

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. See the [full CMI](#) for further details.

1. Why is my child using Increlex[®]?

Increlex[®] is a solution for injection that contains mecasermin which is a synthetic insulin-like growth factor-1 (IGF 1), which is similar to the IGF 1 made by your body. It is used to treat children and adolescents from 2 to 18 years old who are very short for their age because their bodies do not make enough IGF 1. This condition is called primary IGF 1 deficiency.

For more information, see Section [1. Why is my child using Increlex[®]?](#) in the full CMI.

2. What should I know before my child uses Increlex[®]?

Do not use if your child has ever had an allergic reaction to mecasermin or any of the ingredients listed at the end of the CMI.

Talk to your child's doctor if your child has any other medical conditions, takes any other medicines, is pregnant or plans to become pregnant or is breastfeeding.

For more information, see Section [2. What should I know before my child uses Increlex[®]?](#) in the full CMI.

3. What if my child is taking other medicines?

Some medicines may interfere with Increlex[®] and affect how it works. These include insulin or other anti-diabetes medicines. A dose adjustment may be needed for these medicines.

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

4. How does my child use Increlex[®]?

- The typical dose is 0.08 to 0.12 mg/ kg of patient weight administered twice a day, shortly before or after a meal.
- Inject Increlex[®] just under your child's skin.

More instructions can be found in Section [4. How does my child use Increlex[®]?](#) in the full CMI.

5. What should I know while my child is using Increlex[®]?

Things you should do	<ul style="list-style-type: none">• Tell your child's doctor, dentist, pharmacist, surgeon or anaesthetist that they visit that your child is using Increlex[®].
Things you should not do	<ul style="list-style-type: none">• Do not give Increlex[®] to treat any other complaints unless your child's doctor tells you to.• Do not give Increlex[®] to anyone else, even if they have the same condition.• Do not stop using Increlex[®] or lower the dose without checking with your child's doctor.
Driving or using machines	<ul style="list-style-type: none">• Your child should be careful driving or operating machinery until you know how Increlex[®] affects them.• Children should be careful when riding bicycles or climbing trees.
Looking after your medicine	<ul style="list-style-type: none">• Keep the vial in the outer carton until it is time to use it. Protect from light.• Keep Increlex[®] in the refrigerator where the temperature stays between 2°C and 8°C. Do not freeze.

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

6. Are there any side effects?

The most common side effects are low blood sugar, dizziness, pain in the upper belly, joint pain, pain in limbs, headache, tremors, breast enlargement, skin thickening, moles, abnormal hair texture and weight increase. In addition, there may also be minor injection site reactions. Serious side effects which may require urgent medical attention are increased blood sugar levels, infection (especially in the middle ear), hearing loss, ear pain, enlarged tonsils/adenoids, snoring, difficulty breathing or swallowing, sleep apnoea, seizures/fits, becoming unconscious, visual changes, headache, nausea, vomiting; a localised rash or other signs of a generalised allergic reaction (hives, trouble breathing, faintness or collapse and feeling generally unwell) or excessive daytime sleeping.

For more information, including what to do if your child has 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.

Increlex[®] (inn-kra-leks)

Active ingredient(s): *mecasermin* (mee-kas-err-min)

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

- [1. Why is my child using Increlex[®]?](#)
- [2. What should I know before my child uses Increlex[®]?](#)
- [3. What if my child is taking other medicines?](#)
- [4. How does my child use Increlex[®]?](#)
- [5. What should I know while my child is using Increlex[®]?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why is my child using Increlex[®]?

Increlex[®] contains the active ingredient mecaseimerin.

Increlex[®] is used for the long-term treatment of growth failure in children and adolescents from 2 to 18 years with severe primary insulin-like growth factor 1 deficiency (Primary IGFD).

2. What should I know before my child uses Increlex[®]?

Warnings

Do not use Increlex[®] if:

- Your child currently has any tumour or growth, either cancerous or non-cancerous; has had cancer in the past; or has any conditions which may increase the risk of cancer.
- Your child is a premature baby or newborn.
- Your child has ever had an allergic reaction to mecaseimerin or any of the ingredients listed at the end of the CMI.
- Your child has finished growing (the bone growth plates are closed).
- Your child is pregnant.

