SOGROYA®

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.

▼ This medicine is new or being used differently. Please report side effects. See the full CMI for further details.

1. Why am I using Sogroya®?

Sogroya® contains the active ingredient somapacitan, a growth hormone. Sogroya® is used to treat children ≥ 2 years of age and adolescents with growth failure due to not making enough growth hormone and adults who do not make enough growth hormone.

For more information, see Section 1. Why am I using Sogroya®? in the full CMI.

2. What should I know before I use Sogroya®?

Do not use this medicine if you or your child have ever had an allergic reaction to Sogroya®, any other growth hormone, or any of the ingredients listed at the end of the CMI.

Talk to a doctor if you or your child taking this medicine has any other medical conditions, takes any other medicines, or is pregnant or plans to become pregnant, or is breastfeeding.

For more information, see Section 2. What should I know before I use Sogroya®? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Sogroya® 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 Sogroya®?

- The Sogroya® dose is calculated by your doctor based on your individual needs.
- Sogroya® is for injection under the skin once a week using a pre-filled pen.
- Follow the detailed instructions on how to inject Sogroya®, the instructions for use in this leaflet.

More instructions can be found in Section 4. How do I use Sogroya®? and the instructions for use in the full CMI.

5. What should I know while using Sogroya®?

Things you should do	• Tell your doctor if you, or your child, become pregnant. • Remind any doctor, dentist, pharmacist or nurse you visit that you or your child are using Sogroya®.
Things you should not do	• Do not stop using this medicine without talking to your doctor.
Driving or using machines	• Sogroya® does not affect your ability to ride a bicycle, drive and use machines.
Drinking alcohol	• There is no information on the effects of using Sogroya® with alcohol.
Looking after your medicine	• Store your Sogroya® pen in the refrigerator. Do not allow it to freeze.

	• Always remove the injection needle after each injection and store the pen without a needle attached. • Keep Sogroya® in the outer carton with the pen cap on to protect from light.

For more information, see Section 5. What should I know while using Sogroya®? in the full CMI.

6. Are there any side effects?

The most common side effects include headache, joint pain and swollen hands or feet due to fluid retention. The most serious side effects are increased pressure in the brain and a condition when your body is not making enough adrenal steroid hormones.

For more information, including what to do if you or your child have any side effects, see Section 6. Are there any side effects? in the full CMI.

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

SOGROYA® (suh-GROY-uh)

Active ingredient(s): *somapacitan*

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

1. Why am I using Sogroya®?
2. What should I know before I use Sogroya®?
3. What if I am taking other medicines?
4. How do I use Sogroya®?
5. What should I know while using Sogroya®?
6. Are there any side effects?
7. Product details

1. Why am I using Sogroya®?

Sogroya® contains the active ingredient somapacitan, a long acting version of the natural growth hormone produced by the body.

Sogroya® is used to treat growth failure in children and adolescents if they have no or very low production of growth hormone (growth hormone deficiency).

It replaces the growth hormone in adults with growth hormone deficiency and regulates the composition of fat, muscle and bone.

2. What should I know before I use Sogroya®?

Warnings

Do not use Sogroya® if:

- you or your child are allergic to somapacitan, phenol, or any of the ingredients listed at the end of this leaflet in Section 7. Product details.
  Always check the ingredients to make sure you can use this medicine.
- you or your child have a tumour which is growing. You must have completed anti-tumour treatment before you start to use Sogroya®. Sogroya® must be discontinued if the tumour grows.

- you have had open heart or stomach surgery, trauma, or have serious breathing problems.
- your child has bones that have already stopped growing (closure of the growth plates).

Check with your doctor if you or your child:

- have diabetes or high blood sugar (hyperglycaemia) as your blood sugar may need to be checked regularly and the dose of your diabetes medicines may need to be adjusted
- have ever had any kind of cancer or another kind of tumour
- have severe or recurring headaches, eyesight problems, nausea (feeling sick) or vomiting. These could be symptoms of increased pressure in the brain (benign intracranial hypertension) and your treatment may need to be stopped.
- have thyroid problems, your thyroid hormones need to be checked regularly and your dose of thyroid hormone may need to be adjusted
- have a condition where your body is not making enough steroid hormones (adrenocortical insufficiency) and have replacement therapy with glucocorticoids. You should consult your doctor regularly, as you may need adjustment of your glucocorticoid dose
- have had heart or stomach surgery, are experiencing trauma or serious breathing problems
- are a woman taking oral contraception or hormonal replacement therapy with estrogen, as your dose of Sogroya® may need to be higher. If you stop using

oral estrogen, your dose of Sogroya® may need to be reduced. Your doctor may recommend you change the route of estrogen administration (e.g. transdermal, vaginal) or use another form of contraception.

- take any medicines for any other condition.

Antibodies

You or your child are not expected to develop antibodies against somapacitan. However, as it happens with other growth hormone treatments, it may happen with this treatment. If your doctor suspects you or your child have developed antibodies, they may test for antibodies to somapacitan.

