

STRENSIQ®

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 Strensiq?

Strensiq contains the active ingredient asfotase alfa *rch*. Strensiq is an enzyme replacement therapy for patients with paediatric-onset hypophosphatasia or HPP.

For more information, see Section [1. Why am I using Strensiq?](#) in the full CMI.

2. What should I know before I use Strensiq?

Do not use if you have ever had an allergic reaction to Strensiq or any of the ingredients listed at the end of the CMI.

Patients receiving Strensiq have had allergic reactions including life-threatening allergic reactions requiring medical treatment. These may occur within minutes of receiving Strensiq or after a longer period of time on therapy.

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

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

3. What if I am taking other medicines?

The effect of Strensiq with other medicines has not been studied. Ask your doctor or nurse if you have any questions.

For more information, see Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Strensiq?

Your doctor will tell you how much of this medicine (number of milligrams) you need to inject based on your body weight.

If you are injecting this medicine yourself, you will be shown how to prepare and give the injection by your doctor, pharmacist, or nurse. Do not inject this medicine yourself unless you have received training and you understand the procedure.

Allow unopened Strensiq vial(s) to reach room temperature before injecting and administer injections within 3 hours. Follow the instructions in this leaflet carefully regarding the use of sterile disposable needles to withdraw and inject the medicine.

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

5. What should I know while using Strensiq?

Things you should do	<ul style="list-style-type: none">• If you are having any blood tests, tell your doctor that you are using this medicine.• Keep all your doctor's appointments so that your progress can be checked.
Things you should not do	<ul style="list-style-type: none">• Do not stop taking your medicine or lower the dosage without checking with your doctor.
Looking after your medicine	<ul style="list-style-type: none">• Keep your medicine in the packaging until it is time to use it.• Keep your medicine in the refrigerator (2°C to 8°C).• Do not use after the EXP date and talk to your pharmacist about disposing of unwanted medicine

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

6. Are there any side effects?

The common side effects of Strensiq treatment are reactions at the injection site. These can include fatty lumps under the surface of the skin or localised loss of fat tissue, and allergic reactions.

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.

Strensiq

Active ingredient(s): [asfotase alfa rch]

Consumer Medicine Information (CMI)

This leaflet provides important information about using Strensiq.

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 Strensiq.

Where to find information in this leaflet:

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

1. Why am I using Strensiq?

Strensiq contains the active ingredient asfotase alfa rch.

Strensiq is an enzyme replacement therapy for patients with paediatric-onset hypophosphatasia or HPP.

Patients with HPP have low levels of an enzyme called alkaline phosphatase, which is naturally present in the body and necessary for the proper hardening of bones and teeth. Patients have problems with bone growth and strength, which can lead to broken bones, bone pain, and difficulty walking, as well as difficulties with breathing and a risk of seizures (fits).

Strensiq has been shown to benefit patients' mineralization of the skeleton and growth.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

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

2. What should I know before I use Strensiq?

Warnings

Do not use Strensiq if:

- you are allergic to Strensiq, or any of the ingredients listed at the end of this leaflet.

Patients receiving Strensiq have had allergic reactions including life threatening allergic reactions requiring medical treatment like anaphylaxis. Patients who experienced anaphylaxis-like symptoms had difficulty breathing, choking sensation, nausea, swelling around the eyes, and dizziness. The reactions occurred within minutes after taking Strensiq and can occur in patients who were

taking Strensiq for more than one year. If you experience any of these symptoms, discontinue Strensiq and seek medical help immediately.

Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- take any medicines for any other condition
- you are not sure whether you should be treated with Strensiq
- have previously had an allergic reaction to Strensiq, your doctor will discuss with you the next steps and the possibility to restart Strensiq under medical supervision.
- if you have allergies to any other medicines, foods, preservatives, or dyes.
- notice any change in the shape of your infant's head. Early fusion of the bones of the head in children below 5 years of age has been reported in clinical studies of infants with hypophosphatasia, with and without use of Strensiq.
- have problems with your vision, some eye-related side-effects have been reported in clinical studies both in patients using Strensiq and those who were not, probably associated with hypophosphatasia.

