Sumatriptan 6 mg/0.5 ml
NL/H/1375/001/DC

PACKAGE LEAFLET

Package Leaflet: Information for the patient

Sumatriptan 6 mg/0.5 ml Solution for Injection

Sumatriptan

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 or pharmacist.
- 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. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Sumatriptan Injection is and what it is used for

The active substance in Sumatriptan Injection is Sumatriptan. It is one of a group of medicines called $5HT_1$ receptor agonists.

Sumatriptan Injection is used to treat migraine headache and a rare condition called cluster headache. The symptoms of migraine may due to temporary swelling of blood vessels in the head. Sumatriptan is believed to work by reducing the size of these blood vessels.

2. What you need to know before you use Sumatriptan Injection

Do not use Sumatriptan Injection
- If you are allergic to sumatriptan or any of the other ingredients of this medicine (listed in Section 6).
- If you have heart problems or you already had a heart attack
- If you have circulation problems in your arms and legs
- If you have had a stroke or a mini-stroke (also called a transient ischaemic attack or TIA)
- If you have serious liver disease
- If you have severe or uncontrolled high blood pressure.
- With other migraine medicines containing ergotamine, or similar medicines like methylsergide, or any triptan or 5-HT agonist.
- With MAOIs (monoamine oxidase inhibitors) or if you have taken a MAOI in the last two weeks.

Warnings and precautions
Talk to your doctor before using Sumatriptan Injection, if
- you have any of the following medical conditions: heart disease such as heart failure, angina or coronary thrombosis (heart attack), high blood pressure, disease of the liver or kidneys, epilepsy or brain disease (especially postmenopausal women and males over 40 years of age should have their heart and blood vessels checked before using this medicine),
- you have any risk factors for heart disease such as family history of heart disease; sugar diabetes; high blood cholesterol; if you are a regular cigarette smoker or if you are very overweight,

- you are allergic to certain antibiotics (sulphonamides); people allergic to sulphonamides may experience an allergic reaction to sumatriptan.
- you use certain medicines to treat a depression (a so called SSRI or SNRI) or lithium (a medicine used to treat manic/depressive (bipolar) disorders). You may develop the serotonin syndrome (including mental confusion, increased heart rate, shivering, sweating and muscle twitching). Ask your doctor for advice if you notice any of these symptoms.

After discussing the above, your doctor may still advise you to use Sumatriptan Injection and will instruct you about using the injection.
As with other migraine treatments, overuse could make your migraine worse and make them occur more often.

You may only use Sumatriptan Injection when your doctor is certain that you suffer from migraine headache or cluster headache.

Other medicines and Sumatriptan Injection
Before using Sumatriptan Injection tell your doctor if:
- you are taking any medicines for your migraine which contain ergotamine or ergotamine derivatives, such as ergotamine tartrate or methysergide maleate (if so, you should stop taking them at least 24 hours before using Sumatriptan Injection),
- you are taking any medicines on a doctor's prescription for the treatment of depression such as MAOI's or SSRI's (including citalopram, fluoxetine, fluvoxamine, paroxetine and sertraline), or if you have taken an MAOI in the last 2 weeks,
- you are taking lithium (a medicine used to treat manic/depressive (bipolar) disorders),
- you are taking any medicines on a doctor's prescription to help you lose weight, or for the treatment of epilepsy,
- you are taking anything containing the herbal remedy St John's Wort (*Hypericum perforatum*). Taking this together with Sumatriptan Injection may increase the likelihood of you suffering side effects.

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Pregnancy and breast-feeding
Ask your doctor or pharmacist for advice before taking this medicine
- if you are pregnant, think you may be pregnant or are planning to have a baby
- if you are breastfeeding. Your doctor may still advise you to use sumatriptan, but breastfeeding should be avoided for 12 hours after a dose and during this time any breast milk expressed should be discarded.

Some breastfeeding women report breast and/or nipple pain after use of sumatriptan. The pain is usually temporary and disappears in 3 to 12 hours.

Driving and using machines
Sumatriptan Injection may cause drowsiness. If you are affected do not drive or operate machinery.

