

Clozaril[®]
(clozapine)
—connect—



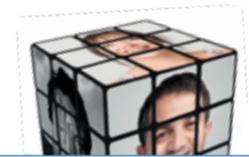
What to expect from Clozaril[®]

Only for patients who have
been prescribed Clozaril[®]

Always refer to the patient information
leaflet for detailed information



VIATRIS



Contents

This booklet is intended only for patients who have been prescribed Clozaril[®] and/or their family/carers. Further information can be found on the Patient information Leaflet available at www.medicines.org.uk/emc/product/4411/pil

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Clozaril[®]

What is Clozaril[®] and who is it for?

Clozaril[®] is an antipsychotic drug used in the treatment of people with schizophrenia. It is specifically used to treat treatment resistant schizophrenia (TRS), which affects approximately 1 in 3 people with the condition.

These people include those who:

- ◆ Have tried at least two other antipsychotic medications that did not work very well including an atypical antipsychotic
- ◆ Are unable to tolerate other antipsychotics because of their side-effects

Clozaril[®] is the brand name of the drug, the active ingredient is called clozapine.

Clozaril[®] is also used to treat psychotic disorders occurring during the course of Parkinson's disease, where standard treatment has failed.

How does Clozaril[®] work?

People with schizophrenia have too much chemical activity in their brain. Clozapine interacts with receptors in the brain to decrease the chemical activity.

Parkinson's disease medication can cause increased activity of brain receptors, which may lead to thought disturbances. Clozapine helps by lowering the activity of these receptors.

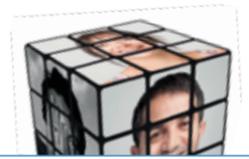
How many people have taken Clozaril[®]?

To date, more than 60,000 people in the UK have taken Clozaril[®]

Clozapine can be a very effective treatment but is not used for all people with schizophrenia because it can sometimes reduce the number of white blood cells in your body. It specifically affects a type of white blood cell called a neutrophil. Neutrophils play a major role in helping your body fight infections.

A small fall in neutrophil levels leads to a condition called neutropenia, while a big fall is called agranulocytosis. Having fewer neutrophils can increase your risk of getting infections.





Blood Monitoring

Regular blood tests are important to check the number of white blood cells you have. A drop in your level may not cause symptoms until an infection develops. Having your levels checked regularly means changes can be spotted quickly. You will not be allowed to take Clozaril[®] unless you have a recent blood result.

Why do you monitor white blood cell levels?

Very few people taking Clozaril[®] experience a significant drop in their neutrophil (a type of white blood cell) level.

- ◆ Approximately 3% of patients taking Clozaril[®] will experience a small fall in their neutrophil level: this is called neutropenia.
- ◆ Less than 1% of patients taking Clozaril[®] will experience a large fall in their neutrophil level: this is called agranulocytosis.

However, if agranulocytosis or neutropenia occur, it is usually within the first 18 weeks of treatment with Clozaril[®].

It is not possible to predict who will develop the condition so everyone treated with Clozaril[®] must be monitored for as long as they take the drug. Monitoring consists of regular blood tests to measure the number of white cells in the blood. Anyone who develops agranulocytosis or neutropenia while receiving clozapine should not be given clozapine again.

How often will I need to have blood tests?

Before you take Clozaril[®] you will need to have a blood test to check you have a 'normal' level of white blood cells. If this is okay and you start taking Clozaril[®], you will need to have a blood test every week for 18 weeks. If everything is okay, testing can change to once a fortnight.

After you have been on treatment for a year, blood tests should only be needed once every four weeks for as long as you take Clozaril[®]. If you stop taking Clozaril[®] either permanently or for a short while, you will still need to have blood tests for some time afterwards to check your white blood cell level is okay.

How much blood is needed for testing?

Only about 2-3 mL of your blood is required for a blood test. Taking such a small amount has no effect on your body.

Who organises the blood monitoring?

Routine blood monitoring will be organised by your treatment team.

What happens to my blood sample?

Most samples are sent to a central laboratory and some may be analysed on site in the clinic. Once it has been checked and your white blood cells have been counted, the sample is graded using a 'traffic light' system:

Red results
(red alerts)

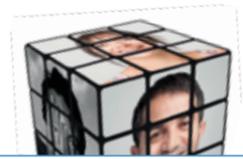
Amber
results

Green
results

This means you have a low number of white blood cells. The blood monitoring advisors and pharmacists will contact your doctor straight away. Your treatment team will arrange a blood test straight away to confirm the result of the first test. Your treatment will be stopped immediately until the result is available. If the number of white cells in your blood is confirmed to be low, you will not be able to have clozapine again. Your treatment team will monitor you closely until your white cell count returns to normal.

