than one patient, even if the ne

Pregnancy and breastfeeding

- glucagon (for very low blood sugar level) isoniazid (for tuberculosis)
- protease inhibitors (for HIV). diuretics (for high blood press re or fluid retention)

• Discard it and use a new nen

#### If you think there is a p doctor, pharmacist or no ablem with your nen-consult the If you used more Toujeo than required

If you used more loujeo than required If you injected too much Toujeo, your blood sugar Jevel may too low (hypoghcemia). Check your blood sugar level and eat me food to prevent your blood sugar Jevel from getting too low. instructions for treating hypoghcemia at the end of the leafle

If you forgot to use Toujee
When necessary, Toujee can be injected up to 3 hours before or after the time you usually inject if throughout the day,
If you skipped a Toujee dose, or if you did not inject enough insulin, your blood sugar level may be too high (hypergykemia). somatropin (growth hormone). through demones (for throid gland disorders), estrogens and progestogens (present, for example, in birth control pills), olanzapine, closzapine and phenothiazine derivatives (for mental health problems), sympathomimetic medicines (such as epinephrine [adrenaline], salbutamdi, terbutaline, for asthma).

- Do not inject a double dose to compensate for a forsoften
- dose. Check your blood sugar level and then inject the next planned dose at the regular time.
- See instructions for treating hyperglycemia in the box at the end of the leaflet.

# If you stopped using Toujed

Do not stop using Toujeo without consulting the doctor.
Discontinuation of use may lead to very high blood sugar level
and ketoacidosis (build-up of acid in the blood).

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

you need them.

If you have further questions regarding use of the medicine, consult the doctor, pharmacist or nurse.

## 4. SIDE EFFECTS

As with any medicine, use of Toujeo may cause side effects in some users. Do not be alarmed when reading the list of side effects, You may not suffer from any of them. If you notice signs indicating that your blood sugar level is

too low (hypoglycemia), take action to increase your blood sugar level straight away (see the box at end of the leaflet). Hypoglycemia can be very serious and is very common with insulin treatment (may affect more than 1 in 10 people). w blood sugar means that there is not enough sugar in your

- If your blood sugar level falls too much, you may become
- unconscious.

   Very low sugar level may cause brain damage and may be life-threatening.

   For further information, see the box at the end of the leaflet.

Severe allergic reactions (rare, may affect up to 1 in 1000 people). Symptoms can include rash and itching all over the body, swelling of the skin or mouth, shortness to breath, leeling faint (a sharp drop in blood pressure) with fast heartbeats and sweating. Severe allergic reactions may become life-threatening. Refer to the doctor immediately if you experience signs of a severe allergic reaction.

# Other side effects

Refer to the doctor, pharmacist or nurse if you experience any of the following side effects: Skin changes at the injection site:

If you inject insulin too often in the same place, the skin me either shrink (ilponatrophy) (may difect up to 1 in 100 peopl or thicken (fijohypetrophy) (may difect up to 1 in 100 people. Lumps under the skin may also form from builk-up to a protei called amyloid (cutaneous amyloidosis, unknown frequenc. The insulin that you inject may not work well if you inject in in la lumpy area. Change the injection site with each injection I help prevent these skin changes.

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

- Skin and allergic reactions at the injection site. The sign can include reforess, unusually interes pain when injecting, tiching, rash, swelling or inflammation. The reactions may also spread around the injection site. Most minor reactions to insulins usually disappear within a few days to a few weeks.

Rare side effects (may affect up to 1 in 1000 people)

 Eye reactions: A marked change (improvement or worsenin in control of blood sugar levels can disturb vision. If yo have proliferative retinopathy (an eye disease associated with diabetes), very low blood sugar attack may cause temporary

 Swelling of the calves and ankles, caused by temporary buildup of water in the borb Very rare side effects (may affect up to 1 in 10000 people):

# If a side effect occurs, if any of the side effects worsen, or if you suffer from a side effect not mentioned in this leaflet, consult the doctor. Side effects can be reported to the Ministry of Health by clicking

Side effects can be reported to the Ministry of Health by clicking on the link "Reporting side effects due to drug treatment! found on the Ministry of Health homepage (<a href="https://www.health.csv.il">www.health.csv.il</a> that directs you to the online form for reporting side effects, or via the link: https://sideeffects health\_csv.il</a>

# 5. HOW SHOULD THE MEDICINE BE STORED

5. HOW SHOULD THE MEDITURE BESTORED Avoid poisoning! This medicine and any other medicine must be kept in a sale place out of the reach and sight of children and/or infants in order to awoid poisoning.
Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.

