

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 is my child taking DIACOMIT?

DIACOMIT contains the active ingredient stiripentol. DIACOMIT is an antiepileptic medicine. It is taken together with other antiepileptic medicines to treat a form of epilepsy called severe myoclonic epilepsy in infancy (Dravet syndrome), which affects infants and children.

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

2. What should I know before my child takes DIACOMIT?

Your child must not take DIACOMIT if they have ever had an allergic reaction to stiripentol or any of the ingredients listed at the end of the CMI, or if they have ever had attacks of delirium (confused, excited, restless and/or have hallucinations).

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

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

3. What if my child is taking other medicines?

Some medicines may interfere with DIACOMIT and affect how it works or increase the chance of side effects.

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

4. How do I give my child DIACOMIT?

The dose of DIACOMIT to give to your child is worked out by their doctor, based on your child's body weight.

It will be gradually increased over several weeks. The recommended dose is 50 mg per kg of body weight per day, split into 2 or 3 doses and taken during meals.

More instructions can be found in Section [4. How do I give my child DIACOMIT?](#) in the full CMI.

5. What should I know while my child is taking DIACOMIT?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that your child is using DIACOMIT.• Tell your child's doctor or pharmacist if you think that the effect of this medicine is too strong or too weak or if your child has any side effects.• Make sure your child keeps any appointments with the doctor or to have any blood tests, so that your child's doctor can monitor their liver function, blood count and growth rate.• Watch for any change in behaviour or mood and call your child's doctor or go straight to hospital if your child has suicidal thoughts or actions.
Things you should not do	<ul style="list-style-type: none">• Do not stop giving this medicine to your child suddenly.• Do not give DIACOMIT to anyone else, even if they have the same symptoms as your child.
Driving or using machines	Your child should not ride bicycles, climb trees or play on playground equipment while taking DIACOMIT until they know how it affects them. DIACOMIT may make your child feel sleepy, dizzy or uncoordinated.
Looking after your medicine	Store DIACOMIT below 25°C in the original package in order to protect from light.

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

6. Are there any side effects?

Common side effects include lack of appetite, feeling or being sick, weight loss, problems with movement and muscle strength, problems sleeping, feeling sleepy, mood changes. Serious side effects include hypersensitivity (allergic) reactions (such as rash, itching, hives on the skin; swollen face, tongue, throat or other parts of the body; shortness of breath, wheezing or problems breathing); suicidal thoughts and actions. 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.

DIACOMIT®

Active ingredient: *stiripentol*

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

- [1. Why is my child taking DIACOMIT?](#)
- [2. What should I know before my child takes DIACOMIT?](#)
- [3. What if my child is taking other medicines?](#)
- [4. How do I give my child DIACOMIT?](#)
- [5. What should I know while my child is taking DIACOMIT?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why is my child taking DIACOMIT?

DIACOMIT contains the active ingredient **stiripentol**. DIACOMIT is an antiepileptic medicine.

DIACOMIT is used to treat a form of epilepsy called severe myoclonic epilepsy in infancy (Dravet syndrome), which affects infants and children. It should always be taken together with other prescribed antiepileptic medicines under the direction of a doctor.

2. What should I know before my child takes DIACOMIT?

Warnings

Your child must not take DIACOMIT if:

- they are allergic to stiripentol, or any of the ingredients listed at the end of this leaflet
- they have ever had attacks of delirium (where they become confused, excited, restless and/or have hallucinations)

Always check the ingredients to make sure your child can take this medicine.

Check with your doctor if your child:

- has any other medical conditions such as kidney or liver problems
- takes any medicine for any other condition
- has a condition called phenylketonuria (a genetic disorder) if they are taking the Powder for Suspension.

This medicine contains a source of phenylalanine which may be harmful for people with phenylketonuria, a rare genetic disorder where the body can't break down protein properly

- has an intolerance to aspartame or some sugars if they are taking the Powder for Suspension
- is on a sodium-controlled diet. The capsules contain 0.16 mg sodium per 250 mg capsule and 0.32 mg sodium per 500 mg capsule. The Powder for Suspension contains 0.11 mg sodium per 250 mg sachet and 0.22 mg sodium per 500 mg sachet

During treatment, your child may be at risk of developing certain side effects. It is important you understand these DIACOMIT risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your child's doctor if your child is pregnant or could become pregnant. During pregnancy, effective antiepileptic treatment should NOT be stopped.

Talk to your child's doctor if your child is breastfeeding or intends to breastfeed. Breastfeeding is not recommended during treatment with this medicine.