Your level is within the normal range, but they need to keep a check on it. You can keep taking your tablets, but will need another blood test fairly soon to make sure everything is okay.

Normal blood test – you can continue to receive treatment.



How else can regular blood testing help me?

The most important reason for regular blood testing is to check your white blood cell level. However, regular testing also means you will have regular contact with your treatment team, which gives you a chance to:

- ◆ Check your progress and ask any questions
- ◆ Discuss side-effects and ways to cope with them
- ◆ Have an on-going health check
- ◆ Introduce your family or carers to the team
- ◆ Get referred to other teams if necessary

What happens if I miss a blood test?

There is one very important rule with Clozaril[®] – no blood result, no drug treatment. If you miss a blood test, please notify your treatment team as soon as possible so they can arrange for you to have the test. It is important to have regular blood tests. Your white blood cell level must always be checked before your doctor gives you Clozaril[®].



Taking Clozaril[®]

Before starting Clozaril[®]

Before you start Clozaril[®] your doctor will:

- ◆ Ask you questions about your general health
- ◆ Carry out a physical examination
- ◆ Take a blood sample to check your white blood cell level is normal

Your doctor might want you to have a trace recording of your heart (an electrocardiogram or ECG) before you start Clozaril[®]. Some patients taking Clozaril[®] have had side-effects relating to their heart.

You should tell your doctor about any medical problems or illness you have or had in the past, e.g., history of low white blood cell counts; heart, liver or kidney problems; seizures or fits.

As with all medication, Clozaril[®] may interact with other drugs. It is important that you tell your doctor about any other medications you are taking, including any you have bought (this includes herbal preparations).

Starting Clozaril[®]

Clozaril[®] can be started in a hospital, out-patients clinic, day hospital or sometimes while you are at home. During this starting period, a combination of hospital and home care may be possible.

For your first few weeks of treatment with Clozaril[®], you will have safety checks, which may include:

- ◆ Pulse
- ◆ Blood pressure
- ◆ Temperature

To help reduce the risk of side-effects, your doctor will start you on a low dose. It will be increased slowly so they can check how you react. The aim is to find the lowest effective dose for you: the dose that has the best effect with the least side-effects.

If you are a smoker, you should discuss this with your doctor, along with options for giving up. Stopping smoking can result in high levels of Clozaril[®] in your blood, which could lead to side-effects.



How do I take Clozaril[®]?

Clozaril[®] is available in 2 strengths, 25 mg and 100 mg tablets.

Your doctor will probably start you on 12.5 mg (half a 25 mg tablet) taken once or twice on the first day. The dose can then slowly be increased. The tablets should be taken with water. You can take Clozaril[®] with food if necessary.

Finding the right dose

You will be monitored after you have had your first dose of Clozaril[®]. You may feel a bit drowsy, your blood pressure may go down or your heart rate may go up. As you get used to the medication, the dose can slowly be increased by 25 to 50 mg each day until you reach a level that is right for you.

Most patients take between 200 mg and 450 mg of Clozaril[®] a day, although some may need more. Usually the dose is divided into 2 doses.

The dose is increased more slowly for patients who are older or who have other health problems, e.g., epilepsy, or any heart problems.

How long will it take before Clozaril[®] begins to work?

Some people feel the benefit of Clozaril[®] within a few days, others don't feel the full benefit for a few months or even a year.

Clozaril[®] should be taken for at least 6 months to give it a chance to work (unless you develop a side-effect that means you have to stop taking it).



How will I know that Clozaril[®] is working?

Your relatives, friends or carers may notice the change before you do

Eventually, you may experience some, or all, of the following:

- ◆ You feel better, becoming less withdrawn and more involved in life around you
- ◆ Some of your symptoms ease and your ability to concentrate improves
- ◆ Your relationships improve and you find it easier to mix with people
- ◆ You may feel less aggressive and more able to control your anger
- ◆ If you are in hospital you may become well enough to go home
- ◆ If you are unemployed you can get and hold onto a job or you are able to sign up for a course and start studying

If you feel well enough to go home from hospital, arrangements for your care and blood tests will be put in place before you go home. Your treatment team will be in close contact with you.