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

Cancer

- Do not give Increlex[®] if your child currently has or has had in the past any tumour or growth, either cancerous or non-cancerous.

- There is an increased risk of tumours and growths (both cancerous and non-cancerous) in children and adolescents treated with Increlex[®]. If any new growth, skin lesion or symptom of cancer occurs during treatment or after treatment tell your child's doctor immediately.

Pregnancy and breastfeeding

- Do not use Increlex[®] if your child is pregnant. It may affect the developing baby if used during pregnancy.
- Do not use Increlex[®] while your child is breastfeeding. Talk to your child's doctor if your child is breastfeeding or intends to breastfeed. It is not known if the active ingredient in Increlex[®] (mecasermin) will pass into breast milk and it is not known if it will affect the baby.

Children that have finished growing

- Do not give Increlex[®] to your child if they have finished growing (the bone growth plates are closed).
- In this case Increlex[®] cannot help them grow and should not be used.
- Your child's doctor will advise you of this.

Premature and newborn babies

- Do not give Increlex[®] to premature babies or newborns because it contains benzyl alcohol.
- Benzyl alcohol can cause toxic or allergic reactions in premature babies or newborns.

Check with your doctor if your child:

- has any other medical conditions such as
 - a curved spine (scoliosis).
 - if they have a limp or hip or knee pain.
 - if they have enlarged tonsils (tonsillar hypertrophy).
 - if they have symptoms of increased pressure in the brain (intracranial hypertension), such as visual changes, headache, nausea and/or vomiting.
 - if they have had a localised reaction at the injection site or generalised allergic reaction with Increlex[®] from a previous injection.
- takes any medicines for any other condition.

During treatment, your child 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?](#)

Children younger than 2 years of age

- Safety and effectiveness in children younger than 2 years have not been established.

3. What if my child is taking other medicines?

Tell your child's doctor or pharmacist if your child is 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 Increlex® and affect how it works.

These include insulin or other anti-diabetes medicines. A dose adjustment may be needed for these medicines.

These medicines may be affected by Increlex® or may affect how well it works. Your child may need different amounts of their medicines, or they may need to take different medicines.

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

4. How does your child use Increlex®?

How much to take

- Your child's doctor or pharmacist will tell you how much to give.
- The typical dose is 0.08 to 0.12 mg/kg of patient weight administered twice a day.
- Follow the instructions provided and use Increlex® until your child's doctor tells you to stop.

When to take Increlex®

- Give Increlex® at about the same time each day.
- Giving it at the same time each day will have the best effect. It will also help you to remember when to give it.
- Give Increlex® shortly before or after a meal or snack (within 20 minutes) because it may cause low blood sugar levels.
- If an Increlex® dose cannot be given shortly before or just after a meal, that dose should not be given. The following dose should be the usual one and not doubled to make up for the missed dose
- Do not inject the dose of Increlex® if your child cannot eat for any reason.
- Until your child's doctor advises otherwise, vigorous physical activity should be avoided by your child for 2-3 hours after the injection. If physical activity takes place after breakfast, a snack should be taken.

How to take Increlex®

- Follow all directions given to you by your child's doctor or pharmacist carefully.
- Please read all of the instructions carefully before starting the Injection.
- Your child's doctor or other healthcare professional will show you how to inject Increlex® before first use.
- Increlex® should be administered using sterile disposable syringes and needles of a small enough volume so that the prescribed dose can be withdrawn from the vial with accuracy as directed by your doctor.

Method of administration

- The following instructions explain how to inject Increlex®.

Step 1 – Wash your hands

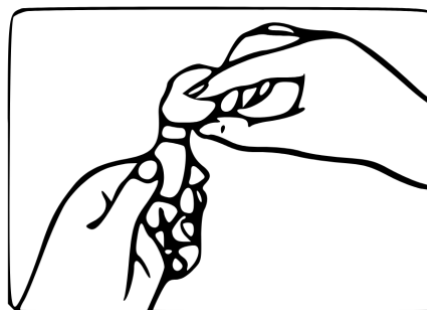
- Wash your hands before you get Increlex® ready for the injection.

