

Package leaflet: Information for the patient

Procarbazine 50mg Capsules

Procarbazine hydrochloride

Read all of this leaflet carefully before you start 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 signs of illness 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 Procarbazine 50mg Capsules are and what they are used for
2. What you need to know before you take Procarbazine 50mg Capsules
3. How to take Procarbazine 50mg Capsules
4. Possible side effects
5. How to store Procarbazine 50mg Capsules
6. Contents of the pack and other information

1. What Procarbazine 50mg Capsules are and what they are used for

Procarbazine is one of the group of medicines known as alkylating agents, which interfere with the growth of certain types of cells in the body.

Procarbazine is used as one of the chemotherapy drugs in the treatment of some cancers.

In adults, Procarbazine is used on its own or in combination with other drugs in the treatment of cancers such as Hodgkin's disease (a cancer of the lymph glands).

In children (aged 2-18 years), Procarbazine is used in combination with other drugs in the treatment of Hodgkin's disease.

2. What you need to know before you take Procarbazine 50mg Capsules

Do not take Procarbazine 50mg Capsules:

- if you are allergic to procarbazine or any of the other ingredients of this medicine (listed in section 6)

- if you have anything wrong with your blood, in particular, too few white cells or platelets (your doctor will be able to advise you).
- if you suffer from any severe kidney or liver disorder
- if you have a non-cancerous tumour
- if you are in the first trimester of pregnancy
- if you are breast-feeding

Make sure your doctor knows if any of the above applies to you.

Warnings and precautions

Talk to your doctor before taking Procarbazine 50mg Capsules:

- if you suffer from any kidney or liver disorder
- if you have any disorder of the heart or circulation
- if you are, or could be, pregnant or may want to become pregnant in the future (for further information refer to the following sections of this leaflet: 'Do not take Procarbazine 50mg Capsules' and 'Pregnancy, breast-feeding and fertility')
- if you have a tumour on the adrenal gland (near the kidney), causing high blood pressure
- if you suffer from epilepsy
- if you have had a stroke

Some types of vaccinations should not be given to you during or within at least six months of treatment with chemotherapy drugs such as procarbazine. Your doctor will be able to advise you on this. If you need any other medical treatment or surgery whilst taking Procarbazine 50mg Capsules, remember to tell the doctor or dentist treating you that you are taking this medicine.

Try to avoid people with infections whilst taking procarbazine. Check with your doctor immediately if you get a cough, cold, or any other infection.

Other medicines and Procarbazine 50mg Capsules

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

In particular, check with your doctor or pharmacist if you are taking any of the following:

- strong painkillers (especially Pethidine)
- medicines for anxiety or difficulty in sleeping
- anticholinergic medicines, these include some medicines used for irritable bowel syndrome, asthma or incontinence
- medicines for depression
- medicines for high blood pressure or for your heart
- anaesthetic products
- medicines for epilepsy

- clozapine (an anti-psychotic medication)

It is safe to use plain Paracetamol or Aspirin without speaking to your pharmacist.

Procarbazine 50mg Capsules with food, drink and alcohol

Certain foods, drinks and medicines may cause an unpleasant reaction if taken whilst you are being treated with Procarbazine 50mg Capsules or during the two weeks after the course of treatment is completed. The most important foods and drinks that might cause such an effect are:

Mature cheeses (including processed cheeses), yeast or meat extracts (such as Marmite, Oxo and Bovril), broad bean pods, pickled herring, salami sausage, pepperoni sausage, bologna sausage, overripe fruit, alcoholic drinks (especially heavy red wines such as Chianti), non-alcoholic beers, lagers and wines and other foods which are not fresh, particularly if they have been fermented, pickled, smoked, 'hung' or 'matured'.

These reactions are extremely rare and if you want to eat or drink anything on the list you could try a little at a time, until you are sure that it does not upset you. However, it is best to avoid alcohol altogether.

Pregnancy, breast-feeding and fertility

If you are pregnant, think you might be pregnant, are planning to become pregnant or are breast-feeding, you should tell your doctor.

Pregnancy

Procarbazine should not be taken during the first trimester of pregnancy. Its use should also be avoided throughout the remainder of the pregnancy period.