Sumatriptan Injection contains sodium
This medicinal product contains less than 1 mmol sodium (23 mg) per dose (i.e. 0.5 ml), i.e. essentially 'sodium-free'.

3. How to use Sumatriptan Injection

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

Sumatriptan Injection is usually injected into the thigh.

Carefully read the 'How to use the pre-filled pen' section as provided at the end of this leaflet.

The pre-filled pen will inject a dose of Sumatriptan Injection just below the skin quickly and without pain. The injection must **NOT** be given in any other way than the way shown.

DO NOT inject Sumatriptan Injection into a vein.
DO NOT use Sumatriptan Injection to try and prevent an attack.

For migraine:
Use one pre-filled pen at the first sign of a migraine attack (although it will be equally effective if used at any time during an attack). If, after your first dose, your migraine goes away but then returns, you may use another pre-filled pen, provided it is at least an hour since the first injection. DO NOT use more than TWO injections in 24 hours.
If the injection does not ease your migraine, you may then take your usual 'pain killers', provided they do not contain ergotamine or its derivatives. Wait at least six hours after using Sumatriptan Injection before taking any medicines containing ergotamine or its derivatives.

If your migraine does not go, do not use a second one for the same attack. Sumatriptan Injection can be used for your next attack.

For cluster headaches:
Use ONE pre-filled pen for each cluster attack. It should be used at the first sign of cluster headaches (although it will be equally effective if used at any time during an attack). DO NOT use more than TWO injections in 24 hours and make sure you leave at least one hour between the two doses.

Use in children and adolescents (under 18 years of age)
Sumatriptan Injection should not be used in children and adolescents under 18 years of age.

Use in elderly (over 65 years)
There is little experience of Sumatriptan Injection in those over 65 years of age so it is not usually prescribed for this age group.

If you use more Sumatriptan Injection than you should
Using more than prescribed may make you ill. If an overdose is used, **DO NOT DELAY,** ask your doctor what to do or contact your nearest accident and emergency department.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Very common (may affect more than 1 in 10 people)
- temporary pain at the place the injection was given
- stinging/burning, redness, swelling, bruising and bleeding at the place the injection was given.

Common (may affect up to 1 in 10 people)
- flushing (redness of the face lasting a few minutes), dizziness, feelings of weakness, tiredness and drowsiness
- short lasting increases in blood pressure soon after using the medicine
- feeling sick (nausea) or being sick (vomiting) - when not part of migraine attack
- pain, feelings of unusual sensations including tingling, numbness, heat or cold, heaviness and pressure or tightness. These symptoms usually pass quickly but may be intense and can affect any part of the body including the chest and throat. If these effects continue or are particularly severe, especially chest or heart pain which spreads to the arms, tell your doctor immediately as there have been rare reports of such problems being caused by a heart attack
- shortness of breath

- aching muscles (myalgia).

Rare (may affect up to 1 in 1,000 people)
- Breast pain

Very rare (may affect up to 1 in 10,000 people)
- liver function changes: if you have a blood test to check how your liver is working and have used sumatriptan, tell your doctor as it may affect the results.

Not known (frequency cannot be estimated from the available data)
- hypersensitivity reactions, which may vary from cutaneous reactions like rash, urticaria to anaphylactic reactions such as collapse
- seizures, tremors, muscle contractions, involuntary eye movements
- visual disturbances including flickering, double vision and reduced vision. There have been cases where permanent vision defects have occurred.
- lowering of blood pressure that can lead to feeling of faintness especially on standing up
- slowing or quickening in the speed of your heart beat, palpitations (feeling of fast heart beat), changes in heart rhythm
- Raynaud's phenomenon, which might appear as paleness or a blue tinge to the skin and/or pain of the fingers, toes, ears, nose or jaw in response to cold or stress
- heart attack
- chest pain (angina)
- ischaemic colitis with the following symptoms: abdominal pain, rectal bleeding and fever
- diarrhoea
- stiffness in the neck
- joint pain
- anxiety, sweating
- If you had a recent injury or if you have inflammation (like rheumatism or inflammation of the colon) you may experience pain or pain worsening at the site of injury or inflammation.
- difficulty swallowing.