How long should I take Clozaril[®] for?

Clozaril[®] is a long-term treatment. It should be taken every day as prescribed, for as long as you benefit from taking it.

It is important to keep taking the treatment even if your symptoms improve or completely disappear. If you stop taking Clozaril[®], your symptoms could come back.

Do not stop taking Clozaril[®] without discussing it with your doctor.

If your doctor feels you are ready to stop taking Clozaril[®] (for reasons other than side-effects), they will slowly decrease the dose of Clozaril[®] until eventually you will be able to stop taking it completely. If you stop your Clozaril[®] suddenly, your symptoms may return and you may feel unwell. If your doctor decides you should stop taking Clozaril[®], return any remaining medication to your pharmacist.

What should I do if I miss a dose?

Clozaril[®] should be taken regularly, every day. If you forget to take a dose, take one as soon as you remember. However, if it is nearly time for your next dose, leave out the forgotten tablets and take your next dose at the right time.

Do not try to make up for the missed dose by taking extra tablets.



What should I do if I miss more than one dose?

If you miss more than one dose, contact your nurse or doctor.

What should I do if I take too much Clozaril[®]?

If you think you have taken too much Clozaril[®], contact your nurse or your doctor immediately. If you cannot contact them, go to your nearest casualty department.

Starting Clozaril[®] in Parkinson's disease

Clozaril[®] is also used to treat severe disturbances in the thoughts, emotions and behaviour of people with Parkinson's disease in whom other medicines have not worked. People with Parkinson's disease need a much lower dose of Clozaril[®] than people with treatment resistant schizophrenia.

The first dose of Clozaril[®] will be no more than 12.5 mg (half a 25 mg tablet) taken at night. The dose can then be increased in 12.5 mg increments, with a maximum of two increases in a week. The dose can be increased until you reach the best dose for you. The dose is usually given all in one go at night. The usual dose for people with Parkinson's disease is 25-37.5 mg each day. The maximum dose is 100 mg each day.

If you have Parkinson's disease, you may be more likely to have low blood pressure, so your blood pressure will be taken regularly during the first weeks of treatment.



Side-effects

All drugs, including Clozaril[®], can cause side-effects. Many are dose-related – the higher the dose you take, the more chance you could get them. Your dose of Clozaril[®] is increased very slowly to reduce the risk of any dose-related side-effects. Taking the lowest dose that works for you also lowers the chance of any side-effects.

Some common side-effects that you may notice include:

- ◆ Severe constipation (Your doctor will have to treat this in order to avoid further complications)
- ◆ Fast heart beat
- ◆ Signs of a cold, fever, flu-like symptoms, sore throat or any other infection
- ◆ Seizures
- ◆ Sudden fainting or sudden loss of consciousness with muscle weakness (syncope)
- ◆ Drowsiness
- ◆ Dizziness
- ◆ Increased production of saliva
- ◆ High level of white blood cells (leukocytosis)
- ◆ High level of a specific type of white blood cell (eosinophilia)
- ◆ Weight gain
- ◆ Blurred vision
- ◆ Headache
- ◆ Trembling
- ◆ Stiffness
- ◆ Restlessness
- ◆ Convulsions
- ◆ Jerks, abnormal movements, inability to initiate movement, inability to remain motionless
- ◆ Changes in ECG heart machine
- ◆ High blood pressure
- ◆ Faintness or light-headedness after changing position
- ◆ Nausea (feeling sick)
- ◆ Vomiting (being sick)
- ◆ Loss of appetite
- ◆ Dry mouth
- ◆ Minor abnormalities in liver function tests
- ◆ Loss of bladder control, difficulty in passing urine
- ◆ Tiredness
- ◆ Fever
- ◆ Increased sweating, raised body temperature
- ◆ Speech disorders (e.g. slurred speech)

Not everyone will get side-effects and those people that do may only have a few. The side-effects often get less or even disappear over time.

Many side-effects can be reduced or controlled, generally by taking another medicine to treat them. tell your doctor straight away if you experience side-effects so they can help you manage them quickly and in the best way possible.



General Information

Temperatures or infections

If you think you have a cold, sore throat, fever, flu-like symptoms or any other infection, tell your doctor or nurse immediately. They will arrange a blood test to check the number of white blood cells in your blood. If there is a normal amount you should be able to continue with your treatment, but your doctor will explain this to you.