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. Sogroya® is not recommended in women of childbearing potential not using contraception. Stop treatment with Sogroya® and tell your doctor if you wish to become or do become pregnant while you are using Sogroya®. It is not known if Sogroya® may harm your unborn baby. It is recommended to use contraception while using this medicine. Speak to your doctor if you use, or intend to use, hormonal contraception.

Do not use Sogroya® while you are breast-feeding. This is because the medicine might pass into your breast milk.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you or your child 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.

This includes the following medicines:

- corticosteroids such as hydrocortisone, dexamethasone and prednisolone, medicines that can be used to replace low levels of steroid hormones
- estrogen as part of oral contraception, or hormonal replacement therapy with estrogen
- male sex hormones (androgen medicines) such as testosterone
- gonadotropin medicines (gonad stimulating hormone) which stimulate the production of sex hormones
- insulin or other diabetes medicines
- thyroid hormone medicines such as thyroxine and levothyroxine
- medicines to treat epilepsy or fits (seizures) – such as carbamazepine and diazepam
- medicines to suppress your immune system, such as cyclosporine, which can be used to treat severe skin disease (e.g., psoriasis), rheumatoid arthritis or after transplant surgery.

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

4. How do I use Sogroya®?

How much to use

- **Adults:** The Sogroya® dose is calculated by your doctor based on your individual needs and given once a week.

Adult starting dose recommendation

Adult growth hormone deficiency	**Recommended starting dose**
If you have not received daily growth hormone medicine before, and • **You are between 18 - <60 years** • **You are woman on oral estrogen therapy regardless of age** • **You are 60 years or older**	• 1.5 mg/week • 2 mg/week • 1 mg/week
If you have previously received daily growth hormone medicine, and	• 2 mg/week • 4 mg/week

Adult growth hormone deficiency	Recommended starting dose
• **You are between 18 - <60 years** • **You are woman on oral estrogen therapy regardless of age** • **You are 60 years or older**	• 1.5 mg/week

- **Children and adolescents:** The recommended Sogroya® dose is calculated at 0.16 mg per kg body weight and given once a week.
- Your doctor may increase or decrease your dose step by step and regularly until you are on the right dose based on your need and experience of side effects.
- After the right dose is reached, your or your child's doctor will evaluate the treatment every 6 to 12 months. You or your child may need to have your body mass index checked and blood samples taken.
- Do not use more than a maximum of 8 mg once a week.
- Do not change your dose unless your doctor has told you to.

When to use Sogroya®

- Sogroya® should be used once a week on the same day each week if possible.
- You can give yourself the injection at any time of the day.

How to use Sogroya®

Your doctor or nurse will show you how to inject Sogroya® under your skin. Do not inject it into a vein or muscle.

The best places to give the injection are:

- the front of your thighs
- the front of your waist (abdomen)
- the buttocks
- the upper arms.

Change the place of injection on your, or your child's, body from one week to the next. The injection site of Sogroya® should be rotated to prevent changes to the fatty tissue under the skin, such as skin thickening, skin shrinking or lumps under the skin.

If you or your child are changing from another weekly growth hormone therapy to Sogroya®, you are advised to continue your usual once weekly dosing schedule.

If you or your child are changing from daily growth hormone therapy to once weekly Sogroya® choose the preferred day for the weekly dose and stop using your daily treatment the day before (or at least 8 hours before) taking your first dose of Sogroya®.

Changing from another type or brand of growth hormone should be done by your doctor.

On occasions when administration at the scheduled dosing day is not possible, you can take Sogroya® up to 2 days before or 3 days after your scheduled dosing day. The next dose you can take as usual the following week.

If necessary, you can change the day of the weekly injection of Sogroya® as long as it has been at least 4 days since the last weekly injection. After selecting a new dosing day, continue with once a week dosing on your new day.

Follow the detailed instructions on how to inject Sogroya® in the instructions for use supplied with the product.

These instructions are also available via the following hyperlinks:
5 mg: https://medsinfo.com.au/media/noisog05
10 mg: https://medsinfo.com.au/media/noisog10
15 mg: https://medsinfo.com.au/media/noisog15

How long to use Sogroya®

You or your child may need Sogroya® for as long as your body does not produce enough growth hormone.

If a child:

- is taking Sogroya® for growth failure they will continue using Sogroya® until they stop growing
- still lacks growth hormone after they stop growing, they may need to continue using Sogroya® into adulthood.

Do not stop using Sogroya® without discussing this with your doctor first.

If you forget to use Sogroya®

Sogroya® should be used regularly at the same time each week.

If you miss your dose at the usual time, and:

- it is 3 days or less after you should have used Sogroya®, use it as soon as you remember. Then inject your next dose on your usual injection day the following week.
- it is more than 3 days since you should have used Sogroya®, skip the missed dose. Then inject your next dose as usual on your next scheduled day.

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

If you use too much Sogroya®

If you think that you or your child have used too much Sogroya®, urgent medical attention may be needed.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Accident and 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 Sogroya®?

Things you should do

Call your doctor straight away if you or your child become pregnant.

Keep all your or your child's doctor's appointments so that your progress may be checked.

Your doctor may recommend some tests to monitor your or your child's levels of blood sugar and certain hormones (e.g., thyroid hormone).