If you get the following side effects, you should contact your doctor **immediately** and do **not** use any more Sumatriptan unless your doctor tells you to do so.
- sudden wheeziness, fluttering or tightness in the chest, swelling of eyelids, face or lips, skin rash - red spots or hives (skin lumps), which may be signs of an allergic reaction
- fits (usually in people with a history of epilepsy)
- inflammation of the colon (part of the intestine), which may present as lower left-sided tummy pain and/or bloody diarrhoea
- Raynaud's phenomenon, which might appear as paleness or a blue tinge to the skin and/or pain of the fingers, toes, ears, nose or jaw in response to cold or stress
- chest pain (angina)
- heart attack.

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

5. How to store Sumatriptan Injection

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 pack. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Do not use this medicine if you notice any particles in the solution.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use, and how to dispose of the used pre-filled pens, or follow local instructions for disposal of the used pens. These measures will help to protect the environment.

6. Contents of the pack and other information

What Sumatriptan Injection contains

- The active substance is sumatriptan. Each pre-filled pen contains 6 mg of sumatriptan, as sumatriptan succinate.
- The other ingredients are sodium chloride and water for injection.

What Sumatriptan Injection looks like and contents of the pack

Pre-filled pen, containing a clear colourless to pale solution for injection.
Each carton contains 1, 2, 6 or 12 pre-filled pens.

Not all package sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Sun Pharmaceutical Industries Europe B.V.
Polarisavenue 87
2132 JH Hoofddorp
The Netherlands

This medicinal product is authorised in the Member States of the EEA under the following names:

Germany	TEMPIL 6 mg/0,5 ml Injektionslösung
Denmark	Sumatriptan SUN 12 mg/ ml injektionsvæske, opløsning
Spain	Sumatriptán SUN 6 mg/0,5 ml solución inyectable EFG
France	Sumatriptan SUN 6 mg/0,5 ml solution injectable
Italy	Sumatriptan SUN 6 mg/0,5 ml soluzione iniettabile
Netherlands	Sumatriptan SUN 6 mg/0,5 ml oplossing voor injectie
Norway	Sumatriptan SUN 12 mg/ml injeksjonsvæske, oppløsning
Sweden	Sumatriptan SUN 12 mg/ml injektionsvätska, lösning
United Kingdom	Sumatriptan 6 mg/0.5 ml solution for injection

This leaflet was last revised in 08/2025

HOW TO USE THE PRE-FILLED PEN

Sumatriptan 6 mg/0.5 ml, Solution for Injection

Figure 1 (frontal view of pre-filled pen)

This leaflet explains how to use the Sumatriptan pre-filled pen.
Read it TWICE before you begin the first step. If you have any questions, ask your doctor or pharmacist.
Only for use in patients for whom a 6 mg dose has been prescribed.

CAUTIONS:

- **Check** the appearance of Sumatriptan, through the inspection window. It must be a clear, colorless to pale yellow solution. Do not inject the solution if it looks discolored or cloudy or contains lumps, flakes, or particles.
- **Do not** remove the white needle shield from the pre-filled pen until you are ready to inject.
- **NEVER** put the white needle shield back into the pre-filled pen.
- **NEVER** put or press thumb, fingers, or hand over white needle cover.

How to use the pre-filled pen

No figure (X)

a) Wash your hands thoroughly.

b) Find a comfortable, well-lit place and put everything you need where you can reach it (pre-filled pen, alcohol or sterile swabs).

c) Identify the application area with an adequate fatty tissue layer, for example on the upper arm or thigh.
Do not inject into areas where the skin is tender, bruised, red, or hard.

Figure 2

d) Wipe the injection site with alcohol or a new sterile swab and allow your skin to dry. Do not touch this area again before giving the injection.

e) Take out the pre-filled pen from carton box.

f) Pick up the pre-filled pen in one hand and smoothly remove the white needle shield by pulling it straight off with your other hand. Do not twist it off, and do not recap the white needle shield, as either of these may damage the needle inside the pre-filled pen.

