

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 ALLMERCAP®?

ALLMERCAP® contains mercaptopurine monohydrate as the active ingredient. ALLMERCAP® is used solely or in combination with other medicines to treat acute leukaemia, a cancer of certain blood cells.

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

2. What should I know before I take ALLMERCAP®?

Do not use if you have ever had an allergic reaction to mercaptopurine monohydrate or any of the oral liquid suspension ingredients listed at the end of this CMI.

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

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

3. What if I am taking other medicines?

Some medicines may be affected by ALLMERCAP® or may affect how well 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 take ALLMERCAP®

- ALLMERCAP® is taken in the evening as an oral liquid suspension.
- Your doctor will decide what dose and for how long you will be taking ALLMERCAP® depending on factors such as your age and weight, pre-existing medical condition, whether you are taking any other medications, and your response to treatment.

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

5. What should I know while taking ALLMERCAP®?

Things you must do	<ul style="list-style-type: none">• Tell your doctor if, for any reason, you have not taken your medicine exactly as directed.• Tell any other specialist, doctor, dentist or pharmacist that you are on ALLMERCAP®.• Tell your doctor if you become pregnant, are trying to become pregnant or trying to father a child.• Use a sunscreen with a high SPF and protective clothing and limit exposure to sunlight and UV light.
Things you must not do	<ul style="list-style-type: none">• Do not give this medicine to anyone else, even if their symptoms seem similar to yours.• Do not use ALLMERCAP® to treat any other complaints unless your doctor says to.
Driving or using machines	<ul style="list-style-type: none">• Be careful driving or operating machinery until you know how ALLMERCAP® affects you.
Looking after your medicine	<ul style="list-style-type: none">• Keep it in a cool, dry place, protected from light, where the temperature stays below 25°C.• Do not leave it in a car, on window sills, near a sink or in the bathroom.• Keep it where children cannot reach it.

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

6. Are there any side effects?

If you get any of the following side effects, tell your doctor immediately or go to Accident and Emergency at your nearest hospital: wheezing, swelling of the lips/mouth, difficulty in breathing, lumpy rash (hives), fainting, sudden abdominal pain with nausea and vomiting.

Tell your doctor if you notice any of the following: nausea and vomiting, diarrhoea, fever, severe chills, sore throat or mouth ulcers, bruising or bleeding more easily than normal, loss of appetite and/or weight loss, jaundice, tiredness, headache, shortness of breath, dizziness, looking pale, painful/swollen joints, skin rash, hair loss, skin nodules.

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.

ALLMERCAP®

Active ingredient(s): *mercaptopurine monohydrate*

Consumer Medicine Information (CMI)

This leaflet answers some common questions about ALLMERCAP®. 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 risks of you taking ALLMERCAP® against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine.

You may need to read it again.

Where to find information in this leaflet:

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

1. Why am I using ALLMERCAP®?

ALLMERCAP® contains mercaptopurine monohydrate as the active ingredient. It belongs to a group of medicines called cytotoxics (also called chemotherapy).

ALLMERCAP® is used alone or in combination with other medicines to treat acute leukaemia, a cancer of certain blood cells.

It works by interfering with the growth of cancer cells.

Ask your doctor if you have any questions about why ALLMERCAP® has been prescribed for you.

2. What should I know before I take ALLMERCAP®?

Warnings

When you must not take it

Do not take ALLMERCAP® if you have ever had an allergic reaction to:

- Mercaptopurine monohydrate
- any of the oral liquid suspension ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty in breathing; swelling of the face, lips, tongue or any other parts of the body; rash, itching or hives on the skin.

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

Do not receive the yellow fever vaccine whilst you are taking ALLMERCAP®.

Do not take ALLMERCAP® after the expiry date printed on the bottle.

If you take it after the expiry (EXP) date has passed, it may not work as well.

Do not take it if the packaging is torn or shows signs of tampering.

ALLMERCAP® contains aspartame (E951), hydroxybenzoates and sorbates.

Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

Low blood sugar has sometimes been seen in children, mainly in children under the age of six or with a low body mass index. Common symptoms of low blood sugar include, but are not limited to, fast heart rate, shaking, sweating, hunger, confusion and loss of consciousness. Talk to your child's doctor if this happens.

Check with your doctor if you:

- are allergic to any other medicines or any other foods, dyes or preservatives.
- have received the yellow fever vaccine.

