

# Clustran

(Sumatriptan succinate)

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

### 1. Why am I using Clustran?

Clustran contains the active ingredient sumatriptan succinate. Clustran is used to relieve a migraine attack or cluster headache with or without what is known as 'aura'. For more information, see Section [1. Why am I using Clustran?](#) in the full CMI.

### 2. What should I know before I use Clustran?

Do not use if you have ever had an allergic reaction to sumatriptan succinate or any of the ingredients listed at the end of the CMI, or latex (the syringe needle shield may contain latex).

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use Clustran?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with Clustran and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use Clustran?

The first time you ever have Clustran it must be under the supervision of a doctor. The recommended dose for adults aged 18 to 65 years is one injection pen of 6 mg, just under the skin, on the outside of the thigh. If the first Clustran helps your migraine or cluster headache, but the headache/migraine comes back later, you may use another Clustran. You must wait at least one hour between using the first and second Clustran. Do not use more than 2 pre-filled pens (2 x 6 mg) in any twenty-four hours.

More instructions can be found in Section [4. How do I use Clustran?](#) in the full CMI.

### 5. What should I know while using Clustran?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using Clustran.</li><li>• Tell your doctor if, for any reason you have not taken your medicine exactly as directed.</li><li>• Tell your doctor if you become pregnant or are trying to become pregnant.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not give this medication to anyone else, even if their symptoms seem similar to yours.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Be careful driving or operating machinery until you know how Clustran affects you. Clustran may cause drowsiness in some people.</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>• Tell your doctor if you drink alcohol.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Keep this medicine where children cannot reach it, such as in a locked cupboard.</li><li>• Keep Clustran in a cool, dry place where it stays below 25°C and protect from light.</li><li>• Keep Clustran in its pack until time to use.</li></ul>

For more information, see Section [5. What should I know while using Clustran?](#) in the full CMI.

### 6. Are there any side effects?

Some mild side effects include pain, tingling, heat or flushing in any part of the body, feeling of sleepiness, dizziness or tiredness, nausea or vomiting, a change in blood pressure, feelings of faintness, problem with your eyesight, pain in the lower tummy and bloody diarrhea, shaking or tremors, uncontrolled movements, shortness of breath. Some serious side effects include irregular heartbeats, fits or convulsion, wheezing or swelling of the lips/mouth, difficulty in breathing, hay fever, lumpy rash ("hives"), fainting, feelings of heaviness, pressure or tightness in any part of the body including the chest or throat, or have persistent purple discoloration and/or pain in the fingers, toes, ears, nose or jaw in response to cold.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# Clustran

**Active ingredient: Sumatriptan succinate**

## Consumer Medicine Information (CMI)

This leaflet provides important information about using Clustran. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Clustran.**

**Where to find information in this leaflet:**

- [1. Why am I using Clustran?](#)
- [2. What should I know before I use Clustran?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Clustran?](#)
- [5. What should I know while using Clustran?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I using Clustran?

**Clustran contains the active ingredient sumatriptan succinate.** This medicine belongs to a group of drugs called serotonin agonists.

Clustran is used to relieve a migraine attack or cluster headache. It should not be used to prevent migraine attacks or cluster headaches from occurring. Clustran may be used for migraine headaches with or without what is known as 'aura'.

It is thought that migraine headaches and cluster headaches are due to widening of certain blood vessels in the head. Clustran works by making those vessels normal again and eases the symptoms of migraine and cluster headaches.

Clustran does not work in other types of headache which are not a migraine or a cluster headache.

Clustran should not be administered to patients with hemiplegic, basilar or ophthalmoplegic migraine.

Clustran is not addictive.

## 2. What should I know before I use Clustran?

### Warnings

**Do not use Clustran if:**

- you are allergic to sumatriptan succinate, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- you have or have had
  - heart disease or heart attack.
  - shortness of breath, pain or tightness in chest, jaw or upper arm.
  - peripheral vascular disease (pain in the back of the legs) or are prone to cold, tingling or numb hands and feet.

- Prinzmetal's angina (an uncommon form of angina where pain is experienced at rest rather than during activity).
- angina and/or severe chest pain or tightness.
- high blood pressure.
- severe liver disease.
- stroke or mini stroke (TIAs)
- you have taken an ergotamine-containing medicine or an ergot-type medicine (such as dihydroergotamine or methysergide) in the last 24 hours.
- you have taken a monoamine oxidase inhibitor (MAOI) for depression in the last 2 weeks.
- The expiry date (EXP) printed on the pack has passed.
- The packaging is torn or shows signs of tampering.