Figure 3

How to start the injection:

(1) **Without** pressing the blue activation button, place the open end of the pre-filled pen on the injection site, straight up at a right angle (90º) and push the safety needle cover firmly against the skin to unlock. The pre-filled pen works **only** when the safety needle cover is **fully retracted**.

Continue to hold the pre-filled pen firmly against the skin. **Figure 4**

Figure 5

(2) Press and release the blue activation button (a first click will sound). This starts the injection.
(3) Do not lift the pre-filled pen off the skin.
(4) Wait until you hear a second click. The inspection window will turn blue, confirming that the injection is complete.
(5) Lift the pre-filled pen straight up from the injection site. The injection is finished.

If the inspection window is not blue, do not try to use the pre-filled pen again.

(6) The safety needle cover on the pre-filled pen will automatically extend to cover the needle and lock into place. The needle will not be visible now. **Figure 6**

There is no need to replace the white needle shield.

NEVER ATTEMPT TO REUSE A PRE-FILLED PEN.

If you suspect you have not received the full dose, do not repeat the injection using a new pre-filled pen.

(7) If you notice a spot of blood at the injection site, dab away with a cotton ball or tissues. Do not rub the injection site. If needed, you may cover the injection site with a bandage.

Figure 1

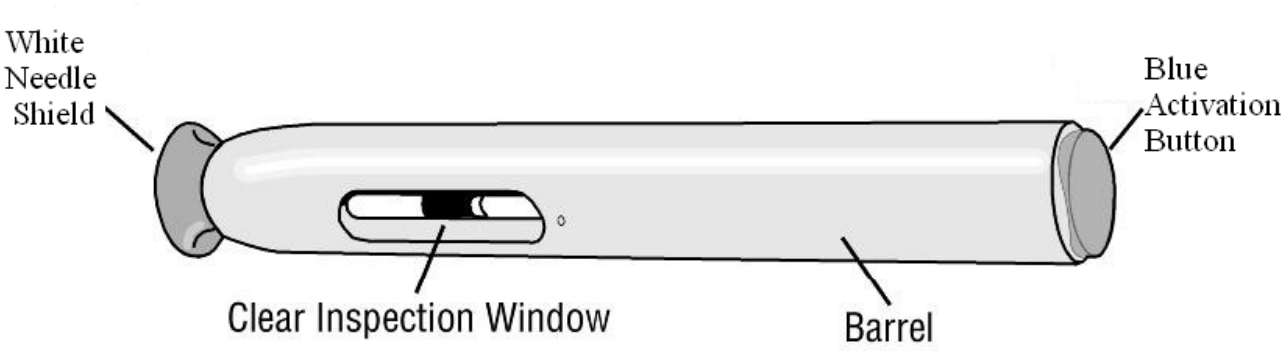


Figure 2

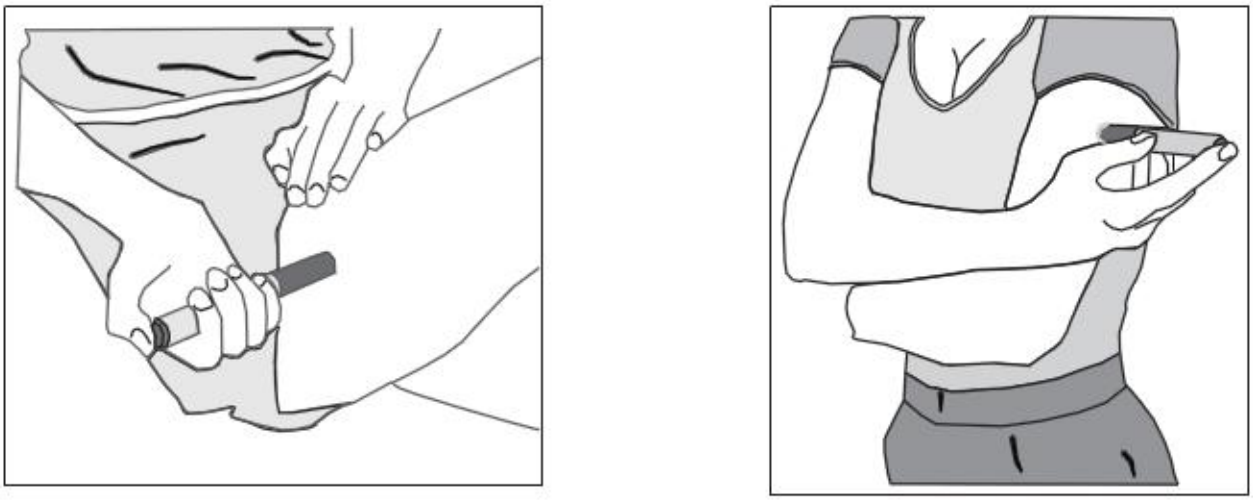


Figure 3

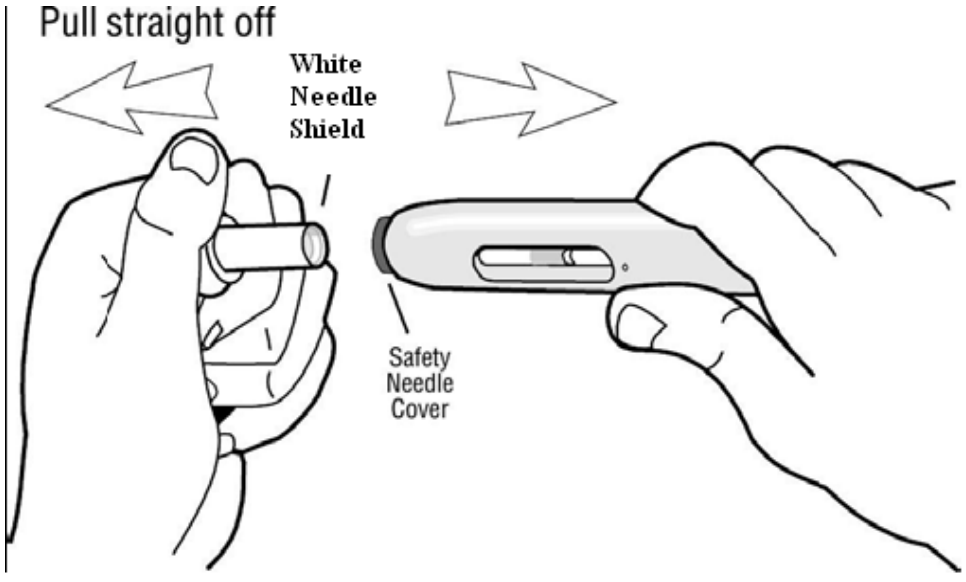
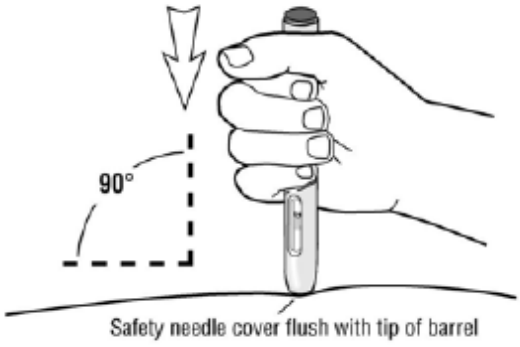