Tell your doctor if you have or have had any of the following conditions:

- have recently received or are receiving radiotherapy or chemotherapy
- have recently been vaccinated or are planning to be vaccinated
- have chickenpox, shingles or hepatitis B (a liver disease caused by a virus)
- have kidney or liver disease
- have a condition where your body produces too little of a natural chemical called thiopurine methyltransferase (TPMT).
- have inflammatory bowel disease – some patients with inflammatory bowel disease who have received mercaptopurine monohydrate have developed a rare and aggressive type of cancer called Hepatosplenic T-cell Lymphoma
- have an inherited mutation in the NUDT15 gene (a gene which is involved in the break down of Allmercap in the body) – you may have a higher risk of infections and hair loss and your doctor may give you a lower dose.
- Vitamin B3 deficiency (pellagra) – Tell your doctor immediately if you have diarrhoea, localised pigmented rash (dermatitis) or deterioration of your

- memory, reasoning and thinking skills (dementia), as these symptoms may indicate a vitamin B3 deficiency.
- have Lesch-Nyhan Syndrome, a rare inherited condition where there is a deficiency of the hypoxanthine-guanine-phosphoribosyltransferase enzyme.

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.

Do not take ALLMERCAP® if you are planning to become pregnant or father a child unless you and your doctor have discussed the risks and benefits involved.

As with all cytotoxic drugs, ALLMERCAP® may harm eggs and sperm. Reliable contraceptive methods must be used to avoid pregnancy whilst you or your partner are taking this medicine, and for at least 3 months after treatment for men, and 6 months after treatment for women.

Do not take ALLMERCAP® if you are pregnant unless you and your doctor have discussed the risks and benefits involved.

It may affect your developing baby if you take it during pregnancy.

Taking Allmercap during pregnancy may cause severe, excessive itching without a rash. You may also experience nausea and loss of appetite at the same time, which may indicate a condition called cholestasis of pregnancy (a disease of the liver during pregnancy). Talk with your doctor immediately, as this condition can cause harm to your unborn child.

Do not take this medicine whilst breast feeding.

It is not recommended for use while breast feeding as it is found in breast milk.

3. What if I am taking other medicines?

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

Some medicines may be affected by ALLMERCAP® or may affect how well it works. You may need to take different amounts of your medicine or you may need to take different medicines. These include:

- allopurinol, oxipurinol and/or thiopurinol
- methotrexate (used to treat cancer, rheumatoid arthritis or skin disease (severe psoriasis))
- infliximab (used to treat certain bowel diseases (Crohn's disease and ulcerative colitis), rheumatoid arthritis, ankylosing spondylitis or skin disease (severe psoriasis))
- medicines to treat or prevent blood clots e.g. warfarin
- 6-thioguanine

- aminosalicylate derivatives such as olsalazine, mesalazine or sulphasalazine
- vaccinations with 'live' organism vaccines
- Other medicines used to suppress the body's immune defence system agents
- ribavirin
- anti-epileptic medicines such as phenytoin. Blood levels of anti-epileptic medicines may need to be monitored and doses adjusted if necessary.
- febuxostat

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

4. How do I take ALLMERCAP®?

How much to take

Take ALLMERCAP® exactly as directed by your doctor.

Your doctor will decide what dose and for how long you will be taking ALLMERCAP®. This depends on factors such as:

- your age and weight
- any pre-existing conditions such as kidney or liver disease
- your response to the treatment
- other medicines taken in combination with ALLMERCAP®.

For children the usual dose is 2.5 mg/kg bodyweight/day, but your dose will be carefully adjusted by your doctor depending on your condition. Your doctor may change the dose and frequency of your medicine as your condition changes. Your doctor may order regular blood cell count, liver function and urine tests while you are taking ALLMERCAP® in order to monitor your condition and to change your dose if necessary.

When to take ALLMERCAP®

It is important to take ALLMERCAP® in the evening to make the medicine more effective.

How to take it

You can take your medicine with food or on an empty stomach but the choice of method should be consistent from day to day. You should take your medicine at least 1 hour before or 2 hours after having milk or dairy products.

Your pack of ALLMERCAP® contains a bottle of medicine, a cap, a bottle adaptor and two dosing syringes (a 1 mL syringe and an 5 mL syringe). Always use the syringes provided to take your medicine. The syringes provided must only be used with ALLMERCAP®.

