

DIACOMIT[®]

Stiripentol

250 mg and 500 mg capsule and powder for oral suspension

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about DIACOMIT. As this leaflet does not contain all the available information, it is important that you talk to your doctor or pharmacist. All medicines have risks and benefits. Your doctor has weighed the risks of you receiving DIACOMIT against the benefits this medicine is expected to have for you.

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

Keep this leaflet. You may need to read it again.

What DIACOMIT is used for

Stiripentol, the active ingredient of DIACOMIT, belongs to a group of medicines called antiepileptics.

It is used in conjunction with other antiepileptic medicines to treat a certain form of epilepsy called severe myoclonic epilepsy in infancy (Dravet syndrome), which affects infants and children.

Your doctor has prescribed this medicine to help treat your epilepsy. It should always be taken in combination with other prescribed antiepileptic medicines under the direction of a doctor.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is only with a doctor's prescription.

Before you take DIACOMIT

When you must not take it

Do not take DIACOMIT:

- if you have ever experienced attacks of delirium (a mental state with confusion, excitement, restlessness and hallucinations).

Do not take DIACOMIT if you have an allergy to:

- any medicine containing stiripentol
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Do not use this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should take this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

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

- kidney problems
- liver problems.

Your liver function and blood counts will be assessed prior to starting DIACOMIT and checked every 6 months.

Treatment with a combination of DIACOMIT, clobazam and valproate can frequently cause gastrointestinal side effects such as loss of appetite and vomiting. The growth rate in children will be carefully monitored.

Antiepileptic medicines may cause suicidal thoughts or actions.

Ask your doctor if you notice any unusual changes in your mood or behaviour or have thoughts of harming or killing yourself.

Tell your doctor if you are pregnant, think you may be pregnant or are planning to have a baby or are breast-feeding.

Antiepileptic treatment must not be stopped during pregnancy. Your doctor can discuss with you the risks and benefits involved.

Do not breast-feed if you are taking DIACOMIT.

Ask your doctor or pharmacist for advice before taking any medicine.

If you have not told your doctor about any of the above, tell him/her before you start taking DIACOMIT.

Taking other medicines

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

Some medicines and DIACOMIT may interfere with each other. These include:

- cisapride and omeprazole used to treat heartburn or stomach ulcers
- pimozide used to treat the symptoms of Tourette's syndrome (e.g. vocal outbursts and uncontrolled, repeated movements of the body)
- ergotamine and dihydroergotamine used to treat migraines
- halofantrine used to treat malaria
- quinidine, bepridil and calcium channel blockers used to treat heart rhythm problems or angina
- ciclosporin, tacrolimus and sirolimus used to suppress the immune system or prevent rejection after organ transplants
- simvastatin and atorvastatin used to reduce cholesterol in the blood
- medicines containing phenobarbital, primidone, phenytoin, carbamazepine or diazepam used to treat epilepsy
- midazolam, triazolam or alprazolam used to reduce anxiety and sleeplessness. When these medicines are used in combination with DIACOMIT they may make you very sleepy
- chlorpromazine and haloperidol used to treat mental illness such as psychosis
- caffeine used to increase mental alertness and theophylline used to treat asthma. The use of these medicines with DIACOMIT should be avoided as it may increase side effects such as digestive disorders, racing heart and insomnia

- citalopram, fluoxetine, paroxetine, sertraline, imipramine and clomipramine used to treat depression
- protease inhibitors used to treat the human immunodeficiency virus (HIV)
- astemizole and chlorpheniramine used to treat allergies
- oral contraceptives
- propranolol, carvedilol, timolol used to treat high blood pressure
- codeine and tramadol used to treat severe pain
- dextromethorphan commonly contained in cough medicines.

These medicines may be affected by DIACOMIT or may affect how well it works. You may need different amounts of your medicines, or may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take DIACOMIT

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the medicine, ask your doctor or pharmacist for help.

How much should you take

The dose is adjusted by the doctor according to your age, weight and condition.

The dose is generally 50 mg per kg body weight per day. The daily dose should be split into 2 or 3 doses as advised by your doctor.

Dose adjustments

Dose increases should be gradual, taking place over a few weeks while

the doses of the other antiepileptic medicines are reduced at the same time. Your doctor will tell you the new doses of the other antiepileptic medicines.

If you have the impression that the effect of this medicine is too strong or too weak, talk to your doctor or pharmacist. The dose will be adjusted by the doctor according to your condition.

Please contact your doctor if you notice any side effects as the doctor may have to adjust the dose of this medicine and the other antiepileptic medicines.

Switching between capsules and powder for oral suspension

There are slight differences between the DIACOMIT capsules and powder for oral suspension. Switching between capsule and powder formulations should be done under the close supervision of your doctor.

If you experience any problems when switching from taking the capsules to the powder for oral suspension or vice versa please inform your doctor.

How to take it

You should take this medicine at regular intervals as directed by your doctor.

It is recommended to split the medicine dose in 2 or 3 daily intakes (totalling 50 mg per kg per day), for example morning, noon and bedtime, to cover the night-and-day period.

Capsules

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

Powder for oral suspension

DIACOMIT powder for oral suspension should be mixed in a glass of water and should be taken immediately after mixing during a meal.