Step 2 – Use a new needle and syringe

- Use a new needle and syringe every time you give a dose.

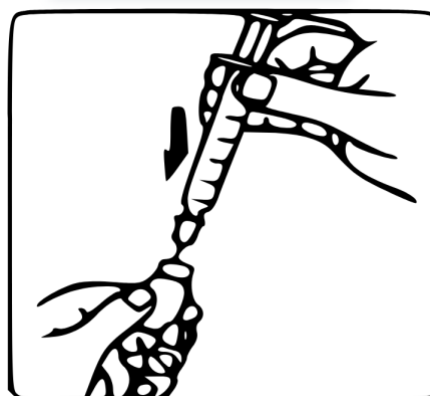
Step 3 – Prepare the syringe

- Check the liquid to make sure it is clear to slightly cloudy and colourless to slightly yellow – do not use it if it is cloudy or if you see particles, and do not use it after the expiry date.
- If you are using a new vial, remove the protective cap but do not remove the rubber stopper, which you should wipe with an alcohol swab to prevent contamination.



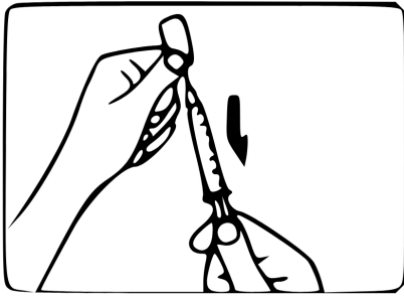
Step 4 – Inject air into the vial

- Before putting the needle into the vial, withdraw the plunger to draw an amount of air into the syringe that is equal to the Increlex® dose.
- Push the needle through the rubber top of the vial and then push the plunger to inject air into the vial.



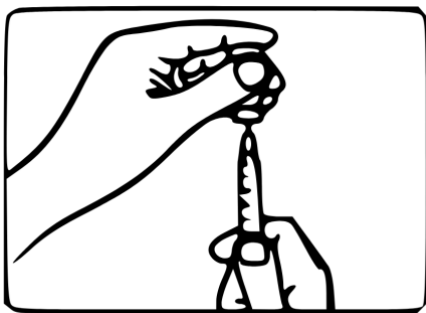
Step 5 – Withdrawing the dose

- Leave the syringe in the vial and turn both upside down. Hold the syringe and vial firmly. Make sure that the tip of the needle is in the liquid and then pull the plunger to withdraw the correct dose into the syringe.



Step 6 – Remove air bubbles and fill syringe

- Before you take the needle out of the vial, check the syringe for air bubbles. If air bubbles are in the syringe, hold the vial and syringe with the needle straight up and tap the side of the syringe until the bubbles float to the top. Push the bubbles out by using the plunger and then draw liquid back until you have the correct dose.



Step 7 – Ready to inject

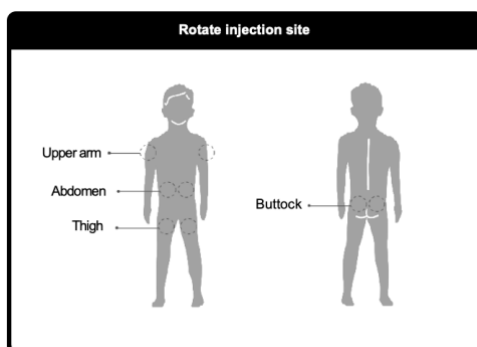
- Remove the needle from the vial.
- Do not let the needle touch anything. You are now ready to inject.

Injecting the dose:

- Inject Increlex® as instructed by your child’s doctor.
- Do not give the Increlex® injection if your child is unable to eat within 20 minutes before or after the injection.

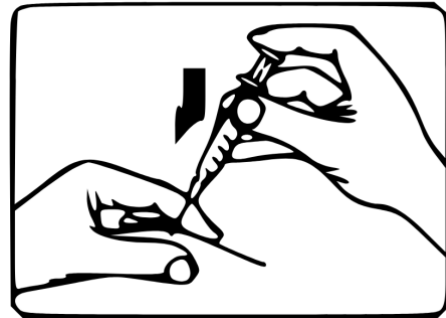
Step 8 – Decide on a site of injection

- Decide on an injection area – upper arm, thigh, buttock, or abdomen. The injection site should be changed for each **injection**.
- Use alcohol, or soap and water, to clean the skin where you are going to inject your child. The injection site should be dry before you inject.



