

## 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 TRECONDI?

Trecondi is used as a treatment before blood stem cell transplantation

- in adults with blood cancers called acute myeloid leukaemia (AML) or myelodysplastic syndromes (MDS),
- in adolescents and children older than one month with cancer found in the blood or bone marrow and non-cancerous disorders.

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

### 2. What should I know before I use TRECONDI?

Do not use if you have ever had an allergic reaction to treosulfan.

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

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

### 3. What if I am taking other medicines?

Some medicines may interfere with TRECONDI 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 TRECONDI?

- This medicine is used in combination with other chemotherapeutic agents. Your dose will be calculated by your doctor.
- This medicine will be given to you by your doctor or a nurse. It is given by drip (infusion) into a vein over 2 hours for 3 days before blood stem cell infusion.

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

### 5. What should I know while using TRECONDI?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Tell your doctor if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription</li><li>• Undertake regular blood tests during treatment to check your blood cell counts do not fall too low.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• You must not get pregnant during treatment with this medicine and up to 6 months after treatment. Use an effective method of contraception when either you or your partner is receiving this medicine.</li><li>• You should not father a child during and up to 6 months after treatment.</li><li>• You must not receive live vaccines during treatment with treosulfan.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• This medicine can cause nausea, vomiting and dizziness which may reduce your ability to drive or use machines. If you are affected, do not drive or use machines.</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>• Talk to your doctor about the risks associated with drinking alcohol before and after your treatment.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• This medication is cytotoxic and appropriate precautions must be taken when handling treosulfan. For this reason, your medicine will be handled and stored by trained personnel at the hospital.</li></ul>

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

### 6. Are there any side effects?

Like all medicines, this medicine can cause side effects, although not everybody gets them. Some of the common side effects are: infection; allergic reactions; sleeping problems; headache; dizziness; abnormalities in heart rhythm; high or low blood pressure; flushing; difficulty breathing; bleeding from the nose; sore red mouth; diarrhoea; nausea; vomiting; pain; upset stomach; constipation; difficulty swallowing; rash; itchy skin; hair loss; muscle weakness; kidney damage; blood in the urine; tiredness; retention of fluid in the body causing swelling; abnormal laboratory results. If you experience a fever, chest pain, bleeding or sudden weight gain consult your doctor immediately.

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.



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](http://www.tga.gov.au/reporting-problems).

# TRECONDI

**Active ingredient:** *treosulfan*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using TRECONDI. **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 TRECONDI.**

**Where to find information in this leaflet:**

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

## 1. Why am I using TRECONDI?

TRECONDI contains the active ingredient **treosulfan**. TRECONDI belongs to a group of medicines called alkylating agents.

**TRECONDI is used as a treatment before blood stem cell transplantation** in adults with blood cancers called acute myeloid leukaemia (AML) or myelodysplastic syndromes (MDS), and in adolescents and children older than one month with cancer found in the blood or bone marrow and non-cancerous disorders.

## 2. What should I know before I use TRECONDI?

### Warnings

**Do not use TRECONDI if:**

- you are allergic to treosulfan,
- if you suffer from an active uncontrolled infection,
- if your heart, lung, liver or kidneys are not working properly
- if you suffer from hereditary DNA repair disorder, a condition that reduces the ability to repair DNA (which carries your genetic information),
- if you are pregnant, think you may be pregnant or are breastfeeding.

**Check with your doctor if you:**

- have any other medical conditions
- take any medicines for any other condition

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?](#)

TRECONDI may increase the risk of having another cancer in the future. You will have regular follow up with your doctor after treatment with TRECONDI is completed.

TRECONDI may cause symptoms of the menopause (absence of menstrual periods).

### Vaccines

You must not receive live vaccines during treatment with treosulfan.

### 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.

You must not get pregnant during treatment with this medicine and up to 6 months after treatment. Use an effective method of contraception when either you or your partner is receiving this medicine.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before you receive this medicine.

