

Package Leaflet: Information for the patient

Sumatriptan 3 mg/0.5 ml solution for injection in pre-filled pen

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

1. What Sumatriptan is and what it is used for

The active substance in Sumatriptan is sumatriptan. It is one of a group of medicines called 5HT₁ receptor agonists.

This medicine is used to treat migraine headache. The symptoms of migraine may be due to temporary swelling of blood vessels in the head. This medicine is believed to work by reducing the size of these blood vessels.

2. What you need to know before you use Sumatriptan

Do not use Sumatriptan

- 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 moderate to severe or mild uncontrolled **high blood pressure**
- **with other migraine medicines** containing ergotamine, or similar medicines like methysergide, 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, 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 if you are a heavy smoker or a user of nicotine replacement therapy, and especially if you are a man aged over 40, or a woman who has been through

the menopause. In very rare cases, people have developed serious heart conditions after using sumatriptan, even though they had no signs of heart disease before. If any of the risk factors mentioned applies to you it could mean you have a greater risk of developing heart disease, and your heart function should be checked before using this medicine.

- 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).

After discussing the above, your doctor may still advise you to use this medicine 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 this medicine when your doctor is certain that you suffer from migraine headache.

Seek immediate medical help if you experience symptoms such as mental confusion, increased heart rate, shivering, sweating and muscle twitching. This may be signs of a very serious condition called “serotonin syndrome”.

Other medicines and Sumatriptan

Before using Sumatriptan 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)
- 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 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 of sumatriptan, and during this time any breast milk expressed should be discarded.

Driving and using machines

This medicine may cause drowsiness. If you are affected do not drive or operate machinery.

Sumatriptan contains sodium

This medicinal product contains less than 1 mmol sodium (23 mg) per dose (3 mg) that is to say essentially ‘sodium-free’.

3. How to use Sumatriptan

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

Sumatriptan SUN is usually injected into the thigh or upper arm.

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 this medicine 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 into a vein.

DO NOT use Sumatriptan to try and prevent an attack.

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 your migraine goes away but returns

If, after your first dose, your migraine goes away but then returns, you may use a second pre-filled pen at any time in the next 24 hours, provided it is at least an hour since the first injection. Do not use more than two pre-filled pens per 24 hours.

If your migraine does not go away

Do not use a second dose for the same attack. This medicine can, however, be used for your next attack at any time in the next 24 hours, provided it is at least an hour since the first injection. Do not use more than two pre-filled pens per 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 this medicine before taking any medicines containing ergotamine or its derivatives.

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 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.

Serious side effects

The following side effects have been reported (frequency not known).

If you get the following side effects, you should contact your doctor immediately and do not use any more of this medicine 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, with fever (ischaemic colitis)
- 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.

Other side effects

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).

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)

- 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
- 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.

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

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 temperature storage conditions. Store in the original package in order to protect from light.

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. These measures will help to protect the environment.

6. Contents of the pack and other information

What Sumatriptan contains

- The active substance is sumatriptan. Each pre-filled pen contains sumatriptan succinate equivalent to 3 mg of sumatriptan.
- The other ingredients are sodium chloride and water for injection.

What Sumatriptan looks like and contents of the pack

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

Not all package sizes may be marketed.

Marketing Authorisation Holder

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

Manufacturers

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

Terapia S.A.
Str. Fabricii nr 124
Cluj-Napoca, Județul Cluj
Romania

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

Germany	MIGRAPEN
Spain	Sumatriptán SUN
France	Sumatriptan SUN
Italy	Sumatriptan SUN Pharma
Netherlands	Sumatriptan SUN
Norway	Sumatriptan SUN
Poland	Sumatriptan SUN
Romania	Sumatriptan SUN
Sweden	Sumatriptan SUN
United Kingdom	Sumatriptan

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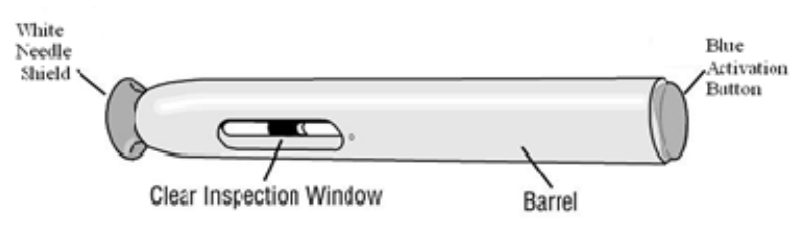
How to use Sumatriptan 3 mg/0.5 ml solution for injection in pre-filled pen

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 3 mg dose has been prescribed.