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. Your doctor can discuss with you the risks and benefits involved.

Talk to your doctor if you are breastfeeding or intend to breastfeed. It is not known whether Strensiq passes into breast milk. You should not breast feed while using Strensiq unless you have discussed it with your doctor.

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.

The effect of Strensiq on other medicines has not been studied. Ask your doctor or nurse if you have any questions.

4. How do I use Strensiq?

How much to use

- Your doctor will tell you how much of this medicine (in number of milligrams) you need to inject based on your body weight.
- The correct dose will be calculated by your doctor based on a total of 6 milligrams of Strensiq, per kg of body weight, per week.
- Your doctor may adjust your dose as your weight changes.
- The maximum amount of Strensiq to be injected is 1 mL. If more than 1 mL is required, split the volume equally between two or more syringes, and administer each injection using a separate site.

When to use

- You will inject either 3 or 6 times a week, depending on the recommendation of your doctor.

How to inject Strensiq

- Follow all directions given to you by your doctor, nurse, or pharmacist carefully. They may differ from the information contained in this leaflet.
- “How to inject Strensiq” will be explained to you by a healthcare professional. After being trained by the doctor or specialised nurse, you can inject Strensiq yourself at home.
- Strensiq must not be injected into a vein or muscle. Strensiq is intended for subcutaneous (under the skin) injection.
- If you do not understand these instructions, ask your doctor, nurse, or pharmacist for help.
- When injecting, it is important to change the injection site to different areas of the body, to help reduce potential pain and irritation and lipodystrophy (clumping or loss of fat under the skin).
- Areas with a good amount of fat below the skin (thigh, upper arm, abdomen, or buttocks) are the most suitable areas to inject.

Injection technique:

1) Before you begin, take your vial(s) of Strensiq out of the refrigerator 15 to 30 minutes before injecting to allow the liquid to reach room temperature.

Do not warm Strensiq in any other way (for example in a microwave or in hot water).

It is recommended to administer the medicine within 3 hours after removing the vial (s) from the refrigerator.

Always use a new vial. Each vial is for single use and should only be punctured once.

2) Wash your hands thoroughly with soap and water.

3) Place all the items you will need on a clean surface where you will not be disturbed. These should include:

- vial(s) of Strensiq
- syringes (small enough to withdraw the correct volume accurately)
- needles (25 G and 29 G)
- alcohol swabs
- gauze or cotton wool
- wool
- sharps container
- adhesive bandage
- injection diary (or other recording means e.g. paper or notebook).

4) Visually check the vial before use. Strensiq should be clear, colourless to slightly yellow and may have a few small translucent or white particles in it. Do not use it if the liquid is discolored or contains any lumps or large particles in it and get a new vial.

5) Remove the protective cap from the Strensiq vial to reveal the sterile rubber seal.

6) Place a drawing up needle (e.g. 25G) on an empty syringe and with the protective cap on, push down and turn clockwise the needle onto the syringe until it is tight. Remove the plastic cap covering the syringe needle and place it on a flat surface, you will need this later to recap your needle. Pull the plunger back to draw air into the syringe, equal to the volume of medicine to be injected. The volume per injection should not exceed 1mL. If this is the case, multiple injections should be done at different sites.

7) Holding the syringe and vial at 45° angle, insert the needle through the sterile rubber top. Push the plunger in completely to inject air into the vial.



8) Turn the vial and syringe upside down. With the needle in the solution, pull the plunger to withdraw the volume of the correct dose into the syringe.



9) Before removing the needle from the vial check that the appropriate volume has been withdrawn and check the syringe for air bubbles.



If bubbles are present, hold the syringe with the needle pointing upwards and gently tap the side of the syringe until the bubbles float to the top.