Breast-feeding

Do not take Procarbazine if you are breast-feeding.

Fertility

Procarbazine may cause infertility which might mean that you are not able to have children.

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

Driving and using machines

Procarbazine can cause drowsiness. If affected you should not drive or use machinery.

3. How to take Procarbazine 50mg Capsules

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Procarbazine is usually given in combination with other drugs and it is important that you (or your child) take each medicine at the right time. Sometimes treatment starts with a small dose (1 capsule per day) and is increased each day up to a maximum of six capsules per day.

If you take more Procarbazine 50mg Capsules than you should

If you swallow too many capsules or someone else accidentally takes your medicine, contact your doctor, pharmacist or nearest hospital straight away. Overdose can cause severe vomiting and feeling sick, dizziness, imagining sensations (hallucinations), depression, fits, low blood pressure and increased pulse rate.

If you forget to take Procarbazine 50mg Capsules

If you miss a dose, take it as soon as you remember unless your next dose is due within a couple of hours. In this case you should skip the missed dose, go back to your regular dosing schedule and check with your doctor. Do not take a double dose to make up for a forgotten capsule. The same applies if you forget to give a dose to your child at the right time.

After taking Procarbazine 50mg Capsules

Patients and carers should use gloves when handling urine or vomit produced for up to 48 hours after a dose of procarbazine has been taken.

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.

All medicines can cause allergic reactions although serious allergic reactions are very rare. Any sudden wheeziness, difficulty in breathing, swelling in any part of the body, rash or itching (especially affecting your whole body) should be reported to a doctor immediately.

Procarbazine may cause the following side effects:

- Infertility, which might mean that you are not able to have children
- Skin rash or any unusual bleeding or bruising. If you (or your child) develop these side effects, check with your doctor as soon as possible
- Nausea and vomiting. Do not stop taking procarbazine if it makes you (or your child) sick in the first few days, as this side effect should disappear. However if it is very bad, or if vomiting occurs shortly after taking a dose, check with the hospital or your own doctor who will tell you what to do. It may be possible to reduce this unpleasant effect
- Liver disorder. If you (or your child) develop signs of liver disorder which include persistent vomiting, feeling sick, feeling tired and yellowing of the

skin or the whites of the eyes (jaundice) you should stop treatment and contact your doctor immediately

- Loss of appetite, especially at the start of treatment. This usually improves after a few days
- Lowering of your white blood cell count. Common symptoms include infections, lack of energy, headache, fever and irritability
- Drowsiness and a lack of enthusiasm
- Inflammation of lung tissue. Symptoms include shortness of breath, cough, and a burning sensation in the chest.

Procarbazine in combination with other chemotherapy drugs has been associated with an increased occurrence of a rare cancer of the blood cells.

It is very important that you keep all hospital appointments whilst taking procarbazine so that your progress can be checked.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the internet at www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Procarbazine 50mg Capsules

Keep this medicine out of the sight and reach of children – preferably in a locked cupboard or medicine cabinet.

Do not use this medicine after the expiry date which is stated on the carton and blister. The expiry date refers to the last day of that month.

In order that Procarbazine 50mg Capsules are always clearly identified they should not be removed from their blister packaging until you are ready to take them. Do not mix loose Procarbazine 50mg Capsules with other loose capsules or tablets. Store in the original container in order to protect from moisture. Do not store above 25°C.

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 Procarbazine 50mg Capsules contain

The active substance is procarbazine hydrochloride. There is 50mg of procarbazine in each capsule. The other ingredients are mannitol, maize starch, talc and magnesium stearate. The capsule shells are made from gelatin, and also titanium dioxide (E171), shellac, propylene glycol, ammonium hydroxide and black iron oxide (E172).

What Procarbazine 50mg Capsules look like and contents of pack

Procarbazine 50mg Capsules are white, with 'CL50' on one half. They are produced in blister strips, each pack contains 50 capsules.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder: Alliance Pharmaceuticals Limited, Avonbridge House, Bath Road, Chippenham, Wiltshire, SN15 2BB, UK.

Manufacturer: EirGen Pharma Ltd., Westside Business Park, Old Kilmeaden Road, Waterford, Ireland.

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