**Tell your doctor if you:**

- are allergic to foods, dyes, preservatives, or any other medicines, including any that contain sulfur (e.g. sulfonamide antibiotics).
- you are allergic to latex (the syringe needle shield may contain latex).
- have or have had medical conditions like:
  - liver or kidney problems.
  - heart problems or a stroke. Risk factors including high blood pressure even if it is under control, a family history of heart problems.
  - high blood cholesterol levels,
  - obesity
  - diabetes
  - you are a male and over 40 years of age
  - you are female and have undergone menopause
  - you smoke.
  - suffer from epilepsy, seizures, or fits or been told that you are prone to this problem.
  - are under 18 or over 65 years of age
  - think that this headache is different and worse than your usual migraine
  - have difficulty moving one side of your body when you have the migraine headache.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

### Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Sumatriptan is excreted into breast milk. To reduce infant exposure, avoid breastfeeding for 24 hours after using Clustran. Expressed milk during this time should be discarded.

Some breastfeeding women have reported temporary breast or nipple pain after using sumatriptan.

### 3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

**Some medicines may interfere with Clustran and affect how it works.**

**Do not use Clustran if**

- you have taken an ergotamine-containing medicine or an ergot-type medicine (such as dihydroergotamine or methysergide) in the last 24 hours.
- you have taken a monoamine oxidase inhibitor (MAOI) for depression in the last 2 weeks.

**Tell your Doctor if you are taking**

- SSRIs (Selective Serotonin Reuptake Inhibitors) or SNRIs (Serotonin-noradrenaline Reuptake Inhibitors) to treat depression.
- any triptan/5-HT<sub>1</sub> agonist.
- herbal products containing St John's Wort.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Clustran.**

### 4. How do I use Clustran?

**How much to use**

For adults aged 18 to 65, the dose is one injection pen of 6 mg.

If the first Clustran helps your migraine or cluster headache, but the headache/migraine comes back later, you may use another Clustran. You must wait at least one hour between using the first and second Clustran.

Do not use more than 2 pre-filled pens (2 x 6 mg) in any twenty-four hours.

Do not use a second pre-filled pen, if the first has not provided any relief from your symptoms. You may take your usual headache relief medication provided it does not contain ergotamine or methysergide. If you are not sure what to do, ask your doctor or pharmacist.

If your migraine or cluster headache is not relieved by Clustran, you may use Clustran on another occasion to treat another attack. Provided there are no side effects, you can use Clustran to treat at least three separate migraine or cluster headache attacks before you and your doctor decide this medicine is ineffective for you.

**When to use Clustran**

- when the migraine headache or cluster headache begins; or
- when other symptoms of the migraine begin, such as nausea (feeling sick), vomiting or your eyes becoming sensitive to light.

If you use Clustran later during the attack it will still work for you. Do not use your Clustran before the above symptoms occur.

**How to use Clustran**

**The first time you ever have Clustran it must be under the supervision of a doctor.** After this you must use the injection as your doctor has instructed.

**See the Patient Instructions For Use below or overleaf for information on how to use the pre-filled pen and how to discard it.** If there is something you do not understand, ask your doctor or pharmacist.

**Clustran should be injected just under the skin on the outside of the thigh using the pre-filled pen.**

**If you use too much Clustran**

If you think that you have used too much Clustran, you may need urgent medical attention.

**You should immediately:**

- **In Australia:** phone the Poisons Information Centre (by calling 13 11 26), or  
**In New Zealand:** phone the National Poisons Centre on 0800 POISON (0800 764 766), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

### 5. What should I know while using Clustran?

**Things you should do**

**Tell your doctor or pharmacist if, for any reason, you have not taken your medicine exactly as directed.** Otherwise, your doctor or pharmacist may think that is not working and change your treatment unnecessarily.

Remind any doctor, dentist or pharmacist you visit that you are using Clustran.

**Things you should not do**

Do not give his medicine to anyone else, even if their symptoms seem similar to yours.

If you use Clustran too often, it may make your headache worse. If this happens, your doctor may tell you to stop using Clustran.