Step 9 – To inject the dose

- Lightly pinch the skin. Insert the needle in the way that your child’s doctor has showed you. Release the skin.
- Slowly push in the plunger of the syringe all the way, making sure that you have injected all the liquid.



Step 10 – Pull the needle straight out

- Pull the needle straight out and gently press on the spot where you injected your child with gauze or a cotton ball for a few seconds.
- Do not rub the area.
- Do not recap the syringe. The used needle and syringe should be placed in a sharps container which should be sealed and disposed of properly.

If you forget to use Increlex®

Increlex® should be used regularly at the same time each day.

Do not make up the missed dose by giving two doses the next time. The next dose should be given as usual, with a meal or snack.

If you are not sure what to do, ask your child's doctor or pharmacist.

If you have trouble remembering to give the medicine, ask your pharmacist for some hints.

If you use too much Increlex®

If you think that you have used too much Increlex®, your child may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling **13 11 26**), or
- contact your child’s doctor, or
- take your child to the Emergency Department at your nearest hospital.

You should do this even if your child has no signs of discomfort or poisoning.

Symptoms of an overdose may include low blood sugar levels.

5. What should I know while my child is using Increlex®?

Things you should do

- If you are about to give your child any new medicine, remind your child's doctor and pharmacist that they are using Increlex®.
- Tell any other doctors, dentists, and pharmacists who treat your child that they are being given Increlex®.
- If your child is going to have surgery, tell the surgeon or anaesthetist that your child is being given Increlex®. It may affect other medicines used during surgery.
- Keep all of your child's doctor's appointments so that their progress can be checked. Your child's doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects. These tests may include:
 - Your child should have periodic examinations by their doctor for enlarged tonsils.
 - Your child's doctor will also continue to monitor their heart function (echocardiogram) during treatment and if treatment is stopped.
 - It is recommended that your child's doctor perform a skin check before starting treatment and regularly during treatment to check for lesions, growths or coloured patches on the skin such as birthmarks or moles.
- If your child has or develops scoliosis (sideways curvature of the spine caused by rapid growth), your child's doctor should monitor its progression.

Call your doctor straight away if:

- Your child experiences severe low blood sugar, called hypoglycaemia.

Things you should not do

- Do not give Increlex® to treat any other complaints unless your child's doctor tells you to.
- Do not give your child's medicine to anyone else, even if they have the same condition.
- Do not stop giving your child their medicine or lower the dosage without checking with your child's doctor. A disruption or early ending of treatment with mecasemin may impair the success of the growth therapy. Please ask your child's doctor for advice before stopping the treatment.

Hypoglycaemia

Hypoglycaemia is the medical name for a low blood sugar level. Increlex® is related to insulin, a naturally occurring hormone in the body that decreases blood sugar levels, so Increlex® can affect blood sugar levels. As a result, hypoglycaemia is a possible side effect of Increlex® therapy.

Hypoglycaemia is one of the most common side effects and can happen when the correct dose is given.

If hypoglycaemia does occur, it is usually in the first month of treatment and the problem lessens as treatment goes on.

It is recommended that the blood glucose levels of your child are regularly monitored. The blood glucose monitoring of your child is recommended at the start of treatment, when their dose is increased or decreased, when they are not taking enough food or if they are unwell and suffering from any other disease. Discuss the need for blood glucose monitoring for your child with their doctor.

It is important that you read all of this leaflet and any other information provided by your child's doctor about hypoglycaemia to minimise the risks of it occurring.

Make sure that you, your child, friends, family, your child's teachers and other carers can recognise the symptoms of hypoglycaemia and know how to treat them. Hypoglycaemia can occur suddenly.

