Package Leaflet: Information for the User

# Diacomit® 500 mg hard capsules

(stiripentol)

Your medicine is known by the above name, but will be referred to as Diacomit® throughout this leaflet.

This product is available in other strengths.

**Read all of this leaflet carefully before 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 doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects, talk to your 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

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 Dravet's syndrome (DS). Your doctor has prescribed this medicine to help treat your epilepsy.

## 2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE DIACOMIT®

**You must NOT take Diacomit®**

- if you are allergic to stiripentol or to any of the other ingredients of this medicine (listed in section 6).
- if you have ever experienced attacks of delirium (a mental state with confusion, excitement, restlessness and hallucinations).

**Warnings and precautions**

Talk to your doctor or pharmacist before taking Diacomit®.

- If you have kidney or liver problems.
- Your liver function should be assessed prior to starting Diacomit® and checked every 6 months.
- Your 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 growth rate should be carefully monitored.

**Other medicines and Diacomit®**

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Tell your doctor if you are 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 you very sleepy); chlorpromazine (used for mental illness such as psychosis).
  - If you are taking 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 your blood levels, leading to digestive disorders, racing heart and insomnia.
- If you are taking 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.

**Diacomit® with food and drink**

Do NOT take Diacomit® with 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 you are pregnant or breast-feeding, think you may be pregnant or are 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 you feel sleepy.

You should not use any tools, machines, ride or drive if affected in this way. Check with your 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®

You should always take these capsules exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

**Dosage**

The dose is adjusted by the doctor according to your age, weight and condition, generally 50 mg per kg bodyweight and per day.

**When to take Diacomit®**

You should take this medicine two or three times a day at regular intervals as directed by your 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 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 doctor or pharmacist. The dose will be adjusted by the doctor according to your condition.

Please consult your 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 you experience 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 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. For food and drinks to be avoided, see the section *"Diacomit® with food and drink"* above.

**If you take more Diacomit® than you should**

Contact your doctor if you know or think you have taken more medicine than you should have.

**If you forget to take Diacomit®**

It is important that you take this medicine regularly at the same time each day. If you forget to take a dose, you 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. You should not take a double dose to make up for a forgotten individual dose.

**If you stop taking Diacomit®**

You 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 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);
- 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.

**Not known** (frequency cannot be estimated from the available data)

- pneumonia (infection of the lungs).

To eliminate these side effects, your doctor may have to change the dose of Diacomit® or one of the other medicines prescribed to you.

**Reporting of side effects**

If you get any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**. By reporting side effects, you can help provide more information on the safety of this medicine.

## 5. HOW TO STORE DIACOMIT®

- **Keep out of the sight and reach of children.**
- You 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.
- If the medicines become discoloured or show any other signs of deterioration, consult your pharmacist who will tell you what to do.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

## 6. CONTENTS OF THE PACK AND OTHER INFORMATION

**What Diacomit® 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® looks like and contents of the pack**

Diacomit® hard capsule is white and printed with "Diacomit® 500 mg".

The hard capsules are supplied in plastic bottles containing 60 capsules in cardboard cartons.

Manufactured by Biocodex, 1 avenue Blaise Pascal, F-60000 Beauvais, France.

Procured from within the EU and repackaged by the Product Licence Holder Beachcourse Ltd., Unit 2-3, Townsend Industrial Estate, Waxlow Road, London, NW10 7NU.

For any information about this medicinal product, please contact the Product Licence Holder: Beachcourse Ltd., 020 8896 9054.

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