**Driving or using machines**

**Be careful before you drive or use any machines or tools until you know how Clustran affects you.**

As with many other medicines, Clustran may cause drowsiness in some people.

**Drinking alcohol**

Tell your doctor if you drink alcohol.

## Looking after your medicine

- Keep your pre-filled pen where children cannot reach them, such as in a locked cupboard.
- Keep Clustran in a cool, dry place where it stays below 25°C and protect from light. Brief temperature excursions below and above 25°C permitted.
- Do not leave in a car, on a window sill or in a bathroom.
- Keep Clustran in its pack until time to use.

**Product is for single use in one patient only.** Discard any residue.

## Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> <li>• temporary pain at the site of injection.</li> <li>• pain, tingling, heat, flushing, cold sensation or feeling strange in any part of the body.</li> <li>• sleepiness, dizziness, weakness or tiredness.</li> <li>• headache.</li> <li>• nausea (feeling sick) or vomiting.</li> <li>• difficulty swallowing.</li> <li>• changes in taste.</li> <li>• problems affecting the mouth or tongue.</li> <li>• a change in blood pressure.</li> <li>• feelings of faintness.</li> <li>• shaking, tremors or uncontrolled movements.</li> <li>• shortness of breath.</li> <li>• blocked or irritated nose or sinuses.</li> <li>• Sweating.</li> <li>• pale skin (pallor).</li> <li>• muscle aches or pain (myalgia).</li> <li>• increased pain or swelling in an area recently affected by injury or inflammation.</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

## Serious side effects

serious side effects	What to do
<ul style="list-style-type: none"> <li>• feel heaviness, pressure or tightness in any part of the body including the chest or throat.</li> <li>• irregular heartbeats or change in ECG.</li> <li>• have a fit or convulsion.</li> <li>• problem with your eyesight.</li> <li>• pain in the lower tummy and bloody diarrhoea (ischaemic colitis).</li> <li>• allergic reactions such as: <ul style="list-style-type: none"> <li>• wheezing, swelling of the lips/mouth</li> <li>• difficulty in breathing</li> <li>• hay fever</li> <li>• lumpy rash (hives)</li> <li>• fainting</li> </ul> </li> <li>• have persistent purple discolouration and/or pain in the fingers, toes, ears, nose or jaw in response to cold.</li> </ul>	<p><b>Call your doctor straight away, or; go straight to the Emergency Department</b></p>

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people. Do not be alarmed by this list of possible side effects. You may not experience any of them.

### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to:

**In Australia:** The Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems), or

**In New Zealand:** The Centre for Adverse Reactions Monitoring (CARM) via <https://pophealth.my.site.com/carmreportnz/s/>

By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your me**

## 7. Product details

This medicine is only available with a doctor's prescription.

### What Clustran contains

<b>Active ingredient (main ingredient)</b>	Sumatriptan succinate
<b>Other ingredients (inactive ingredients)</b>	sodium chloride water for injection
<b>Potential allergens</b>	latex (the syringe needle shield may contain latex)

**Do not take this medicine if you are allergic to any of these ingredients.**

### **What Clustran looks like**

Clustran is packed in a box containing either one or two pre-filled pens. Each Clustran pre-filled pen contains one dose of 6 mg sumatriptan (as succinate) in 0.5 mL of solution.

Not all pack sizes may be marketed in Australia or New Zealand.

Australia Registration Number AUST R 209316

### **Who distributes Clustran**

Australia

Sun Pharma ANZ Pty Ltd 12 Waterloo Road Macquarie Park  
Sydney NSW 2113 Australia  
customerservice.aus@sunpharma.com  
Tel: 1800 726 229

New Zealand

Douglas Pharmaceuticals Ltd  
P O Box 45 027  
Auckland 0651 New Zealand  
Phone: (09) 835 0660

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# INSTRUCTIONS ON HOW TO USE CLUSTRAN

This leaflet explains how to give a dose of Clustran.

Read these instructions TWICE before you begin the first step. If you have any questions, ask your doctor or pharmacist.

## PRECAUTIONS:

- Check the appearance of the medicine, through the inspection window (figure 1). It must be a clear, colourless to pale yellow solution. Do not inject the solution if it looks discoloured 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.
- When the white needle shield is removed NEVER put or press, thumb, fingers, or hand over the exposed grey tip.