You should stop breast-feeding before starting treatment with this medicine and not breastfeed for at least 6 months after treatment.

If you are a man treated with this medicine, you should not father a child during and up to 6 months after treatment.

This medicine may make you infertile and it may not be possible for you to get pregnant after treatment with it. If you are concerned about having children, you should discuss this with your doctor before treatment. Men should seek advice about the possibility of sperm preservation before starting therapy.

### Children and adolescents

Fits (seizures or convulsions) may occur very rarely in infants of less than 4 months of age. Children younger than 1 year may have more severe side effects that affect breathing. Your child will be monitored for signs of side effects affecting nerves and breathing problems.

Nappy rash with ulceration of the area around the anus (perianal) may occur in infants, toddlers and children wearing nappies because treosulfan passed out in the urine can damage the skin. Therefore, nappies should be changed frequently during 6–8 hours after each dose of this medicine. Skin should be kept clean and dry on days of treosulfan infusion to avoid rash or similar skin reactions.

There is not sufficient information on the use of treosulfan in children aged less than 1 month.

### 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.

**Some medicines may interfere with TRECONDI and affect how it works.**

**TRECONDI may interfere with some medicines and affect how they work.**

- Digoxin, a medicine used for treatment of heart failure

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

### 4. How do I use TRECONDI?

#### How much to use

This medicine is used in combination with other chemotherapeutic agents. Your dose will be calculated by your doctor based on your body size (height and weight).

Your treatment with TRECONDI will be continuously supervised by an experienced doctor in a hospital or in a specialised centre for stem cell transplantation.

#### How TRECONDI is given

- This medicine will be given to you by your doctor. It is given by drip (infusion) into a vein over 2 hours for 3 days before blood stem cell infusion.

#### If you forget to use TRECONDI

As you will be given this medicine by a doctor or a nurse it is unlikely that a dose will be missed. **You must not be given a double dose to make up for a missed dose.**

#### If you use too much TRECONDI

This medicine is given by a doctor or nurse. However, if you think you have received more of this medicine than you should, tell your doctor or nurse as soon as possible.

## 5. What should I know while using TRECONDI?

### Things you should do

TRECONDI is a cell-killing (cytotoxic) medicine that is used to decrease the number of blood cells. At the recommended dose, this is the desired effect. You will have regular blood tests during treatment to check your blood cell counts do not fall too low.

Your doctor will monitor your blood liver enzymes regularly to check your liver is working normally.

In order to prevent and treat infections, you will be given medicines, such as antibiotics, antifungals or antivirals.

Since inflammation of the lining of the mouth is a common side effect of this medicine, you should pay attention to adequate oral hygiene. Preventative use of mouthwashes (e.g. with barrier protectants, antibacterial agents) or application of ice to the lining of the mouth (lessens blood flow to the lining of the mouth and reduces the amount of treosulfan reaching the healthy skin) is recommended.

### Call your doctor straight away if you:

- experience a fever (high temperature) while using TRECONDI

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

### Driving or using machines

**Be careful before you drive or use any machines or tools until you know how TRECONDI affects you.**

TRECONDI can cause nausea, vomiting and dizziness which may reduce your ability to drive or use machines. If you are affected, do not drive or use machines.

### Drinking alcohol

#### Tell your doctor if you drink alcohol.

Your doctor will explain the risks associated with drinking alcohol before and after your treatment.

### Looking after your medicine

This medication is cytotoxic and appropriate precautions must be taken when handling treosulfan. For this reason, your medicine will be handled and stored by trained personnel at the hospital.

TRECONDI is stored below 25°C.

**Keep it where young children cannot reach it.**

## 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.

Your doctor will perform regular blood tests and other observations to check for blood counts, high sugar (glucose) levels in the blood, changes in the body's ability to manage sugar (glucose), unusual amount of acid in the blood (acidosis /alkalosis), unusual amount of salts in the body, increased liver enzymes, increased C-reactive protein (a marker of inflammation in the body) and increased blood level of bilirubin. Your doctor will also check for signs of a second, unrelated cancer.

