

Clustran

Solution for injection in pre-filled pen

(Sumatriptan succinate)

Consumer Medicine Information

What is in this leaflet?

Please read this leaflet carefully before you start using Clustran.

This leaflet answers some common questions about Clustran. It does not contain all of the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the expected benefits of you using Clustran against the risks this medicine could have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What is Clustran used for?

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'.

There is no information on the use of sumatriptan (Clustran) injection in special kinds of migraine known as 'basilar migraine', 'ophthalmoplegic migraine' or 'hemiplegic migraine'.

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.

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

Clustran is not addictive.

Before you use Clustran

Do not use if:

You must not use Clustran if:

- **you have ever had an allergic reaction to sumatriptan succinate (See "Side-Effects") or any of the ingredients listed toward the end of this leaflet. (See "Ingredients").**
- **you have or have had:**
 - heart disease or heart attack.
 - shortness of breath, pain or tightness in the 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 or severe chest pain or tightness.
- high blood pressure that isn't under control.
- stroke.
- temporary loss of oxygen to the brain – also called TIAs or mini-strokes.
- severe liver disease.
- **you have taken any of these medicines in the last 24 hours:**
 - ergotamine (eg Cafergot)
 - dihydroergotamine (eg Dihydergot)
 - methysergide (eg. Deseril)
 - naratriptan (eg Naramig)
 - zolmitriptan (eg Zomig).
- **you have taken any of these medicines in the last two weeks:**
 - monoamine oxidase inhibitors (MAOIs), a type of medicine used for depression.
 - SSRIs (Selective Serotonin Reuptake Inhibitors) eg paroxetine, fluoxetine, citalopram, nefazodone, sertraline or cenlafaxine.
 - SNRIs (Serotonin-Noradrenaline Reuptake Inhibitors) used to treat depression eg venlafaxine.
- **the expiry date (EXP) printed on the pack has passed.**
- **the packaging is torn or**

shows signs of tampering.

Tell your doctor if:

You must tell your doctor if:

- you have not had your headache diagnosed as a migraine by a doctor
- 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.
- Have not responded to your first dose of Clustran injection.
- you are allergic to foods, dyes, preservatives or any other medicines, including any that contain sulphur (eg. sulphonamide antibiotics).
- you are taking or have taken any other medicines in the last two weeks, including medicines you buy without a prescription, particularly herbal preparations containing St John's Wort and medicines prescribed for depression.
- You are allergic to latex (the syringe needle shield may contain latex).
- you are breastfeeding, pregnant or trying to become pregnant. Your doctor will discuss the risks and benefits of taking Clustran injection if you are pregnant or breastfeeding.
- you have or have had medical conditions like
 - liver or kidney problems
 - heart problems. Risk factors including high blood pressure, even if it is under control.
 - high blood cholesterol levels, a family history of

heart problems, obesity, diabetes, you are male and over 40 years of age, you are female and have menopause or you smoke.

- Your doctor may check if your heart is healthy before prescribing Clustran injection. Your doctor may also decide to do tests if you get certain symptoms with Clustran. This is because Clustran injection can make certain types of heart disease worse.
- epilepsy, seizures, or fits or been told that you are prone to this problem.
- Stroke

How do I 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 also the patient Instructions for Use below for information 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.

How much to use?

For adults aged 18 to 65, the dose 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.

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

How to use it

Clustran should be injected just under the skin on the outside of the thigh using the pre-filled pen (see the patient Instructions For Use below).

Do not administer Clustran by intravenous injection.

When to use it?

It is best to use your Clustran -

- i. when the migraine headache or cluster headache begins; or
- ii. 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.

What do I do if I use too much (Overdose)?

Immediately telephone your doctor or Poisons Information Centre (telephone Australia 13 1126 or telephone New Zealand 0800 POISON (0800 764766) for advice if you think you or anyone else may have used too many Clustran pens, even if there are no signs of discomfort or poisoning. You may need urgent medical attention. If you are not sure what to do, contact your doctor or pharmacist.

While you are using Clustran

Things you must do

Tell your doctor or pharmacist that you are using Clustran injection if you are about to be started on any new medicines.

Tell your doctor if you become pregnant or are trying to become pregnant.

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

Things you must not do

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

Do not change the dose of your Clustran injection without first checking with your doctor.

Things to be careful of

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

Be careful driving or operating machinery until you know how Clustran affects you.

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

What are the side effects?

Check with your doctor as soon as possible if you think you are experiencing any side effects or allergic reactions due to using Clustran, even if the problem is not listed below.

Like other medicines, Clustran can cause some side effects. If they occur, they are most likely to be minor and temporary. However, some may be serious and need medical attention.

A common side-effect with Clustran is temporary pain at the site of injection.

Tell your doctor if you experience any of the following after using Clustran:

- pain, tingling, heat or flushing in any part of the body.
- feelings of sleepiness, dizziness or tiredness.
- nausea (feeling sick) or vomiting.

- a change in blood pressure.
- feelings of faintness.
- problems with your eyesight.
- pain in the lower tummy and bloody diarrhoea (ischaemic colitis).
- shaking or tremors.
- uncontrolled movements.
- shortness of breath.