Remind any doctor, dentist, pharmacist, or nurse you visit that you or your child are using Sogroya®.

Things you should not do

- Do not stop using this medicine without talking to your doctor.
- Do not use Sogroya® every day.

Driving or using machines

Sogroya® does not affect your ability to ride a bicycle, drive and use machines.

Looking after your medicine

- Store Sogroya® in the refrigerator (between 2°C and 8°C). Keep away from the cooling element. Do not allow the medicine to freeze.
- Always remove the injection needle after each injection and store the pen without a needle attached.
- Keep Sogroya® in the outer carton with the pen cap on to protect from light.

If you cannot refrigerate (for example during travelling):

- Sogroya® may be kept temporarily at temperatures below 30°C for up to a total of 72 hours (3 days).
- Keep as cool as possible.
- Keep away from direct heat and light.
- Return Sogroya® to the refrigerator again after storage at this temperature.
- If you store out of the refrigerator and then return to the refrigerator, the total combined time out of the refrigerator is 3 days. Monitor this carefully.
- Record the time outside the refrigerator:

Keep it where young children cannot reach it.

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

When to discard your medicine

Use within 6 weeks after first use.

Discard the Sogroya® pen if you have kept it outside the refrigerator for more than 72 hours, or for any period of time above 30°C.

Do not use this medicine if the solution does not appear clear to slightly opalescent, colourless to slightly yellow and free from visible particles.

Do not use this medicine after the expiry date which is stated on the pen label and carton after 'EXP'. The expiry date refers to the last day of that month.

Getting rid of any unwanted medicines

If you no longer need to use this medicine or it is out of date, check with your pharmacy about options for safe disposal.

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
Brain and nerves: • headache • feeling of 'pins and needles', tingling or numbness in your fingers, hands or feet **Food and energy:** • increased thirst, urination and fatigue, which could be signs of high blood sugar (hyperglycaemia) **Skin:** • thickening of skin where you inject your medicine **Muscles and joints:** • joint and/or muscle pain • joint and/or muscle stiffness **General conditions:** • feeling very tired or weak	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Less serious side effects	What to do
• redness and pain in the area of injection (injection site reactions) • swollen hands or feet due to fluid retention **Hormone-related:** • Feeling tired, weight gain, sensitive to cold. These could be signs of decreased thyroid hormone	

Serious side effects

Serious side effects	What to do
Brain and nerves: • severe or recurring headaches, eyesight problems, nausea (feeling sick) or vomiting. These could be symptoms of increased pressure in the brain. **Hip and knee pain:** • Persistent hip or knee pain when walking or	**Call your doctor straight away, or go straight to the Accident and Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Serious side effects	What to do
start to limp during treatment. These could be symptoms of o slipped capital femoral epiphysis, that affects the thighbone (femur) where it inserts into the hip. This condition occurs with greater frequency in fast growing children and children with endocrine disorders o loss of bone tissue due to insufficient blood supply (osteonecrosis) Talk to your doctor about persistent pain in any joint **Hormone-related:** • Your body is not making enough adrenal steroid hormones, some symptoms of which are severe weakness,	

Serious side effects	What to do
confusion, abdominal pain, nausea, vomiting	

If you experience any of the following signs of allergic reaction, stop taking Sogroya® and tell your doctor immediately, or go to the Emergency Department at your nearest hospital:

- swelling of the face, lips, tongue or throat which may cause difficulty in swallowing or breathing
- skin rashes over a large part of the body

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 or your child 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 Sogroya® contains

Active ingredient **(main ingredient)**	• somapacitan
Other ingredients **(inactive ingredients)**	• histidine • mannitol • poloxamer • phenol • hydrochloric acid (for pH adjustment) • sodium hydroxide (for pH adjustment) • water for injections

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

What Sogroya® looks like

Sogroya® is a clear to slightly opalescent, colourless to slightly yellow liquid, essentially free from visible particles. Sogroya® comes in a disposable multidose pre-filled pen.

- Sogroya® 5 mg/1.5 mL solution for injection pre-filled pen has a teal dose button and cap. One mL of solution contains 3.3 mg of somapacitan. (AUST R 396877)
- Sogroya® 10 mg/1.5 mL solution for injection pre-filled pen has a yellow dose button cap. One mL of solution contains 6.7 mg of somapacitan. (AUST R 363895)
- Sogroya® 15 mg/1.5 mL solution for injection pre-filled pen has a rubine red dose button and cap. One mL of solution contains 10 mg of somapacitan. (AUST R 396878)

Sogroya® is available in a single pack containing 1 pre-filled pen or a multipack containing 5 packs, each containing 1 pre-filled pen.

Not all strengths and pack sizes may be marketed.

Who distributes Sogroya®

Novo Nordisk Pharmaceuticals Pty. Ltd.

Level 10, 118 Mount Street,

North Sydney, NSW 2060.

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Further information

For further information call Novo Nordisk Medical Information on 1800 668 626.

www.novonordisk.com.au

Always check the following websites to ensure you are reading the most recent version of the Sogroya® Consumer Medicine Information:

- www.novonordisk.com.au
- https://www.ebs.tga.gov.au/

This leaflet was prepared in November 2026.