

Package leaflet: Information for the user

Diacomit 250 mg hard capsule Diacomit 500 mg hard capsule stiripentol

Read all of this leaflet carefully before your child starts taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your child's doctor or pharmacist.
- This medicine has been prescribed for your child only. Do not pass it on to others. It may harm them, even if their symptoms are the same as your child's.
- 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. See Section 4.

What is in this leaflet

1. What Diacomit is and what it is used for
2. What you need to know before your child takes Diacomit
3. How to take Diacomit
4. Possible side effects
5. How to store Diacomit
6. Contents of the pack and other information

1. What Diacomit is and what it is used for

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

It is used in conjunction with clobazam and valproate (other antiepileptic medicines) 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.

2. What you need to know before your child takes Diacomit

Your child must NOT take Diacomit

- if your child is allergic to stiripentol or to any of the other ingredients of this medicine (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

Talk to your child's doctor or pharmacist before taking Diacomit

- 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 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

Tell your child's doctor or pharmacist if your child is using, has recently used or might use any other medicines.

Tell your doctor if your child is taking any of the following medicines:

- 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).
- If your child takes medicines containing:
 - 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.
- If your child takes medicines metabolized by certain liver enzymes:
 - 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 angor 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).

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 and breast-feeding

If your child is pregnant or breast-feeding, think she may be pregnant or is planning to have a baby, ask your doctor for advice before taking this medicine.

During pregnancy, effective antiepileptic treatment must NOT be stopped.

Breast-feeding is not recommended during treatment with this medicine.

Driving and using machines

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.

Diacomit contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially 'sodium-free'.

3. How to take Diacomit

Your child should always take these capsules exactly as your child's doctor 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.

Please consult your child's doctor in the event of any side effects as the doctor may have to adjust the dose 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 doctor. In case of switch between capsule and powder formulations it should be done under the close supervision of your child's 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.

How to take the Diacomit capsules

To ensure that the whole amount of powder is taken by the patient, it is preferable not to open the capsule and to swallow it as a single oral administration unit form.

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 your child takes more Diacomit than he or she should

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

If 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.

4. Possible side effects

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

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);
- hyperkinesia (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 of Diacomit or one of the other medicines prescribed for your child.

Reporting of side effects

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. You can also report side effects directly via [the national reporting system](#) listed in [Appendix V](#).

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Diacomit

- Keep this medicine out of the sight and reach of children.
- Your child should not take Diacomit after the expiry date, which is stated on the label after "EXP". The expiry date refers to the last day of that month.
- Store in the original package in order to protect from light.

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.

6. Contents of the pack and other information

What Diacomit 250 mg contains

- The active substance is stiripentol. Each hard capsule contains 250 mg of stiripentol.
- The other ingredients of the capsule are povidone, sodium starch glycolate and magnesium stearate (E470b).
- The capsule shell is made of gelatin, titanium dioxide (E171), erythrosine (E127), indigotin (E132).
- The printing ink contains shellac (E904), black iron oxide (E172).

What Diacomit 500 mg contains

- The active substance is stiripentol. Each hard capsule contains 500 mg of stiripentol.
- The other ingredients of the capsule are povidone, sodium starch glycolate and magnesium stearate (E470b).
- The capsule shell is made of gelatin, titanium dioxide (E171).
- The printing ink contains shellac (E904), black iron oxide (E172).

What Diacomit 250 mg looks like and contents of the pack

Diacomit 250 mg hard capsule is pink and printed with “Diacomit 250 mg”.

The hard capsules are supplied in plastic bottles containing 30, 60 or 90 capsules in cardboard cartons. Not all pack sizes may be marketed.

What Diacomit 500 mg looks like and contents of the pack

Diacomit 500 mg hard capsule is white and printed with “Diacomit 500 mg”.

The hard capsules are supplied in plastic bottles containing 30, 60 or 90 capsules in cardboard cartons. Not all pack sizes may be marketed.

Diacomit is also available as 250 mg and 500 mg powder for oral suspension in sachets.

Marketing Authorisation Holder

Biocodex, 7 avenue Gallieni - F-94250 Gentilly - France
Tel: + 33 1 41 24 30 00 - e-mail: medinfo@biocodex.com

Manufacturer

Biocodex, 1 avenue Blaise Pascal - F-60000 Beauvais - France

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

AT/BE/BG/CY/EL/ES/FR/HR/HU/IE/IS/IT/LU/MT/NL/PL/PT/SI

Biocodex

7 avenue Gallieni - F-94250 Gentilly

Франция/ Γαλλία/ France/ Francia/ Franciaország/ Frakkland/ Francija/ Franza/ Frankrijk/ Francja

Tél/Tel/Тел/Τηλ/Σίμι: + 33 (0)1 41 24 30 00

e-mail: medinfo@biocodex.com

CZ

Desitin Pharma spol. s r.o

Opletalova 25

11121 Prague 1

Czech Republic

Tel: 00420-2-222 45 375

e-mail: desitin@desitin.cz