Tell your doctor immediately, or seek urgent medical attention, and do not use any more Clustran if you:

- feel heaviness, pressure or tightness in any part of the body including the chest or throat.
- feel irregular heartbeats.
- have a fit or convulsion.
- wheezing, swelling of the lips/mouth, difficulty in breathing, hay fever, lumpy rash ("hives") or fainting. These could be a symptom of an allergic reaction.
- have persistent purple discolouration and/or pain in the fingers, toes, ears, nose or jaw in response to cold.

These side effects are likely to be serious. Stop using Clustran and seek medical attention straight away.

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

How do I store Clustran?

Keep your pre-filled pens 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.

How to dispose of Clustran?

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

Return any unused or expired medicine to your pharmacist.

Needles and syringes may be hazardous and should be disposed of safely and hygienically.

Product description

What Clustran looks like

Clustran is available as a 0.5mL pre-filled pen which contains 6 mg sumatriptan (as succinate), in solution. 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.

Not all pack sizes are marketed in Australia or New Zealand.

Ingredients

Clustran contains the active ingredient sumatriptan succinate.

Clustran also contains sodium chloride and water for injections.

Clustran does not contain added lactose, sucrose or gluten.

Where to go for further information

Your doctor or pharmacist is the best person to give you advice on the treatment of your condition. You may be able to find general information about your disease and its treatment from books, or reliable websites on the internet. Pharmaceutical companies are not in a position to give people medical advice.

Supplier

Australia

Sun Pharma ANZ Pty Ltd
12 Waterloo Road Macquarie
ParkSydney NSW 2113
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

This leaflet was prepared in
September 2023.

The information
provided applies only to:
Clustran.

Clustran

Sumatriptan (as succinate)

6 mg/0.5 mL: AUST R 209316

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.

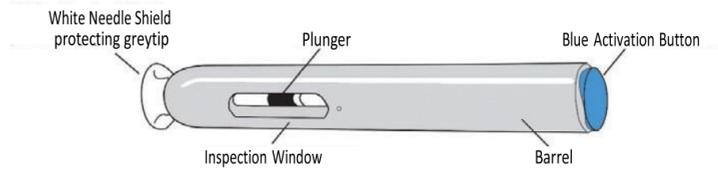


Figure 1

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.

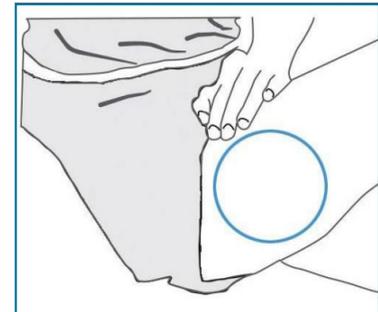


Figure 2

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.

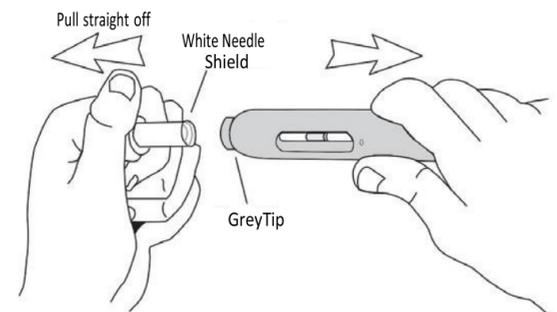
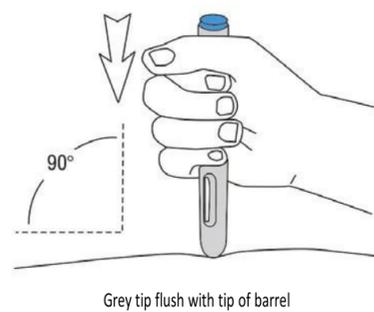


Figure 3

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

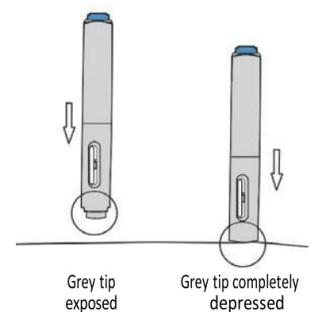
- Place the open end on the site at a 90° angle (Figure 4a).
- Push the grey tip firmly against the skin to unlock (Figure 4a and 4b).
- The grey tip must be completely depressed to inject the medication (Figure 4b).

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

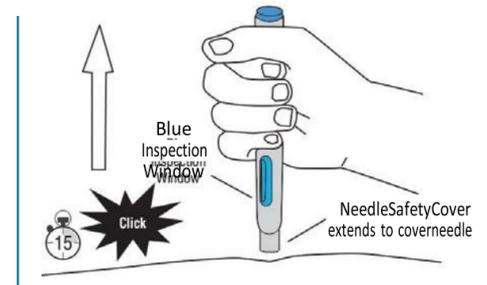


Figure 5b

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

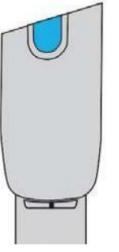
- The needle safety cover will automatically extend and lock into place to conceal the needle (Figure 5b and 6).
- There is no need to replace the white needle shield.
- Do not rub the injection site. If you notice a spot of blood at the injection site, dab away with a cotton ball or tissues. If needed,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



Before Use
(With White
Needle Shield)



Before Use
(Without White
Needle Shield)



After Use
(Needle Safety
Cover down)

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.