Figure 4


90°
Safety needle cover flush with tip of barrel

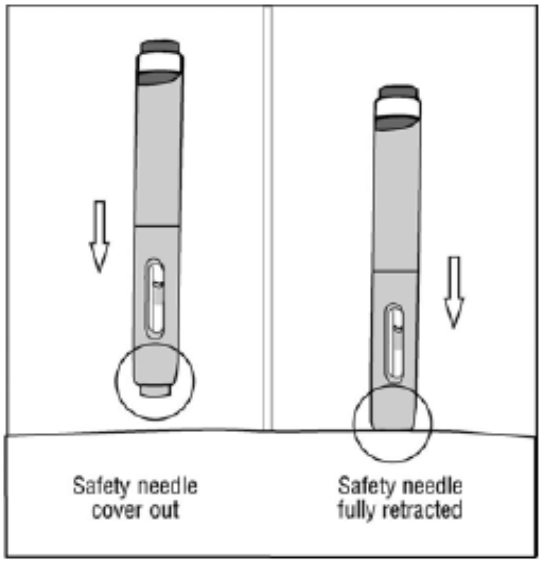

Safety needle cover out
Safety needle fully retracted

Figure 5

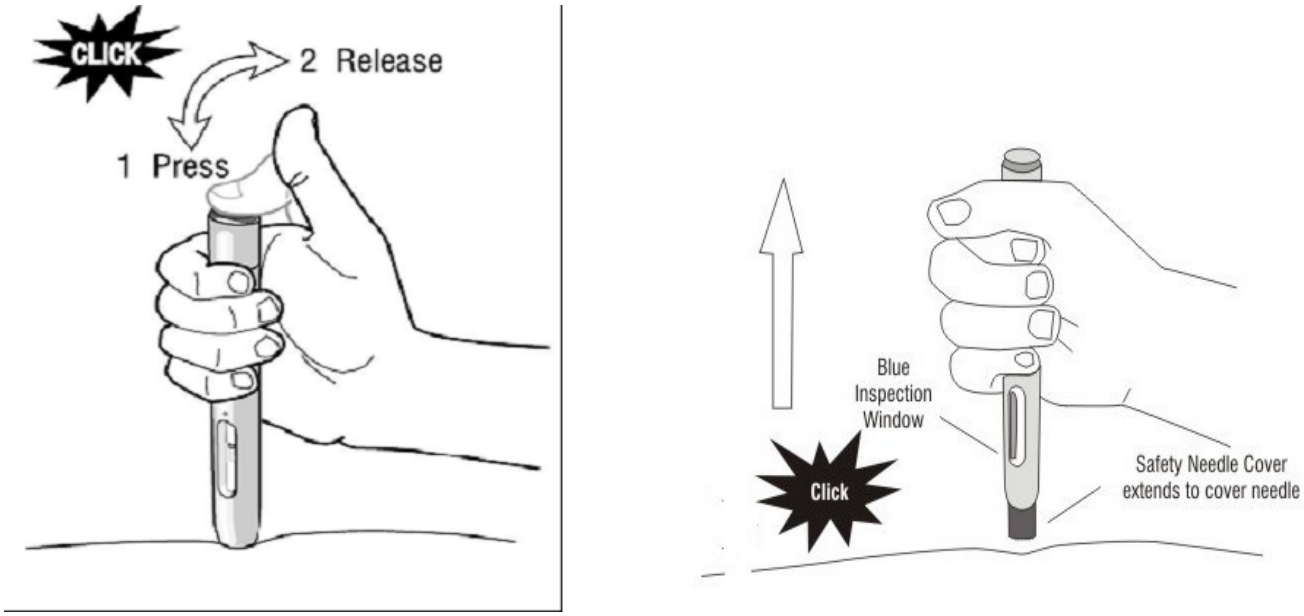
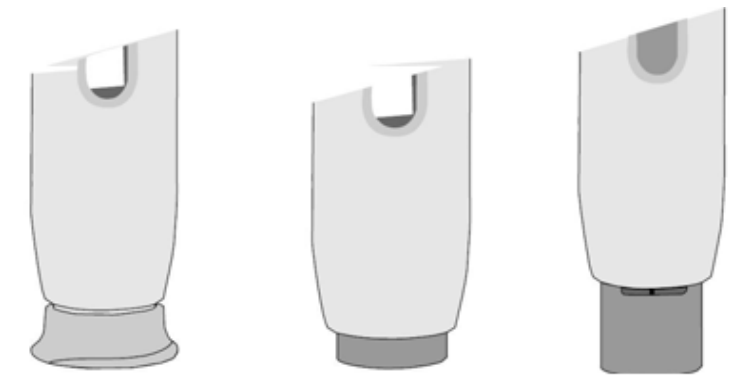


Figure 6



Before use (With White needle Shield)

Before use (Without White needle Shield)

After use (Needle safety cover down)