It is important that you use the correct dosing syringe for your medicine. Your doctor or pharmacist will advise which syringe to use depending on the dose that has been prescribed.

The **smaller** 1 mL syringe, marked from 0.1 mL to 1 mL, is for measuring doses of less than or equal to 1 mL. You should use this one if the total amount you have to take is

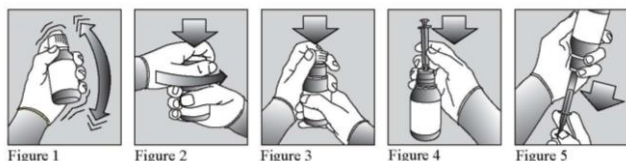
less than or equal to 1 mL (each graduation of 0.1 mL contains 2 mg of mercaptopurine monohydrate).

The **larger** 5 mL syringe, marked 1 mL to 5 mL, is for measuring doses of more than 1 mL. You should use this one if the total amount you have to take is more than 1 mL (each graduation of 0.2 mL contains 4 mg of mercaptopurine monohydrate).

If you are a parent or care giver administering the medicine, wash your hands before and after administering a dose. Wipe up spillages immediately. To decrease the risk of exposure disposable gloves should be used when handling ALLMERCAP®.

If ALLMERCAP® comes into contact with skin, eyes or nose, it should be washed immediately and thoroughly with soap and water.

When you use the medicine follow the instructions below:



1. Put on disposable hand gloves before handling ALLMERCAP®.
2. **Shake the bottle vigorously for at least 30 seconds** to ensure the medicine is well mixed (**figure 1**).
3. Remove the bottle cap (**figure 2**) and push the adaptor firmly into the top of the bottle and leave in place for future doses (**figure 3**).
4. Push the tip of the dosing syringe into the hole in the adaptor (**figure 4**). **Your doctor or pharmacist will advise you of the correct syringe to use, either the 1 mL or the 5 mL in order to give the correct dose.**
5. Turn the bottle upside down (**figure 5**).
6. Pull the plunger of the syringe back so that the medicine is drawn from the bottle into the syringe. Pull the plunger back to the point on the scale that corresponds to the dose prescribed (**figure 5**). If you are not sure about how much medicine to draw into the syringe, always ask your doctor or nurse for advice.
7. Turn the bottle back the right way up and carefully remove the syringe from the adaptor, holding it by the barrel rather than the plunger.
8. Gently put the tip of the syringe into your mouth and to the inside of your cheek.
9. Slowly and gently push the plunger down to gently squirt the medicine into the inside of your cheek and swallow it. **DO NOT** forcefully push down the plunger, or squirt the medicine to the back of your mouth or throat, as you may choke.
10. Remove the syringe from your mouth.
11. Swallow the dose of oral liquid suspension then drink some water, making sure no medicine is left in your mouth.

12. Put the cap back on the bottle with the adaptor left in place. Ensure that the cap is tightly closed.

13. Wash the syringe with warm 'soapy' water and rinse well. Hold the syringe under water and move the plunger up and down several times to make sure the inside of the syringe is clean. Let the syringe dry completely before you use that syringe again for dosing. Store the syringe in a hygienic place with the medicine.

Repeat the above for each dose as instructed by your doctor or pharmacist.

Like all cytotoxic drugs, ALLMERCAP® is irritant to the eyes and skin. To prevent irritation it is important to wash your hands immediately after handling the oral liquid suspension, to avoid contact with the eyes.

How long to take it

Your doctor will tell you how long to take ALLMERCAP® for. Do not stop taking it or change the dose without first checking with your doctor.

If you forget to take ALLMERCAP®

Tell your doctor if, for any reason, you have not taken your medicine exactly as directed.

Otherwise, your doctor may think that it was not working as it should and change your treatment unnecessarily.

Do not take a double dose to make up for the one you have missed. Visit your doctor regularly so they can check your progress and make sure your medicine is working.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (in Australia telephone 131126, in New Zealand telephone 0800 764 766) for advice, if you think you or anyone else may have taken too much ALLMERCAP®, even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

5. What should I know while taking ALLMERCAP®?

Things you must do

Tell any other specialist, doctor, dentist or pharmacist that you are on ALLMERCAP®, especially if you are about to be started on any new medicines, immunisations, vaccinations or radiotherapy.

Tell your doctor if you become pregnant, are trying to become pregnant or trying to father a child.

Use a sunscreen with a high SPF and protective clothing and limit exposure to sunlight and UV light.