Less serious side effects	What to do
<b>Allergic reaction:</b> <ul style="list-style-type: none"> <li>• itchy, bumpy rash</li> </ul> <b>Metabolism and nutrition related</b> <ul style="list-style-type: none"> <li>• decreased appetite</li> </ul> <b>Mental health related</b> <ul style="list-style-type: none"> <li>• problems sleeping (insomnia)</li> <li>• confusion</li> <li>• agitation</li> </ul> <b>Nervous system related</b> <ul style="list-style-type: none"> <li>• headache, dizziness</li> <li>• numbness or weakness in the arms and legs (peripheral sensory neuropathy)</li> <li>• restless, repetitive, or involuntary movements and rapid speech (extrapyramidal disorder)</li> <li>• fainting</li> <li>• tingling or numbness in the hands and feet (paresthesia)</li> </ul> <b>Eye related</b> <ul style="list-style-type: none"> <li>• dry eye</li> <li>• bleeding in the eye (in children)</li> </ul> <b>Ear related</b> <ul style="list-style-type: none"> <li>• feeling of spinning or whirling (vertigo)</li> </ul> <b>Heart related</b> <ul style="list-style-type: none"> <li>• changes and abnormalities in heart rhythm (heartbeat is irregular, too fast or too slow)</li> <li>• breathlessness due to build up of fluids around the lungs or heart</li> </ul> <b>Relating to blood vessels</b> <ul style="list-style-type: none"> <li>• dizziness, lightheadedness or headaches due to high or low blood pressure</li> <li>• flushing</li> <li>• bruising</li> </ul> <b>Lung and airway related</b> <ul style="list-style-type: none"> <li>• bleeding from the nose</li> <li>• coughing</li> <li>• inflammation or pain the throat and mouth</li> <li>• hiccups</li> <li>• changes in voice</li> </ul>	<b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b>

Less serious side effects	What to do
<b>Gastrointestinal related</b> <ul style="list-style-type: none"> <li>• sore red mouth</li> <li>• diarrhoea</li> <li>• nausea</li> <li>• vomiting</li> <li>• belly (abdominal) or throat pain</li> <li>• mouth or gums pain</li> <li>• upset stomach</li> <li>• constipation</li> <li>• difficulty in swallowing</li> <li>• bleeding in the mouth</li> <li>• dry mouth</li> <li>• feeling bloated</li> </ul> <b>Related to the liver</b> <ul style="list-style-type: none"> <li>• liver pain</li> </ul> <b>Related to the skin</b> <ul style="list-style-type: none"> <li>• a type of rash with flat or raised red bumps on the skin (maculopapular rash)</li> <li>• red spots on the skin (purpura)</li> <li>• redness of skin (erythema)</li> <li>• palms of the hands or soles of the feet tingle, become numb, painfully swollen, or red (hand and foot syndrome)</li> <li>• reddening and flaking of most of the skin of the body (dermatitis exfoliative in children)</li> <li>• itching</li> <li>• hair loss</li> <li>• red spots which start of the limbs and may blister or progress to form raised, red, pale-centered marks, associated with sore throat, fever, headache and/or diarrhoea (erythema multiforme)</li> <li>• rash /dermatitis</li> <li>• hives (in children)</li> <li>• spots that look like acne</li> <li>• excessive sweating</li> <li>• dry skin</li> <li>• skin ulcers or blisters</li> <li>• bronze pigmentation of the skin</li> <li>• skin pain (in children)</li> <li>• death of skin tissue</li> <li>• redness of skin covered by diaper, including scrotal skin (in children)</li> </ul> <b>Related to muscles and connective tissues</b> <ul style="list-style-type: none"> <li>• pain in arms or legs</li> <li>• back pain</li> <li>• bone pain</li> <li>• joint pain</li> <li>• muscle pain</li> <li>• muscle weakness</li> <li>• pain in the penis (in children)</li> </ul>	<b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b>