Frontal view of pre-filled pen

Figure 1



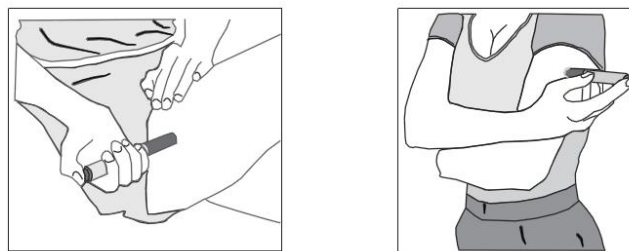
CAUTIONS

- **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

- Wash your hands thoroughly.
- Find a comfortable, well-lit place and put everything you need where you can reach it (pre-filled pen, alcohol or sterile swabs).
- Identify the application area with an adequate fatty tissue layer, for example on the upper arm or thigh (**Figure 2**).
Do not inject into areas where the skin is tender, bruised, red, or hard.

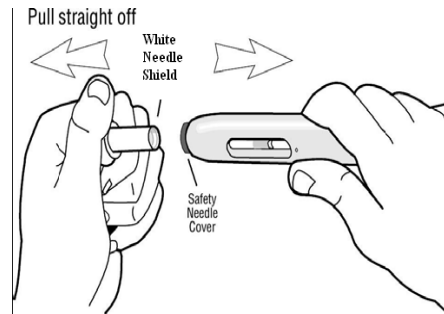
Figure 2



- 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.
- 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 (**Figure 3**). 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

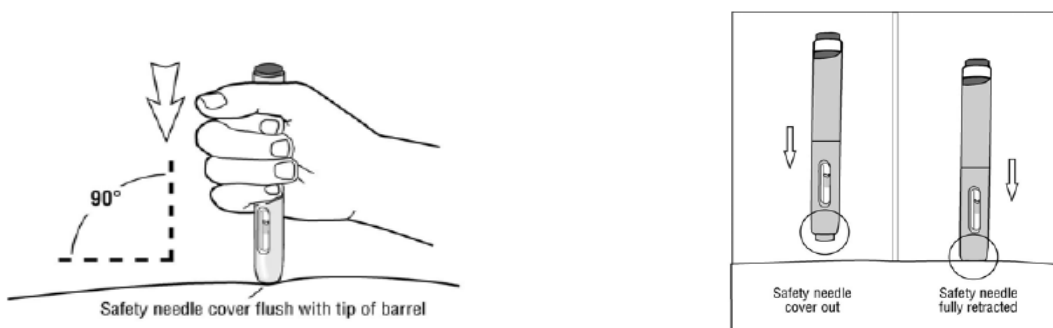


How to start the injection

- 1) Place the open end of the pre-filled pen on the injection site, straight up at a right angle (90°) 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** (**Figure 4**).

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

Figure 4



- 2) Press and release the blue activation button (a first click will sound). This starts the injection (**Figure 5a**).

Figure 5a



- 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 (*Figure 5b*).
- 5) Lift the pre-filled pen straight up from the injection site. The injection is finished.

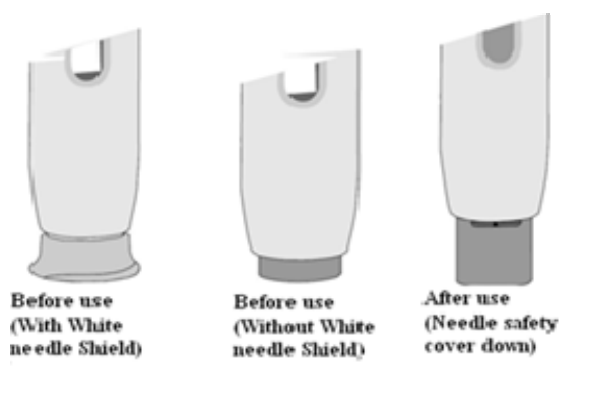
Figure 5b



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. There is no need to replace the white needle shield (*Figure 6*).

Figure 6



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.