▼**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®

250 mg and 500 mg capsule and powder for suspension
Stiripentol

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

Before your child takes DIACOMIT

When your child must not take it:

Your child must NOT take DIACOMIT if he/she:

- is allergic to stiripentol or to any of the other ingredients of DIACOMIT (listed at the end of this leaflet - (See "DIACOMIT description"). Signs of allergic reaction may include a skin rash, itching, shortness of breath or swelling of the face, lips or tongue.
- has ever experienced attacks of delirium (a mental state with confusion, excitement, restlessness and hallucinations).

Before your child takes it:

Before your child starts taking DIACOMIT you should discuss with your child's doctor any of the following points which apply to your child.

- if your child has kidney or liver problems.
- Your child's liver function should be assessed prior to starting DIACOMIT and checked every 6 months.
- Your child's blood count should be assessed prior to starting DIACOMIT and checked every 6 months.
- Because the frequency of gastrointestinal side effects with DIACOMIT, clobazam and valproate, such as anorexia, loss of appetite, vomiting, your child's growth rate should be carefully monitored.
- If your child is pregnant or could become pregnant. During pregnancy, effective antiepileptic treatment must NOT be stopped. Ask your child's doctor or pharmacist for advice before taking any medicine.
- Do not breastfeed if you are taking DIACOMIT. Breast-feeding is not recommended during treatment with this medicine. Ask your doctor or pharmacist for advice before taking any medicine.
- Antiepileptic drugs may cause suicidal thoughts or actions. Ask your child's doctor if your child have any signs of suicidal ideation or behaviour.
- If your child is taking medicines containing:
  - 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);
  - bepridil (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).

Please tell your child's doctor or pharmacist if your child is using or has recently used any other medicines, including medicines obtained without a prescription, dietary supplements and herbal medicines.

How to take DIACOMIT

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 take, when and how often. Follow your child's doctor's instructions. If you are unsure ask your doctor or pharmacist.

How much should your child take:

The dose is adjusted by the doctor according to your child's age, weight and condition, generally 50 mg per kg bodyweight and per day. This should be split into 2 or 3 doses as advised by your child's doctor.

When and how should your child take DIACOMIT:

Your child should take this medicine at regular intervals as directed by your child's 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 - bed-time, to cover the night-and-day period.

Dose increases should be gradual, taking place over a few weeks while the dose(s) of the other antiepileptic medicine(s) is (are) reduced at the same time. Your child's doctor will tell you the new dose(s) of the other antiepileptic medicine(s).

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

Please consult your child's doctor in the event of any side effects as the doctor may have to adjust the dose(s) of this medicine and the other antiepileptic medicine(s).

There are slight differences between the DIACOMIT capsules and powder for oral suspension. If your child experiences any problems when switching from taking the capsules to the powder for oral suspension or vice versa please inform your child's doctor. In case of switch between capsule and powder formulations it should be done under the close supervision of the doctor.

In case of vomiting within the first few minutes of intake it is assumed that no medicine has been absorbed and a new dose should be given.

However, the situation is different if the vomiting occurs more than one hour after medicine intake because stiripentol is quickly absorbed. In such a case, it is assumed that a significant fraction of the administered dose has been absorbed systemically from the digestive tract. Thus, there would be no need

for a new intake or for an adjustment of the next dose.

Capsules: DIACOMIT capsules should be swallowed whole with water. The capsules should not be chewed.

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

Your child should take DIACOMIT with food, it should NOT be taken on an empty stomach. For food and drinks to be avoided, see the section "While your child is taking DIACOMIT" below.

Contact your child's doctor if you know or think your child has taken more medicine than he or she should have.

If you or your child forgets to take DIACOMIT:

It is important that your child takes this medicine regularly at the same time each day. If your child forgets to take a dose, he or she should take it as soon as you remember unless it is time for the next dose. In that case carry on with the next dose as normal. Your child should not take a double dose to make up for a forgotten individual dose.

If your child stops taking DIACOMIT:

Your child must not stop taking this medicine unless the doctor tells you to. Stopping treatment suddenly can lead to an outbreak of seizures.