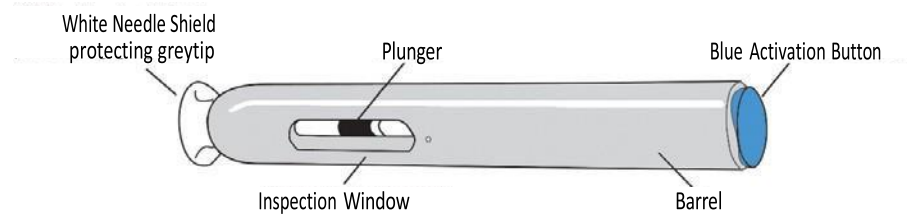


Figure 1

## PREPARING TO ADMINISTER CLUSTRAN

1. Wash your hands thoroughly.
2. Check the appearance of the medicine, through the inspection window (figure 1). It must be a clear, colourless to pale yellow solution. Do not inject the solution if it looks discoloured or cloudy or contains lumps, flakes, or particles.
3. Gather all the equipment you will need (Clustran and alcohol or sterile swabs)
4. Identify the application area (figure 2).
  - Usually the outer thigh or somewhere with an adequate fatty tissue layer.
  - Do not inject into areas where the skin is tender, bruised, red, or hard.
5. Wipe the injection site with alcohol or a sterile swab.
  - Allow your skin to dry.
  - Do not touch this area again before giving the injection.

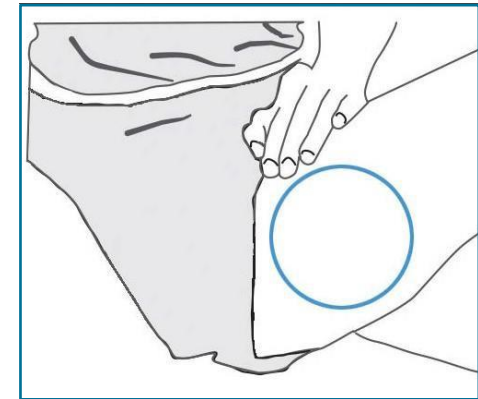


Figure 2

## HOW TO INJECT CLUSTRAN

### PULL Remove the white needle shield by pulling it straight off (Figure 3).

- Do not bend or twist-off the white needle shield.
- Do not put the white needle shield back on as this may damage the needle inside.

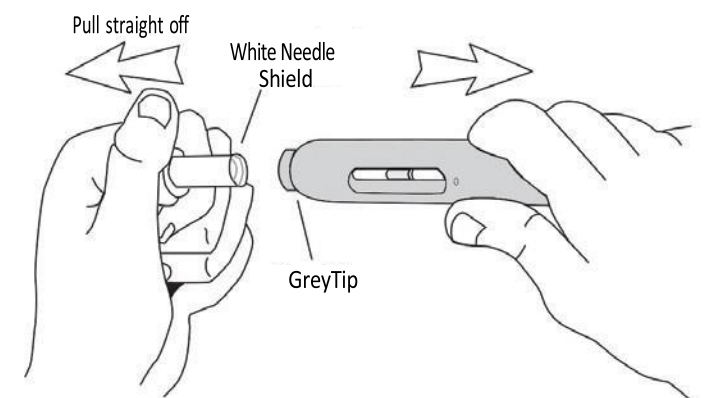
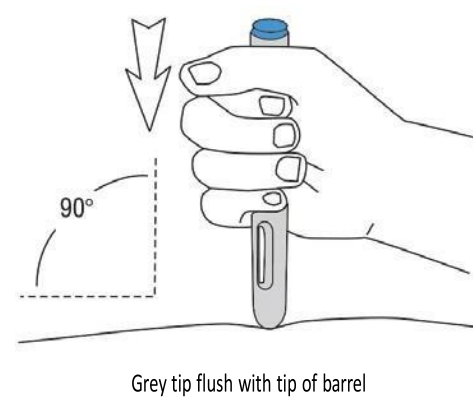


Figure 3

### PLACE Without pushing the blue activation button, place Clustran on the injection site, completely depressing grey tip (Figure 4).