3. What if my child is taking other medicines?

Tell your doctor or pharmacist if your child is taking any other medicines, including any medicines, vitamins or supplements bought without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and DIACOMIT may interact with each other and affect how they work. These include:

- cisapride (used to treat symptoms of night time heartburn)
- pimozide (used to treat the symptoms of Tourette's syndrome e.g. vocal outbursts and uncontrolled, repeated movements of the body)
- ergotamine (used to treat migraine)
- dihydroergotamine (used to relieve the signs and symptoms of decreased mental capacity due to the aging process)
- halofantrine (an antimalarial treatment)
- quinidine (used to treat abnormal heart rhythms)
- bepidil (used to control chest pain)
- cyclosporine, tacrolimus, sirolimus (all three used to prevent rejections of liver, kidney and heart transplants)
- statins (simvastatin and atorvastatin, both used to reduce the amount of cholesterol in blood)

- antiepileptic medicines containing phenobarbital, primidone, phenytoin, carbamazepine, diazepam
- Medicines containing:
 - midazolam or triazolam (medicines used to reduce anxiety and sleeplessness – in combination with DIACOMIT they may make your child very sleepy);
 - chlorpromazine (used for mental illness such as psychosis) ;
 - caffeine (this substance helps restore mental alertness) or theophylline (this substance is used in case of asthma). The combination with DIACOMIT should be avoided as it may increase their blood levels, leading to digestive disorders, racing heart and insomnia
- Medicines metabolized by certain liver enzymes including:
 - citalopram (used in the treatment of depressive episodes)
 - omeprazole (used in case of gastric ulcer);
 - HIV protease inhibitors (used in the treatment of HIV)
 - astemizole, chlorpheniramine (antihistamines)
 - calcium channel blockers (used in the treatment of angina or troubles of heart rhythm)
 - oral contraceptives
 - propranolol, carvedilol, timolol (used in the treatment of high blood pressure)
 - fluoxetine, paroxetine, sertraline, imipramine, clomipramine (antidepressants)
 - haloperidol (antipsychotics)
 - codeine, dextromethorphan, tramadol (used in the treatment of pain)
 - fluoxetine, paroxetine, sertraline, imipramine, clomipramine, citalopram
 - pimozone, haloperidol, chlorpromazine

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

4. How do I give my child DIACOMIT?

How much to give

- It is important that your child takes this medicine as directed by the doctor.
- Your child's doctor will tell you how much you should give them, when and how often. The dose of DIACOMIT to give to your child is worked out by their doctor, based on your child's age, weight and condition, generally 50 mg per kg bodyweight and per day.
- The dose will be gradually increased over several weeks.
- Follow the instructions provided and give DIACOMIT to your child until your doctor says they can stop taking it. Stopping DIACOMIT must be done gradually over about a month to avoid seizures coming back.
- The dose of other medication that your child is taking may be reduced when they start taking DIACOMIT.

Follow the doctor's instructions carefully for these medicines also.

- Your child's doctor will monitor your child closely if they switch between taking the capsules and taking the powder for oral suspension (or the other way around), as the two forms of medicine are not identical.

When to take DIACOMIT

DIACOMIT should be given in divided doses, two or three times a day, e.g. morning and night, or morning, noon and night.

How to take DIACOMIT

The capsules should be swallowed whole with a glass of water during a meal. The capsules should not be chewed.

The powder should be mixed in a glass of water and taken straight away during a meal.

Your child must not take DIACOMIT on an empty stomach.

Your child must NOT take it with dairy products, fizzy drinks, fruit juice or food and drinks that contain caffeine, or theophylline (e.g. chocolate).

If your child vomits within the first few minutes of taking DIACOMIT, they should have a new dose, as no medicine would have been absorbed into the body.

If your child vomits more than one hour after taking the medicine then there is no need for them to have a replacement dose.

If you forget to give DIACOMIT to your child

DIACOMIT should be used regularly at the same time each day. If your child misses a dose at the usual time, they should have it as soon as you or they remember.

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

Your child should not have a double dose to make up for the dose they missed.

If your child takes too much DIACOMIT

If you think that your child has used too much DIACOMIT, they 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
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while my child is taking DIACOMIT?

Things you should do

- Tell your child’s doctor or pharmacist if you think that the effect of this medicine is too strong or too weak or if your child has any side effects. The dose of DIACOMIT and the other medicines they are taking will be adjusted by the doctor according to your child’s condition.
- Make sure your child keeps any appointments with the doctor or to have any blood tests. Your child’s doctor will monitor liver function and blood count before starting DIACOMIT and every six months after that. They will also monitor your child’s growth rate routinely.
- Remind any doctor, dentist or pharmacist your child visits that you are using DIACOMIT.

Call your doctor straight away or take your child to hospital if:

Your child has suicidal thoughts or actions. Antiepileptic drugs may cause suicidal thoughts or actions. All mentions of suicidal thoughts or actions must be taken seriously. Families and caregivers of children and adolescents who are taking this medicine should be especially watchful for any changing behaviour.