Once all the bubbles are at the top of the syringe, gently push on the plunger to force the bubbles out of the syringe and back into the vial.

After removing the bubbles, recheck the dose of medicine in the syringe to be sure you have drawn up the correct amount. You may need to use several vials to withdraw the complete amount needed to reach the correct dose.

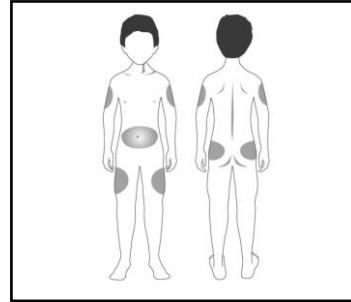
Remove the larger drawing up needle from the vial. Recap with one hand by sliding the exposed needle into the cap on a flat surface, lift it up in a scooping motion and snap it on securely by grasping the cap at its base. Carefully remove the recapped drawing up needle by pushing down and turning counterclockwise. Dispose the needle with the protective cap in your sharps container.

Place a smaller injecting needle (e.g.29 G) on the filled syringe and with the protective cap on, push down and turn clockwise the needle onto the syringe until it is tight. Pull the cap straight off the needle and dispose of it in your sharps container, you will not recap the injecting needle.

Hold the syringe with the needle pointing up and tap the barrel of the syringe with your finger to remove any air bubbles. After removing the bubbles, check the volume of medication in the syringe to be sure you have drawn up the correct amount,

You are now ready to inject the correct dose.

10) Choose an injection site. Strensiq should be administered as a subcutaneous injection into the fatty layer just below the skin. This is called the subcutaneous layer and it is just above the muscle. Areas with a substantial amount of fat below the skin (as shown in the diagram) are the most suitable areas to inject. Your doctor will advise you on the possible injection sites.



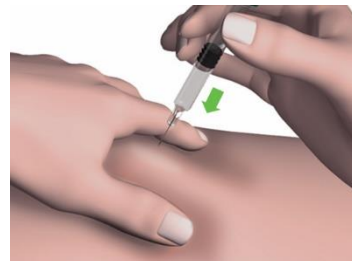
It is important to rotate injection sites, as this may help reduce pain and irritation. Do not inject into areas that are reddened, inflamed, swollen or into any areas in which you feel lumps, firm knots, or pain.

11) Using an alcohol-based (isopropyl alcohol or ethanol) solution wipe or clean the site.

12) If injecting an infant or child, hold your infant or child firmly in a comfortable position. Gently pinch the skin of the chosen injection area between your thumb and index finger.



13) Holding the syringe like a pencil or a dart, insert the needle into the raised skin so it is at an angle of between 45° and 90° to the skin surface.



For children, or patients who have little subcutaneous fat or thin skin, a 45° angle may be preferable.

14) While continuing to hold the skin, push the syringe plunger to inject the medicine slowly and steadily all the way in .



15) Remove the needle, release the skin fold and gently place a piece of cotton wool or gauze over the injection site for a few seconds. This will help seal the punctured tissue and prevent any leakage.

Do not rub the injection site after injection.

16) Dispose of the syringe, needle cap and used vial into your sharps container.

17) Place a small adhesive bandage over the injection site if necessary.

18) If you need a second injection for your prescribed dose, get another Strensiq vial and repeat steps 4 through 17.

19) Record all details of the injection in your injection diary or using another means. It is recommended that you note:

- where you injected
- the dose injected
- date and time of injection
- any injection reactions

If you have any concerns about injection reactions, preparing or administering your injection, discuss them with your doctor or pharmacist.

If you forget to use Strensiq

Strensiq should be used regularly at the same time each day. If you miss your dose at the usual time, do not take a double dose to make up for a forgotten dose. Contact your doctor for advice.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

If you use too much Strensiq

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

You should immediately:

- phone the Poisons Information Centre (by calling **13 11 26**), 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 Strensiq?