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

While your child is taking DIACOMIT

Things you must not do:

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).

During pregnancy, effective antiepileptic treatment must NOT be stopped. If your child may be or is pregnant, please ask your child's doctor for advice.

Breast-feeding is NOT recommended during treatment with this medicine. Ask your doctor or pharmacist for advice before taking any medicine.

This medicine may make your child feel sleepy. Your child should NOT use any tools, machines, ride or drive if affected in this way. Check with your child's doctor.

Do not give DIACOMIT to anyone else, even if they have the same symptoms as your child.

Things you must do:

If your child is about to be started on any new medicine, tell your child's doctor or pharmacist that your child is taking DIACOMIT.

Things to be careful of:

Capsules:

This medicine contains 0.16 mg sodium per 250 mg capsule and 0.32 mg sodium per 500 mg capsule. This should be taken into consideration by patients on a controlled sodium diet.

Powder for suspension:

This medicine contains 0.11 mg sodium per 250 mg sachet and 0.22 mg sodium per 500 mg sachet. To be taken into consideration by patients on a controlled sodium diet.

This medicine contains a source of phenylalanine. 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 medicinal product.

Side Effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Tell your child's doctor if you notice any of the following side effects:

Very common side effects (may affect more than one in 10 people):

- loss of appetite, weight loss (especially when combined with the antiepileptic medicine sodium valproate);
- insomnia (sleeplessness), drowsiness;
- ataxia (inability to coordinate muscle movements), hypotonia (low muscle strength), dystonia (involuntary muscle contractions).

Common side effects (may affect up to 1 in 10 people):

- raised levels of liver enzymes, especially when given with either of the antiepileptic medicines carbamazepine and sodium valproate;
- aggressiveness, irritability, agitation, hyperexcitability (state of being unusually excitable);
- sleep disorders (abnormal sleeping);
- hyperkinesis (exaggerated movements);
- nausea, vomiting;
- a low number of a type of white blood cells.

Uncommon side effects (may affect up to 1 in 100 people):

- double vision when used in combination with the antiepileptic medicine carbamazepine;
- sensitivity to light;
- rash, skin allergy, urticaria (pinkish, itchy swellings on the skin);
- fatigue (tiredness).

Rare side effects (may affect up to 1 in 1,000 people)

- decrease of platelet level in the blood
- Abnormal liver function test

To eliminate these side effects, your child's doctor may have to change the dose(s) of DIACOMIT and/or one of the other medicines prescribed for your child.

If your child gets any side effects talk to your child's doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

Overdosage

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26), or go to the emergency department of your nearest hospital, if you think your child or anyone else may have taken too much DIACOMIT. Do this, even if there are no signs of discomfort or poisoning.

DIACOMIT description

The active substance is stiripentol.

Capsule

Each capsule contains 250 mg or 500 mg of stiripentol.

Each capsule also contains the following inactive ingredients:

- povidone
- sodium starch glycolate type A
- magnesium stearate
- The printing ink contains shellac and iron oxide black

The DIACOMIT 250 mg capsule is pink with a capsule shell that is made of gelatin, titanium dioxide, erythrosine, indigo carmine, and imprinted with "Diacomit 250 mg".

The DIACOMIT 500mg capsule is white with a capsule shell that is made of gelatin, titanium dioxide, and imprinted with "Diacomit 500 mg".

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

Oral suspension

Each sachet contains 250 mg or 500 mg of stiripentol.

Each sachet also contains the following inactive ingredients:

- aspartame
- glucose liquid spray
- povidone
- sodium starch glycolate type A
- erythrosine
- titanium dioxide
- tutti frutti flavour
- carmellose
- hydroxyethylcellulose

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.

Storage

Keep DIACOMIT in the original package in order to protect from light.

Store DIACOMIT below 25°C. Keep the bottle and the sachet pack in a cool, dry place and away from direct heat and sunlight. Do not store in the bathroom or near a sink.

Keep DIACOMIT 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.

Your child should not take DIACOMIT after the expiry date, which is stated on the label. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

DIACOMIT is sponsored in Australia by:

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This leaflet was revised in May 2021

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