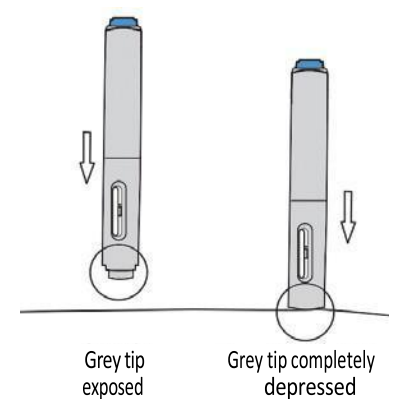
- Place the open end on the site at a 90° angle (Figure 4a).
- Push the grey tip firmly against the skin to unlock (Figure 4a and 4b).
- The grey tip must be completely depressed to inject the medication (Figure 4b).

4



Grey tip flush with tip of barrel

Figure 4a



Grey tip exposed Grey tip completely depressed

Figure 4b

### PRESS Press the blue activation button, hear the click and release your thumb (Figure 5a).

- The first click will sound. Immediately release your thumb (Figure 5a).  
(The blue activation button will not work if the safety needle cover is not completely depressed.)

### HOLD Hold Clustran in place until you hear the second 'click' (Figure 5b).

- If you did not remove your thumb from the blue button, the second 'click' cannot be heard. If this happens, slowly count to 15 to ensure the full dose is delivered.
- The inspection window will turn blue, confirming the injection is complete. If the inspection window is not blue, do not try to use the pre-filled pen again.

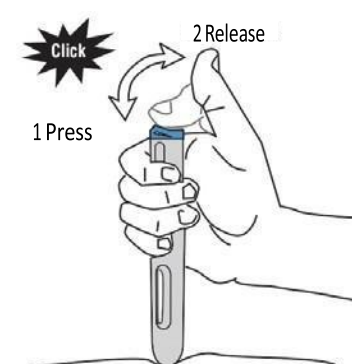


Figure 5a

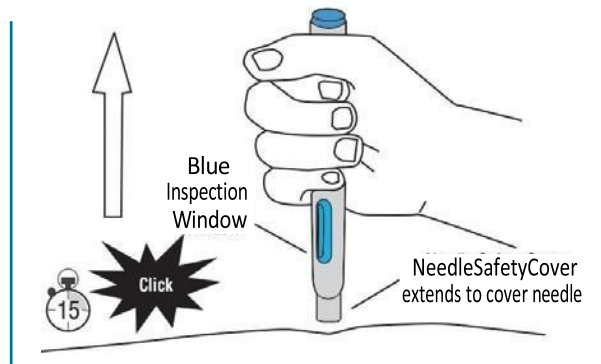
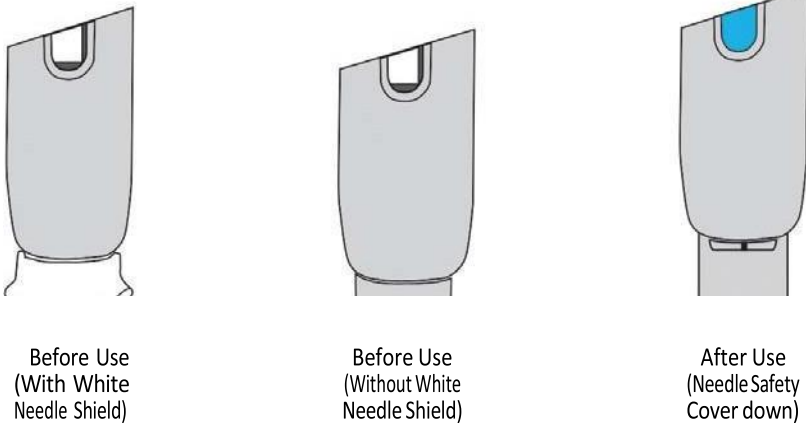


Figure 5b

**REMOVE** Remove Clustran by lifting it straight up from the injection site (Figure 5b).

- The needle safety cover will automatically extend and lock into place to conceal the needle (Figure 5b and 6).
- There is no need to replace the white needle shield.
- Do not rub the injection site. If you notice a spot of blood at the injection site, dab away with a cotton ball or tissues. If needed, you may cover the injection site with a bandage.



**Figure 6**

**NEVER ATTEMPT TO REUSE A Clustran pen.**

If you suspect you have not received the full dose, **DO NOT** repeat the injection using a new Clustran pen for at least 1 hour. Do not use more than two Clustran pens in any 24 hour period

**STORAGE:**

Store below 25°C. Protect from light. Brief temperature excursions below and above 25 °C permitted.