Things you should do

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

Discuss traveling with your medicine with your doctor or pharmacist.

You will need to calculate how many vials you will need for your trip. Take extra in case you are away longer than expected.

Call your doctor straight away if you:

- **If you become pregnant while using Strensiq, tell your doctor immediately.**
Your doctor will discuss the benefits and risks of continuing treatment with Strensiq during pregnancy, including participation in a monitoring program.
- **If you intend to breastfeed whilst using Strensiq, consult your doctor.**
Your doctor will discuss the benefits and risks of continuing treatment with Strensiq whilst breastfeeding, including participation in a monitoring program.

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

Things you should not do

- Do not stop taking your medicine or lower the dosage without checking with your doctor.

Looking after your medicine

- Keep your medicine in the packaging until it is time to use it. If you take the medicine out of the packaging it may not keep well.
- Keep your medicine in the refrigerator (2°C to 8°C). Do not put Strensiq in, or near the freezer compartment, and never inject Strensiq that you know, or suspect, has been frozen.
- Take the unopened Strensiq vial(s) out of the refrigerator 15 to 30 minutes before injecting to allow the liquid to reach room temperature.
- Do not warm Strensiq in any other way (for example, do not warm it in a microwave or in hot water). Upon removal of the vial(s) from refrigeration, Strensiq should be used within 3 hours maximum.

Follow the instructions in the carton on how to take care of your medicine properly.

Keep it where young children cannot reach it.

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
<p><u>Reactions at injection site</u></p> <p>During the injection of the medicine or during the hours following the injection including,</p> <ul style="list-style-type: none"> redness, itching, pain and/or swelling loose skin, discolouration of the skin, skin darkening, bleeding under the skin, bruising, scarring fatty lumps under the surface of the skin or localised loss of fat tissue small dent or depression of the injection site infection of the skin at injection site skin peeling or rash <p><u>Others</u></p> <ul style="list-style-type: none"> kidney stones low blood calcium levels 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<p><u>Allergic reactions</u></p> <p><u>Signs and symptoms may include</u></p> <ul style="list-style-type: none"> fever chills redness or flushing numbness of mouth headache increased heart rate cough nausea and vomiting rash irritability <p><u>Anaphylaxis (Serious allergic reaction)</u></p> <p><u>Signs and symptoms may include,</u></p> <ul style="list-style-type: none"> shortness of breath, wheezing or difficulty breathing swelling of the face, lips, tongue or other parts of the body rash, itching or hives on the skin low blood pressure vomiting fast heart rate choking sensation 	<p>Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</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.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. 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 medicines.

7. Product details

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

What Strensiq contains

Active ingredient (main ingredient)	asfotase alfa <i>rch</i>
Other ingredients (inactive ingredients)	Sodium chloride monobasic sodium phosphate monohydrate

	dibasic sodium phosphate heptahydrate Water for Injection
Potential allergens	Proteins of Chinese hamster origin

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

What Strensiq looks like

Strensiq is a clear, slightly opalescent or opalescent, colourless to slightly yellow, aqueous solution contained in a glass vial. A few small translucent or white particles may be present.

It is available in packs of 12 vials in the following strengths:

40 milligrams (mg) per mL

Volume (mL) per vial	Milligrams (mg) per vial	Aust R
0.3 mL	12 mg	266984
0.45 mL	18 mg	266985
0.7 mL	28 mg	266986
1.0 mL	40 mg	232546

100 milligrams (mg) per mL

Volume (mL) per vial	Milligrams (mg) per vial	Aust R
0.8 mL	80 mg	232545

*Not all vials listed above may be available

Who distributes Strensiq

In Australia, this product is registered by:
Alexion Pharmaceuticals Australasia Pty Ltd
Level 4,
66 Talavera Road,
Macquarie Park NSW 2113

Medical enquiries: 1800 788 189

This leaflet was prepared in December 2022