Vomiting

If vomiting occurs within the first few minutes of taking the medicine,

it is unlikely that the medicine will have been absorbed and a new dose should be given.

If vomiting occurs more than one hour after the medicine has been taken, it will have been absorbed. Do not give another dose in this situation and give the next dose when you are normally meant to.

When to take it

It is important that you take this medicine regularly at the same time each day.

The medicine should be taken with food. Do not take the medicine on an empty stomach.

Do not take DIACOMIT with milk or dairy products (for example yoghurt, soft cream cheeses), fruit juice, fizzy drinks or food and drinks that contain caffeine or theophylline (for example cola, chocolate, coffee, tea and energy drinks).

How long to take it

You should continue taking the medicine for as long as your doctor tells you.

You must not stop taking this medicine unless the doctor tells you to. Stopping treatment suddenly can lead to an increase in seizures.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

If you forget to take it

If it is almost time for the next dose, skip the dose that was missed and give the next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking the medicine as you would normally.

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

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

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

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26 in Australia or 0800 POISON or 0800 764766 in New Zealand) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much DIACOMIT.

Do this even if there are no signs of discomfort or poisoning.

While you are using DIACOMIT

Things you must do

If you are about to be started on any new medicine, tell your doctor or pharmacist that you are taking DIACOMIT.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Things you must not do

Do not take DIACOMIT to treat any other complaints unless your doctor tells you to.

Do not give the medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or lower the dosage without checking with your doctor.

If you stop taking it suddenly, your condition may worsen.

Things to be careful of

Capsules

This medicine contains:

- 0.16 mg sodium per 250 mg capsule
- 0.32 mg sodium per 500 mg capsule.

This should be taken into consideration by patients on a controlled sodium diet.

Powder for oral suspension

This medicine contains:

- 0.11 mg sodium per 250 mg sachet
- 0.22 mg sodium per 500 mg sachet.

This should be taken into consideration by patients on a controlled sodium diet.

This medicine contains a source of phenylalanine and may be harmful for people with phenylketonuria.

If you have been told by your doctor that you have an intolerance to aspartame or some sugars, contact your doctor before taking this medicine.

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

This medicine may make you feel sleepy or drowsy. If you have any of these symptoms, you should not use any tools, machines, ride or drive if affected in this way.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking DIACOMIT.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice you have any of the following and they worry you:

- loss of appetite and weight loss (especially when used in combination with the antiepileptic medicine sodium valproate)
- nausea and vomiting
- sleeplessness or insomnia, drowsiness and sleep disorders
- fatigue
- aggressiveness, irritability, agitation, behaviour disorders and unusually excited
- inability to coordinate muscle movements, low muscle strength, involuntary muscle contractions and exaggerated movements.

The above list includes the more common side effects of your medicine.

Tell your doctor as soon as possible if you have any of the following:

- double vision (when used in combination with the antiepileptic medicine carbamazepine)
- sensitivity to light
- rash, skin allergy, pinkish, itchy swellings on the skin
- frequent infections such as fever, severe chills, sore throat or mouth ulcers.

The above list includes serious side effects that may require medical attention.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

Some of these side effects (for example, changes in liver enzymes, decreases in white blood cells and platelets) can only be found when your doctor does tests from time to time to check your progress.

After using DIACOMIT

Storage

Keep the capsules and powder for oral suspension in the pack until it is time to use them.

Keep the medicine in a cool dry place where the temperature stays below 25°C.

Do not store DIACOMIT or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

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

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

Capsules

DIACOMIT 250 mg are pink capsules imprinted with “Diacomit 250 mg”.

DIACOMIT 500 mg are white capsules 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

DIACOMIT 250 mg and 500 mg powder for oral suspension is a pale pink powder filled in a single dose sachet.

The sachets are supplied in boxes of 60 sachets.

Ingredients

Capsules

DIACOMIT capsules contain 250 mg or 500 mg of stiripentol as the active ingredient.

The other ingredients are:

- povidone
- sodium starch glycolate type A
- magnesium stearate
- the capsule shell contains gelatin, titanium dioxide, erythrosine (250 mg only) and indigo carmine (250 mg only)
- the printing ink contains shellac and iron oxide black.

Powder for oral suspension

DIACOMIT powder for oral suspension contains 250 mg or 500 mg of stiripentol as the active ingredient.

The other ingredients are:

- aspartame
- spray-dried liquid glucose
- povidone
- sodium starch glycolate type A
- erythrosine
- titanium dioxide
- carmellose sodium
- hyetellose
- Arome Polv Tutti Frutti 25 H 245 flavour.

Supplier

DIACOMIT is supplied in Australia by:

Chiesi Australia Pty Ltd
Suite 3, 22 Gillman Street
Hawthorn East Victoria 3123

DIACOMIT is supplied in New Zealand by:

Chiesi New Zealand Ltd
58 Richard Pearse Drive
Airport Oaks
Mangere 2022

Email: medicalaffairs.au@chiesi.com

Website: www.chiesi.com.au

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This leaflet was prepared in
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AUST R 280985 - 250 mg capsule

AUST R 281294 - 500 mg capsule

AUST R 281460 - 250 mg powder
for oral suspension

AUST R 281461 - 500 mg powder
for oral suspension