Less serious side effects	What to do
<b>Related to the kidneys</b> <ul style="list-style-type: none"> <li>• pain and/or increased frequency of urination (cystitis)</li> <li>• pain when passing urine</li> <li>• pain of the urinary tract</li> </ul> <b>General disorders and infusion site conditions</b> <ul style="list-style-type: none"> <li>• tiredness</li> <li>• swelling of the hands, feet or ankles due to retention of fluid in the body (oedema)</li> <li>• fever</li> <li>• chills</li> <li>• chest pain (not related to the heart)</li> <li>• pain</li> <li>• pain, redness or swelling at the site of injection</li> <li>• feeling cold</li> </ul> <b>Laboratory investigations or observations</b> <ul style="list-style-type: none"> <li>• weight gain</li> <li>• weight loss</li> </ul>	<b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b>

## Serious side effects

Serious side effects	What to do
<b>Allergic reaction</b> <ul style="list-style-type: none"> <li>• difficulty breathing</li> <li>• swelling of the face, lips, tongue or throat</li> </ul> <b>Infection related</b> <ul style="list-style-type: none"> <li>• increased susceptibility to infection</li> <li>• fever, chills, confusion or disorientation, difficulty breathing, pain or restlessness due to bloodstream infections (sepsis)</li> </ul> <b>Nervous system related</b> <ul style="list-style-type: none"> <li>• headache and fever, progressing to hallucinations, confusion, paralysis of part or all of the body, disturbances in behavior, speech and eye movements, stiff neck, and sensitivity to light (encephalopathy)</li> <li>• Sudden weakness, tingling or paralysis of the face, arm or leg, confusion, dizziness, and changes in vision due to bleeding in the brain</li> <li>• seizure (in children)</li> </ul> <b>Heart related</b> <ul style="list-style-type: none"> <li>• pressure, pain or tightness in the chest or arms, shortness of breath, cold sweat, sudden lightheadedness or dizziness (heart attack)</li> </ul>	<b>Speak to your doctor straight away if you notice any of these serious side effects.</b>

Serious side effects	What to do
<b>Relating to blood vessels</b> <ul style="list-style-type: none"> <li>• bleeding</li> <li>• swelling, redness, tenderness and a sensation of heat in one arm or leg due to a blood clot</li> </ul> <b>Related to the liver</b> <ul style="list-style-type: none"> <li>• yellowing of the skin</li> </ul> <b>Lung and airway related</b> <ul style="list-style-type: none"> <li>• difficulty breathing, wheezing</li> </ul> <b>Gastrointestinal related</b> <ul style="list-style-type: none"> <li>• blood in vomit or stool, or vomit that looks like coffee grounds (gastrointestinal bleeding)</li> </ul> <b>Related to the kidneys</b> <ul style="list-style-type: none"> <li>• passing little or no urine associated with drowsiness, nausea, vomiting and breathlessness (acute kidney injury)</li> <li>• blood in the urine</li> </ul>	<b>Speak to your doctor straight away if you notice any of these serious side effects.</b>

**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](http://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 TRECONDI contains

<b>Active ingredient (main ingredient)</b>	Treosulfan
<b>Other ingredients (inactive ingredients)</b>	None

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

### What TRECONDI looks like

TRECONDI is a white crystalline powder in a glass vial with a rubber stopper and aluminium cap.

TRECONDI is available in a vial containing 1 g or 5 g of treosulfan powder for injection for infusion. TRECONDI is available in packs containing 1 or 5 vials (type I glass).

TRECONDI 1 g AUST R 369770.

TRECONDI 5 g AUST R 369771.

### **Who distributes TRECONDI**

Link Medical Product Pty Ltd  
5 Apollo Street  
Warriewood NSW 2012  
AUSTRALIA

Ph: 1800 181 060  
[linkhealthcare.com.au](http://linkhealthcare.com.au)

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