Things you should not do

- Do not stop giving this medicine to your child suddenly. Stopping suddenly may make the seizures come back.
- Do not give DIACOMIT to anyone else, even if they have the same symptoms as your child.

Driving or using machines

Your child should not ride bicycles, climb trees or play on playground equipment until you know how DIACOMIT affects them.

DIACOMIT may make your child feel sleepy, dizzy or uncoordinated.

Looking after your medicine

- Store DIACOMIT below 25°C.
- Keep DIACOMIT in the original package in order to protect it from light.

Follow the instructions on 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.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Getting rid of any unwanted medicine

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

Do not take this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<p>Blood</p> <ul style="list-style-type: none"> • low levels of neutrophils (making your child more prone to frequent infections such as fever, severe chills, sore throat or mouth ulcers) • low levels of platelets (making your child likely to bleed or bruise more easily than normal) <p>Digestive system</p> <ul style="list-style-type: none"> • loss of appetite • feeling or being sick <p>Eyes</p> <ul style="list-style-type: none"> • double vision (if your child is also taking carbamazepine) • sensitive to light <p>General body</p> <ul style="list-style-type: none"> • feeling weak or very tired <p>Mental health</p> <ul style="list-style-type: none"> • being or feeling aggressive, irritable, agitated or unusually excitable <p>Metabolism and nutrition</p> <ul style="list-style-type: none"> • weight loss (especially when combined with the antiepileptic medicine sodium valproate) <p>Nervous system</p> <ul style="list-style-type: none"> • unable to sleep or problems sleeping • feeling sleepy or drowsy • uncoordinated, weak, unintended or exaggerated muscle movements <p>Skin</p> <ul style="list-style-type: none"> • rash, skin allergy, urticaria (pinkish, itchy swellings on the skin) 	<p>Speak to your child’s doctor if they have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<p>Hypersensitivity (allergic) reaction* may include:</p> <ul style="list-style-type: none"> rash, itching or hives on the skin, skin redness, swollen face, lips, eyes, tongue or throat or other parts of the body, or trouble breathing <p>Infections</p> <ul style="list-style-type: none"> pneumonia (infection of the lungs) <p>Mental Health</p> <p>All mentions of suicidal thoughts or actions must be taken seriously. Families and caregivers of children and adolescents who are taking this medicine should be especially watchful for any changing behaviour</p>	<p>Call your child's doctor straight away or take your child to hospital if you notice any of these serious side effects.</p>

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

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

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What DIACOMIT contains

Active ingredient (main ingredient)	Stiripentol
Other ingredients (inactive ingredients)	<p>250 mg Capsule</p> <p>povidone sodium starch glycolate type A magnesium stearate The capsule shell contains:</p> <ul style="list-style-type: none"> gelatin titanium dioxide erythrosine indigo carmine <p>The printing ink contains</p> <ul style="list-style-type: none"> shellac iron oxide black <p>500 mg Capsule</p>

	<p>povidone sodium starch glycolate type A magnesium stearate The capsule shell contains</p> <ul style="list-style-type: none"> gelatin titanium dioxide. <p>The printing ink contains</p> <ul style="list-style-type: none"> shellac iron oxide black <p>Powder for oral suspension</p> <p>aspartame spray-dried liquid glucose povidone sodium starch glycolate type A erythrosine titanium dioxide Arome Polv Tutti Frutti 25 H 245 carmellose hydroxyethylcellulose</p>
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Do not take this medicine if you are allergic to any of these ingredients.

What DIACOMIT looks like

Capsule

Each capsule contains 250 mg or 500 mg of stiripentol.

The DIACOMIT 250 mg capsules are pink with a capsule shell that is imprinted with "Diacomit 250 mg".

The DIACOMIT 500 mg capsules are white with a capsule shell that is imprinted with "Diacomit 500 mg".

The 250 mg and 500 mg capsules are supplied in plastic bottles containing 60 capsules in cardboard cartons.

Powder for Oral suspension

Each sachet contains 250 mg or 500 mg of stiripentol.

The DIACOMIT 250 mg and 500 mg sachet of powder for oral suspension contains pale pink powder.

The sachets are supplied in boxes of 60 sachets.

Not all strengths or pack sizes may be available.

ARTG Numbers:

250 mg capsules:	Aust R 280985
500 mg capsules:	Aust R 281294
250 mg powder for oral suspension:	Aust R 281460
500 mg powder for oral suspension:	Aust R 281461

Who distributes DIACOMIT

DIACOMIT is supplied in Australia by:
Chiesi Australia Pty Ltd
Level 7, Suite 1, 500 Bourke Street,
Melbourne, VIC 3000
Australia

E: medinfo.au@chiesi.com

W: www.chiesi.com.au

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This leaflet was prepared in November 2025