PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

DIACOMIT 250 & 500 CAPSULES

Stiripentol

Sugar free

Read all of this leaflet carefully before you start taking DIACOMIT

- Keep this leaflet. You may need to read it again.
- If you have further questions, ask your doctor, pharmacist, nurse or other healthcare provider.
- DIACOMIT has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What DIACOMIT is and what it is used for

DIACOMIT contains stiripentol as active ingredient and belongs to a group of medicines called antiepileptics.

It is used in conjunction with clobazam and valproate to treat a certain form of epilepsy called severe myoclonic epilepsy in infancy (Dravet's syndrome), which affects 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.

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2. What you need to know before you take DIACOMIT

Do not take DIACOMIT:

- if you are allergic (hypersensitive) to stiripentol, or to any other ingredients of DIACOMIT (listed in section 6).
- if your child has ever experienced attacks of delirium (a mental state with confusion, excitement, restlessness and hallucinations).

Warnings and precautions

Take special care with DIACOMIT:

Talk to your child's doctor or pharmacist before taking DIACOMIT:

- if your child is taking other anti-epileptic medicines such as carbamazepine, phenytoin or phenobarbitone (see section Other medicines and DIACOMIT)
- your child's blood count should be assessed prior to starting DIACOMIT and checked every 6 months
- if your child is particularly sleepy especially if your child is taking other medicines called central nervous system depressants
- if your child shows movement disorders
- if your child shows signs of suicidal ideation or behaviour
- your child's liver function should be assessed prior to starting DIACOMIT and checked every 6 months
- if your child has kidney or liver problems
- because the frequency of gastrointestinal side effect with DIACOMIT, clobazam and valproate, such as anorexia, loss of appetite, vomiting, your child's growth rate should be carefully monitored.

Other medicines and DIACOMIT

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Please tell your doctor or pharmacist if your child is taking any of the following medicines:

If your child takes medicines metabolised by certain liver enzymes:

- citalopram (used in the treatment of depressive episodes)

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- 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 anger 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)

If your child takes medicines containing:

- caffeine (this substance helps restore mental alertness)
- 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 containing:

- ergotamine (used to treat migraine)
- dihydroergotamine (used to relieve the signs and symptoms of decreased mental capacity due to the aging process)
- 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)
- halofantrine (an antimalarial treatment)
- quinidine (used to treat abnormal heart rhythms)
- bepridil (used to control chest pain)
- ciclosporin, 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)

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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).

Antiepileptic medicines containing:

phenobarbitone, primidone, phenytoin, carbamazepine, diazepam, ethosuximide, tiagabine.

DIACOMIT with food and drink

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

Pregnancy, breastfeeding and fertility

Effective contraception should be used while a woman is being treated with DIACOMIT.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before using DIACOMIT.

During pregnancy, effective antiepileptic treatment must NOT be stopped.

Breastfeeding is not recommended during treatment with DIACOMIT.

A woman should not breastfeed her baby while she is being treated with DIACOMIT.

Driving and using machines

DIACOMIT 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.

It is not always possible to predict to what extent DIACOMIT may interfere with your daily activities. You should ensure that you do not engage in the driving a vehicle or use machines until you are aware of the measure to which DIACOMIT affects you.

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3. How to take DIACOMIT

Do not share medicines prescribed for you with any other person.

Your child should use DIACOMIT exactly as your child's doctor or pharmacist has told you. You should check with your child's doctor or pharmacist if you are not sure.

Dosage

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.

When to take DIACOMIT

Your child should take this medicine two or three times a day at regular intervals as directed by your child's doctor, for example morning - noon - bed-time to cover the night-and-day period.

Dose adjustment

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 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.

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

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 "Diacomit with food and drink" above.

If you take more DIACOMIT than you should

In the event of overdosage, consult your child's doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

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If you forget to take a dose of DIACOMIT

Your child should not take a double dose to make up for forgotten individual doses.

If you stop 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.

4. Possible side effects

DIACOMIT can have side effects.

Not all side effects reported for DIACOMIT are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using DIACOMIT, please consult your healthcare provider for advice.

If any of the following happens, stop using DIACOMIT and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching.

These are all very serious side effects. If you have them, you may have had a serious reaction to DIACOMIT. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent

- a low number of a type of white blood cells
- anorexia, loss of appetite, weight loss (especially when combined with the antiepileptic medicine sodium valproate)
- aggressiveness, irritability, sleep disorders, hyperexcitability (state of being unusually excitable)
- drowsiness
- ataxia (inability to coordinate muscle movements), hypotonia (low muscle strength), dystonia (involuntary muscle contractions), excessive movement (refers to a wide variety of abnormal involuntary movements)

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- nausea, vomiting
- raised levels of liver enzymes, especially when given with either of the antiepileptic medicines, carbamazepine and sodium valproate.

Less frequent

- decrease of platelet level in the blood (easily bruising)
- double vision when used in combination with the antiepileptic medicine carbamazepine
- sensitivity to light
- skin allergy, urticaria (pinkish, itchy swellings on the skin)
- fatigue (tiredness)
- abnormal liver function test.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of DIACOMIT.

5. How to store DIACOMIT

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Store at or below 25 °C.

Store in the original container to protect from light.

Do not use after the expiry date stated on the label / carton / bottle.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

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What DIACOMIT contains

The active substance is stiripentol.

The other ingredients are:

Diacomit Capsules

Capsule: magnesium stearate, povidone, sodium starch glycolate, type A.

Capsule shell (body and cap): erythrosine (E127), gelatin, Indogotin carmine (E132), titanium dioxide (E171).

What DIACOMIT looks like and contents of the pack

DIACOMIT 250 Capsules: opaque pink capsules of size 2 with "Diacomit" printed in black on cap and "250 mg" printed in black on body with self-locking closure containing a white to pale yellow powder.

DIACOMIT 500 Capsules: opaque white capsules of size 0 elongated (0+) with "Diacomit" printed in black on cap and "500 mg" printed in black on body with self-locking closure containing a white to pale yellow powder.

DIACOMIT 250 and 500 mg capsules are packaged in opaque polyethylene bottles closed with a child-resistant tamper-evident polypropylene screw cap.

The DIACOMIT 250 mg capsules are packaged in 60 mL bottles and the DIACOMIT 500 mg capsules in 100 mL bottles in cardboard cartons.

Each bottle of 250 mg or 500 mg capsules contains 60 capsules.

Holder of Certificate of Registration

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