Two of the most important risk factors for hypoglycaemia are:

- Not eating enough e.g. delaying or missing meals
- Physical exercise without eating sufficiently

Symptoms of hypoglycaemia may include:

- Dizziness
- Tiredness
- Restlessness
- Irritability
- Hunger
- Trouble concentrating
- Sweating
- Nausea
- Fast or irregular heartbeats

In younger children, the most important symptoms to look out for are your child becoming pale, stopping playing and remaining seated, or becoming sleepy.

If the hypoglycaemia is severe, your child may have reduced consciousness or have convulsions.

Symptoms of hypoglycaemia that occur during the night can be restlessness, anxiety or excitability, nightmares, bed wetting, or tiredness in the morning.

If your child experiences any of the symptoms of hypoglycaemia, you need to raise their blood glucose levels.

You can do this by giving your child one of the following:

- 5 to 7 jelly beans.
- 3 teaspoons of sugar or honey.
- half a can of non-diet soft drink.
- 2 to 3 concentrated glucose tablets or glucose gel.

Unless your child is within 20 minutes of their next meal or snack, follow up with extra carbohydrates such as plain biscuits, fruit or milk.

It is important to keep snacks available, especially for younger children, and to teach them to eat as soon as they feel hungry. If hypoglycaemia occurs despite adequate food intake you should tell your child's doctor, who may reduce the dose of Increlex®.

In very rare cases, severe hypoglycaemia can occur. Should it occur, your child may not be conscious enough to swallow. In such cases, you should not try to give your child anything to eat or drink, but instead, you should give an injection of glucagon.

Glucagon raises blood sugar levels when injected. Your doctor may show you how to use glucagon, in case you need to give it to your child.

Tell your child's doctor about all of the occasions when hypoglycaemia may have occurred since your last visit. Keeping a record may help with this.

Intracranial Hypertension (Increased Pressure in the Brain)

High pressure in fluid around the brain (intracranial hypertension) can occur in some patients receiving Increlex[®] treatment. Increased pressure in the brain may be caused by one of several factors other than treatment with Increlex[®]. Therefore, if your child experiences the symptoms of increased pressure in the brain, which include severe headache, pain behind the eyes or visual changes such as blurred vision with nausea and vomiting, it is important to determine the reason for these symptoms.

It is important to tell your doctor if your child has an unexplained, severe, persistent headache or visual disturbance.

By examining your child's eyes, your doctor can confirm whether or not your child has increased pressure in their brain. Your doctor may then perform further tests to determine the cause of these symptoms and may adjust the dose of Increlex[®] or stop treatment if necessary. It may be possible to restart treatment after the symptoms disappear.

Lipohypertrophy (increase in fat under the skin)

Increlex[®] must be given using a different site at every injection, usually the stomach, thigh, buttocks or upper arm, to avoid an increase in fat tissue, also known as lipohypertrophy, around the area you inject.

It is very important to be careful to rotate the injection sites, as lipohypertrophy will stop Increlex[®] being absorbed into the body, and it will therefore not be effective. See the instructions for administration in Section [4. How does my child use Increlex[®]?](#) for more information.

Driving or using machines

Be careful before your child drives or uses any machines or tools until you know how Increlex[®] affects your child.

Increlex[®] may cause low blood sugar levels (hypoglycaemia) that may affect your child's ability to drive and use machines because their ability to concentrate or react may be reduced. Other side effects of Increlex[®] include dizziness and convulsions which could also affect their ability to drive or use machines.

Your child should avoid engaging in any high-risk activities (such as driving or operating machinery) within 2-3 hours after dosing, particularly at the start of Increlex[®] treatment, until a dose has been found which does not cause side effects that make these activities risky.

Children should be careful when riding bicycles or climbing trees.

Drinking alcohol

Tell your doctor if your child drinks alcohol.

Looking after your child's medicine

- Keep the vial in the outer carton until it is time to use it. This will protect from it light.
- Keep the medicine in the refrigerator where the temperature stays between 2°C - 8°C. Do not freeze. Protect from light.
- After first use, the vial may be stored for up to 30 days at 2°C to 8°C.

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

Keep it where young children cannot reach it.

When to discard your child's medicine

Do not use Increlex[®] after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

Getting rid of any unwanted medicine, needles and syringes

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

Used needles and syringes should never be placed in household rubbish or recycling bins. They should be placed in a sharps container which should be sealed and taken to your pharmacy for safe disposal.