## Before first use:

ator (between 2°C-8°C). Do not freeze and do Store in a refrigerator (between 2°C-8°C). Do not freeze not place close to the freezer compartment or a freeze Keep the pens in the box in order to protect from light

After first use/ taking out of the refrigerator:

Do not schedule, before, the defligeration, a pean in use or carried as a spare per may be storred for a period of up to 6 weeks at a temperature below 30°C and kept away from direct heat or light. Dorsard the pean sheet this period. Do not leave the insulin to bload the pean sheet this period. Do not leave the insulin of use of the cap to protect it from light. It is not the cap to protect it from light. It is recommended to write the date of start of use/removal from the refrigerator on the product's label. Do not storred ifferent medications in the same package.

Do not throw away any medicines via household waste. Ask you pharmacist how to throw away medicines you no longer need These measures will help protect the environment.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains the following inactive ingredients: Glycerol (85%), mccresol, zinc chloride, hydrochloric acid, sodium hydroxide, water for injections. What the medicine looks like and the contents of the package:

A pack of 1, 3 or 5 pens. Each pen contains 1.5 ml (450 units) of a clear and colorless injection solution.

a clear and colorless injection solution.

Not all package sizes may be marketed,
This leaflet does not contain all the information about your
medicline. If you have any questions or are not sure about
anything, please ask your doctor.
Lecense Holder, Importer and its address: sanofi-aventis Israel
Idd., 10 Beni Gaon Street, Netamya.
Revised in August 2022 according to MOH gaidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 155-31-34440

#### HYPERGIYCEMIA AND HYPOGIYCEMIA

If you use insulin, always have at least 20 grams of sugar with you, in addition to information identifying you as a diabetic.

Hyperglycemia (high blood sugar levels)
If your blood sugar level is too high (hyperglycemia), you
may not have injected enough insulin.

#### Why does hyperolycemia occur?

- vampres mediae: you did not inject insulin or did not inject enough
- the insulin has become less effective, for example, due to
- incorrect storage.
  your insulin pen does not work properly.
  you are performing less physical activity than usual.
  you are under stress (emotional distress, excitement).
  you have been injured, underwent surgery, have an
  - inflammation or fever. you are taking or have taken certain other medicines (see section 2 "Other medicines and Toujeo"). Warning signs of hyperglycemia

warning signs of hyperglycemia Thirst, increased need to urinate, tiredness, dry skin, redness of the face, loss of appetite, low blood pressure, fast heartbeat, presence of glucose and ketone bodies in the urine. Stomach pain, fast and deep breathing, feeling sleepy or even loss of consciousness may be signs of a serious condition (ketoacidosis) resulting from lack of insultin.

What should you do if you experience hyperglycemia? Check your blood sugar level and your urine for presence of ketones as soon as any of the above symptoms occur. Refer to a doctor immediately if you experience severe hyperglycemia or ketoacidosis, these must always be treated by a doctor, usually in a hospital.

Hypoglycemia (low blood sugar levels)

# If your blood sugar level drops too low, you may lose consciousness. Severe hypoglycemia may cause hearl attack or brain damage and may be life-threatening. You must learn to identify when your blood sugar level has dropped too low, so you will be able to take action to prevent if from getting worse.

Why does hypoglycemia occur?

- examples include: you inject too much insulin, you miss meals or delay meal times, you do not eat enough or eat food containing less sugar (carbohydrate); than normal glougar and subtances similar to sugar are called carbohydrates; however, artificial sweeteners are called carbohydrates; you contain and artificial you lose carbohydrates; you contain and artificial you lose carbohydrates you contain and artificial was a subtance of the carbohydrates of the contains and artificial you may be a subtance of the carbohydrates when the carbohydrates were and the carbohydrates were and the carbohydrates when the carbohydrates are carbohydrates; when the carbohydrates are carbohydrates and the carbohydrates are carbohy
- you drink alcohol, especially if you are not eating much
- you drink alcohol, especially if you are not eating much, you are performing more physical activity than usual or a different type of physical activity, you are recovering from an injury or surgery or other stress, you are recovering from an illness or from fever, you are taking or have stopped taking certain other medicines (see section 2, 7) other medicines and Toujeo).

Hypoglycemia is also more likely to occur if: rypogycemia is also more likely to occur in:
you have just started treatment with insulin or you have
changed the type of insulin - if low blood sugar occurs, it
may be more likely to happen in the morning,
your blood sugar levels are almost regular or are unstable,

your bloom sugar levers are almost regular or are unstaine, you changed the area of skin where you inject insulin (fo example, from the thigh to the upper arm), you suffer from severe kidney or liver disease, or some other disease, such as hypothyroidism.