Things you must not do

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

Do not use ALLMERCAP® to treat any other complaints unless your doctor says to.

Things to be careful of

Do not have any vaccinations without your doctor's approval.

ALLMERCAP® can lower the number of white blood cells and platelets in your blood. This means that you have an increased chance of getting an infection or bleeding. The risk of viral, fungal and bacterial infections is increased and the infections may be more serious.

Driving or using machines

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

Looking after your medicine

Storage

Keep it in a cool, dry place, protected from light, where the temperature stays below 25°C.

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

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

When to discard your medicine

After first opening of the bottle, discard any unused contents after 8 weeks (56 days). Write the date of first opening on the bottle to help you remember.

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
Gut and digestion: <ul style="list-style-type: none">• nausea and vomiting• diarrhoea• burning or tingling sensation in the mouth or lips (inflammation of the mucosa, stomatitis).• cracked or swollen lips (cheilitis).	Tell your doctor if you notice any of the following these less serious side effects.

Signs of infections such as:

- fever
- severe chills
- sore throat
- mouth ulcers

Signs of unusual bleeding such as:

- bruising
- bleeding more easily than normal

Appetite:

- loss of appetite and/or weight loss

Signs of liver problems such as:

- jaundice, a yellowing of the whites of the eyes or the skin

Blood and lymphatic system disorders:

- production of bone marrow cells may be reduced. You may notice an increase in infections. Your doctor will do regular blood tests
- symptoms of anaemia (reduced blood cells) include tiredness, headache, shortness of breath, dizziness, looking pale

Joints:

- painful, swollen joints

Skin and hair:

- skin rash
- hair loss
- skin nodules (erythema nodosum)

Reproduction:

- in men, sperm production may be reduced

Serious side effects

Serious side effects	What to do
Signs of an allergic reaction such as: <ul style="list-style-type: none">• wheezing• swelling of the lips/mouth• difficulty breathing• lumpy rash (hives)• fainting• sudden abdominal pain with nausea and vomiting. Signs of liver problems: <ul style="list-style-type: none">• jaundice - yellowing of the whites of the eyes or the skin• fever or chills	If you get any of these serious side effects, tell your doctor immediately or go to Accident and Emergency at your nearest hospital.

<ul style="list-style-type: none"> • light brown urine <p>Cancer related:</p> <ul style="list-style-type: none"> • as with all cytotoxic medicines, there is an increased risk of some cancers • as with all cytotoxic medicines, there is an increased risk of damage to the genes in some cells. <p>Gut and digestion:</p> <ul style="list-style-type: none"> • vitamin B3 deficiency (pellagra) associated with a localised pigmented skin rash, diarrhoea or decrease in memory, reasoning or other thinking skills. <p>In Children:</p> <ul style="list-style-type: none"> • Low blood sugar (hypoglycaemia) – the frequency is unknown. 	
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Tell your doctor if you notice anything else that is making you feel unwell.

Other side effects not listed above may also 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 (in Australia) or <https://pophealth.my.site.com/carmreportnz/s/> (in New Zealand). By reporting side effects, you can help provide more information on the safety of this medicine.

7. Product details

Ingredients

Active ingredient (main ingredient)	One mL of suspension contains 20 mg of mercaptopurine monohydrate.
Other ingredients (inactive ingredients)	xanthan gum aspartame (E951) concentrated raspberry juice sodium methylhydroxybenzoate (E219) sodium ethylhydroxybenzoate (E215) potassium sorbate (E202) sodium hydroxide purified water.

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

What ALLMERCAP® looks like

ALLMERCAP® is a pink to brown oral liquid suspension. It comes in bottles of 100 mL capped with a child-resistant closure. Each pack contains one bottle, a bottle adaptor and two dosing syringes (a syringe graduated to 1 mL and a syringe graduated to 5 mL). Your doctor or pharmacist will advise which syringe to use depending on the dose that has been prescribed.

Australian Registration Number: AUST R 213881

Who distributes ALLMERCAP®

Sponsor

In Australia:
Link Medical Products Pty Ltd
5 Apollo Street
Warriewood NSW 2012
Australia
Ph: 1800 181 060
linkhealthcare.com.au

In New Zealand:
Link Pharmaceuticals Ltd
Suite 38, Level 8
139 Quay Street
Auckland 1010
New Zealand
Ph: +64 (9) 358 7146

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