6. Are there any side effects?

All medicines can have side effects. If your child experiences 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>Hypoglycaemia (low blood sugar):</p> <ul style="list-style-type: none">• Dizziness• Tiredness• Restlessness• Hunger• Irritability• Trouble concentrating• Sweating• Nausea• Fast or irregular heartbeats <p>General disorders:</p> <ul style="list-style-type: none">• Pain in the upper belly• Joint pain, pain in limbs• Headache• Dizziness, tremors	<p>Speak to your child's doctor if your child has any of these less serious side effects and they worry you.</p>

Less serious side effects	What to do
<ul style="list-style-type: none"> Breast enlargement Skin thickening, moles, abnormal hair texture Weight increase 	
Injection site related: <ul style="list-style-type: none"> Pain Irritation Bleeding Bruising Redness Hardening Swelling 	Speak to your doctor if your child has any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
Severe hypoglycaemia: <ul style="list-style-type: none"> Seizures/fits, becoming unconscious. These are signs of severe low blood sugar levels (hypoglycaemia). If your child is not responsive and cannot drink sugar-containing fluids, you should give an injection of glucagon. The doctor or nurse will instruct you how to give the injection. Glucagon raises the blood sugar when it is injected. Other Disorders <ul style="list-style-type: none"> Visual changes, headache, nausea, vomiting Allergic reaction: Symptoms of an allergic reaction may include: <ul style="list-style-type: none"> A localised rash or other signs of a generalised allergic reaction (hives, trouble breathing, faintness or collapse and feeling generally unwell). 	Call your child's doctor straight away, or go straight to the Emergency Department at your nearest hospital if your child has or you notice any of these serious side effects.
General Disorders <ul style="list-style-type: none"> increased blood sugar levels infection (especially in the middle ear) hearing loss, ear pain enlarged tonsils/adenoids, snoring, difficulty breathing or swallowing, sleep apnoea (a condition where breathing stops briefly during sleep), infections of the ear, excessive daytime sleepiness 	Tell your child's doctor as soon as possible

Cancerous and non-cancerous tumours:

An increase in both cancerous and non-cancerous tumours has been reported in patients treated with Increlex®. The risk of such tumours may be higher if Increlex® is used for a condition other than what is listed above (see Section 1 [Why is my child using Increlex®?](#)) or used at a higher than recommended dose. The proportion of patients affected is not known and cannot currently be estimated based on the available data.

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

Other side effects not listed here may occur in some people.

Some of these side effects (for example, an enlarged thymus (a specialised organ of the immune system), swelling at the back of the eye (due to increased pressure within the brain) or worsening of scoliosis (sideways curvature of the spine – caused by rapid growth)) can only be found when your child's doctor does tests from time to time to check your progress.

Talk to your child's doctor or pharmacist if your child feels down, depressed, or if they feel they have no interest or take any pleasure in doing normal activities, whilst using this medicine. Depression is an uncommon side effect of the medicine.

Reporting side effects

After your child has received medical advice for any side effects they 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 child's doctor or pharmacist before you decide to stop taking any of your child's medicines.

7. Product details

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

What Increlex® contains

Active ingredient (main ingredient)	Increlex® contains 10 mg of mecasermin as the active ingredient.
Other ingredients (inactive ingredients)	Increlex® also contains: <ul style="list-style-type: none"> benzyl alcohol sodium chloride polysorbate 20 glacial acetic acid sodium acetate trihydrate water for injections. This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Potential allergens	Benzyl alcohol can cause toxic or allergic reactions in premature babies or newborns.
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Do not take this medicine if you are allergic to any of these ingredients.

What Increlex® looks like

Increlex® (Aust R 308494) is a clear to slightly cloudy and colourless to slightly yellow solution for injection (injection) supplied in a clear glass vial closed with grey stopper and an aluminium seal with a plastic flip-off button. The vial contains 4 mL of solution.

Who distributes Increlex®

Asteri Pharma Pty Ltd
6 Lux Way
Brunswick, Victoria 3056
Australia

Telephone: 1800 175 659

Website: <https://www.asteripharma.com>

This leaflet was prepared in March 2026.