## Warning signs of hypoglycemia

Warning signs of hypoghcenia The flict signs may be in your boly generally. Examples of symptoms that indicate that your blood signs! level is falling integrate hearthest, high blood pressure, and applications. These symptoms often occur before the symptoms of low sugar level in the brain. These symptoms often occur before the symptoms of low sugar level in the brain agreeable behavior, difficulty conventings, slow reactions, contings, feeling tired, sleepy, readless, sleep disturbances, agreeable behavior, difficulty conventings, slow reactions, depression, continuor, speech disturbances bomenimes loss to move (paralysis, lunging sensation in the hands and legs, numbness and tingling in the mouth area, dazmess, loss of elect control, inability to care few yearself, it and passing out.

## When the signs of hypoglycaemia may be less clear: The first warning signs of I or may not occur at all if:

- unit are elderly
- you are elderly, you have had diabetes for a long time, you suffer from a certain type of nervous disease (diabetic autonomic neuropathy), you hayer executly had too low a blood sugar level (e.g., the
  - your drop in sugar level develops slowly.
- your low blood sugar is always around "normal" or your blood sugar has got much better.
- blood sugar has sof much better, you have recently changed from an animal-derived insulin to a human insulin such as Toujeo. you are taking or have taken certain other medicines (see section 2, "Other medicines and Toujeo", n such cases, you may develop severe hypoglycemia (and veen fainly before you are aware of the problem. Be familian
- with your warning signs. If In necessar, more frequent sugar level tests can help identify mild hypoglycemic events. If you are not sure about your warning signs, avoid situations (e.g., driving a car) in which you or others will be at risk due to hypoglycemia.

# What should you do if you experience hypoglycemia

- Do not inject insulin. Immediately take approximately 10 to 20 grams of sugar, such as glucose, sugar cubes or a sugar-sweetened drink. Do not drink or eat foods with artificial sweeteners (such as diet drinks); they will not help treat
- hypoglycemia. Then eat something that has a long-acting effect on raising your blood sugar level (e.g., bread or pasta). Consult the doctor or nurse if you are uncertain about which food you should eat. Recovery from hypoglycemia may be delayed because Toujeo is long-acting. If the hypoglycemia recurs, take another 10 to 20 grams of
- Sugar. 4. Speak with your doctor immediately if you are unable to control the hypoglycemia or if it recurs.

What should others do if you experience hypoglycemia?

what should others to it you experience hypotycemia: fell your relatives, friends and colleagues to call for medical help immediately if you cannot swallow or if you lose consciousness. You will need an injection of glucose or glucagon (a medicine which increases the blood sugar level). These injections should be given even if it is not certain that you have hypoglycemia.

Check your blood sugar level immediately after taking glucose to check that you really have hypoglycemia.

Read this first

## Toujeo SoloStar contains 300 units/ml insulin glargine in a pre-filled pen

- (which must be discarded after use) containing 1.5 ml.
   Never re-use needles. If you do, you might get a smaller dose than required or get an overdose, as the needle may be blocked.
- on get an overages, as the needle may be blocked.

   Never use a syringe to remove insulin from your pen. If you do, you will get too much insulin. The scale on most syringes is made for non-concentrated
  - The dose selector on your Touien SoloStar pen is set to 1-unit intervals

- lever share the pen it is only for you. Never use the pen if it is damaged or if you are not sure that it is working
- properly.

  Always perform a safety test before you use a new pen for the first time, until you see insulin coming out of the tip of the needle (see Step 3) if you see insulin coming out of the tip of the needle, the pen is ready for use. If you do not see insulin coming out before you take your dose, you may get too small a doer or may not get insulin at all. This may cause a high blood signar level.
- high blood sugar level

  To verify that the pen and needle are working, always perform a
  safety test before each injection until you see insulin coming out of
  the tip of the needle (see Step 3). If you do not perform the safety test
  before each injection, you may receive tool little insulin.
- Always carry a snare nen and snare needles in case they get lost or sto

- in to inject fore using your pen, talk with the doctor, pharmacist or nurse abou
- Periors using your pen, iak wint nie dockor, pharmacs or nuise about how to inject properly.
   This pen is not recommended for use by blind or visually impaired people, without the assistance of a person who has been trained or the correct use of the preparation.
   Read all of the instructions before using your pen. If you do not follow all of these instructions, you may get too much or too little insulin.

# Need help? pharmacist or nurse

f you have any questions about you sen or about diabetes, ask the docto

### Extra items you will need

- a new sterile needle (see STEP 2). a container for used needles and pens



Throwing your pen away

How to store the pen

Before first use Store new pens in a refrigerator, between 2°C and 8°C.
 Do not freeze. After first use

- Keep your pen at room temperature, below 30°C
- . Never nut your nen back in the refrigerator
- Never your pen back in the reingerator.
   Never store your pen with the needle attached to it.
   Store your pen with the cap on.

- How to care for your pen
- Handle your nen with care
- Do not drop your pen or knock it against hard surfaces.
   If you think that your pen has been damaged, do not try to repair it: use a new one.

Protect your pen from dust and dirt

You can clean the outside of your pen by wiping it with a damp cloth.
Do not soak, wash or lubricate your pen—this may damage it.

#### Remove the needle before throwing the nen away.

Throw away your used pen as you have been instructed by the pharmacist.

## STEP 1 - Check your pen

Use your nen for up to 6 weeks after the first use

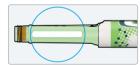
- Take a new pen out of the refrigerator at least one hour before the injection. Cold insulin is more painful to inject.
- ⚠ Check the name and expiration date on the label of the pen.
- . Never use the nen after the expiration date.



Pull off the pen cap.



G Check that the insulin is clear Do not use the pen if the insulin looks cloudy, colored or contains particles.



## STEP 2 - Attach a new needje

- Always use a new sterile needle for each injection. This helps prevent blockage of needles, contamination of the preparation or infection in
- Only use needles that are compatible for use with Toujeo Solostar (e.g. needles from the companies BD, Ypsomed, Artsana or Owen Mumford)

## A Take a new needle and peel off its protective seal.



(3) Keep the needle straight and screw it onto the pen until fixed.



Pull off the outer needle can. Keen this for later



D Pull off the inner needle cap and throw away



## Handling needles

 Take care when ha and cross-infection en handling needles – this is to prevent needle injury

### STEP 3 - Do a safety test

- Always do a safety test before each injection this is to:
- nake sure that you get the correct insulin dose?

  If the pen is new, perform a safety eat before you use it for the
  first time, until you see insulin coming out of the tip of the needle.
  If you is much in coming out of the isp of the needle, the pen is ready
  for use. If you do not see insulin coming out before you take the dose,
  you may get too small a dose or may not get insulin at all. This can
  cause a high blood sugar level.
- Select 3 units by turning the dose selector until the dose pointer is at the mark between 2 and 4.



Press the injection button all the way in. When insulin comes out of the needle tip, your pen is working correctly.



II If you see air bubbles

- If no insulin appears:

   You may need to repeat this step 3 times before seeing insulin.

   If no insulin comes out after the third time, the needle may be blocked. If this happens:

   change the needle (see STEP 6 and STEP 2).
- then reneat the safety test (STEP 3).
- then repeat the safety test (STEP 3).
   Do not use the pen if there is still no insulin coming out of the needle

You see air bubbles
 You may see air bubbles in the insulin. This is normal, they will not harm you.

- Never use a syringe to remove insulin from your pen.

STEP 4 - Select the dose

- X Never select a dose or press the injection button without a needle This may damage your ner accents. This may damage your peri.

  Toujeo SoloStar is meant to supply the number of insulin units prescribed by the doctor to you. Do not recalculate for each dose.
- Make sure a needle is attached and that the dose is set to '0'.



- (3) Turn the dose selector until the dose pointer lines up with

- Turn the dose selector until the dose pointer lines up with your dose.

   If you turned past your dose, you can turn back again.
   If there is not enough insulin left in your pen for your dose, the dose selector will stop at the number of units left.
   If you cannot select your full dose, split the dose into two injections or use a new pen.

How to read the dose window mbers are shown in line with the dose pointer



Odd numbers are shown as a line betw



- Units of insulin in your pen
  Your pen contains 450 units of insulin. You can select doses from 1 to 80 units in steps of 1 unit. Each pen contains more than one dose.
  You can see roughly how many units of insulin are left by looking at where the plunger is on the insulin scale.

### STEP 5 - Inject your dose

- X If you find it hard to press the injection button in, do not use force as this may break your pen. See section || below for help.
- Choose an injection site as shown in the picture.



(B) Push the needle into your skin as shown by your doctor, pharmacist or nurse.



Place your thumb on the injection button. Press all the way in and hold.



 Keep the injection button held in and when you see "0" in the dose window, slowly count to 5. This will make sure you get your full dose



After slowly counting to 5, release the injection button. Then remove the needle from your skin.

- If you still find it hard to press in, use a new pen.
   Never use a syringe to remove insulin from your pen.
- If you find it hard to press the button in:
   Change the needle (see STEP 6 and STEP 2) and then do a safety test (see STEP

Never put the inner needle cap back on.

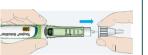
STEP 6 - Remove the need e

Take care when handling needles - this is to prevent needle injury and

- Put the outer needle cap back on the needle, and use it to unscrew the needle from the pen.
  To reduce the risk of needle injury, never replace the inner needle
- cap.

  If your injection is given by another person, or if you are giving an injection to another person, special caution must be taken by the other person where removing and disposing of the needle.

  Follow recommended safety measures for removal and disposal of needles (contact your medical staff) in order to reduce he risk of accidental needle injury and transmission of infectious diseases.



(B) Throw away the used needle in a puncture-resistant container, or as instructed by your pharmacist



Put the pen cap back on.
Do not put the pen back in the refrigerator.