Can I take other drugs whilst I am taking Clozaril[®]?

Some medicines can affect your Clozaril[®] treatment. It is important that you check with your doctor or pharmacist before taking other medicines, even if they are herbal remedies or medicines you bought at a chemist. Recreational drugs such as cannabis and ecstasy can trigger psychotic episodes and should be avoided. If you have a drug dependency you can talk to your treatment team in confidence.

What about... alcohol?

Drinking alcohol while you are on Clozaril[®] therapy can make you feel very drowsy. People taking Clozaril[®] therapy should not drink alcohol. Ask your doctor or nurse for further advice.

What about... smoking?

Changing your smoking habits can affect the amount of Clozaril[®] in your blood. Consult your treatment team should you decide to change your smoking habit.

What about... caffeine?

Changing the amount of caffeine you drink (in things such as tea, coffee or cola) can affect the amount of Clozaril[®] in your blood. Mention any changes in your drinking habits to your treatment team.

Electro-convulsive therapy (ECT)

If you need to have ECT make sure the doctors giving you the ECT know you are taking Clozaril[®].

Contraception

Some antipsychotic medicines affect hormones involved in the menstrual cycle, but this does not happen very often with Clozaril[®]. Women who have switched to Clozaril[®] from other treatments may find their periods return to normal, resulting in the possibility of becoming pregnant. As a result they should discuss contraception issues with their doctor.

Pregnancy and breastfeeding

It is not known whether Clozaril[®] is safe to take during pregnancy. If you think you are pregnant, tell your doctor immediately. Also tell your doctor if you are trying (or thinking of trying) for a baby. Clozaril[®] can be passed from a mother to her baby through breast milk, so mothers taking Clozaril[®] should not breastfeed.

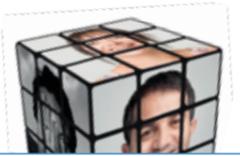
General anaesthetics

If you ever need a general anaesthetic, it is important that you tell your anaesthetist (the doctor who puts you to sleep) you are taking Clozaril[®] as it can interact with some anaesthetic medication.

Driving and using machines

Feeling sleepy is a common side-effect of Clozaril[®], particularly when Clozaril[®] is first started. Driving or operating machinery should be avoided, especially during the initial weeks of Clozaril[®] treatment.





Measuring the amount of Clozaril[®] in your blood

From time to time your doctor may wish to check the level of Clozaril[®] in your blood. This is usually to find out if you are on the right dose, particularly if your symptoms are hard to control or if you developed side-effects whilst taking Clozaril[®]

Your doctor or nurse will take a small amount of blood from you and it will be sent to a laboratory specialising in measuring the amount of Clozaril[®] in blood. The results will be sent back to your doctor and they will decide if your dose of Clozaril[®] is okay or if it needs to be increased or decreased.

I have a lower number of white cells in my blood because of my race. Can I take Clozaril[®]?

Some people, generally people of African or Afro-Caribbean background, have a lower number of white cells in their blood than white people. This is normal for them and they are not at greater risk of developing infections than anyone else. Although they have a lower number of white cells in their blood they may be still able to take Clozaril[®].



Useful Information

What if I want to go away on holiday?

When you are on weekly monitoring it is best to avoid holidays that take you out of your area. If you are on fortnightly monitoring you can go away for two weeks or for four weeks if you are on four-weekly monitoring without requiring a blood test while you are away. Before you go on holiday, make sure you let your treatment team know when and where you are going. They can make any necessary arrangements.

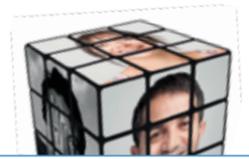
If you want to go away for a period of time that means you will miss a blood monitoring appointment, then special arrangements need to be made. Tell your doctor or nurse so that they can make these arrangements. It is also important that you and anyone travelling with you knows what to do if you develop signs of an infection. If you think you have an infection while you are away, you should contact your doctor or nurse immediately. If you cannot contact them, go to the nearest casualty department. The Clozaril[®] Patient Monitoring Service now have a letter available for a patient to provide to an doctor to explain the medication you are taking. This letter is available in 11 different languages. Please ask your treatment team to obtain a copy of this letter in the language relevant to the country you are planning on holidaying in.

What happens on bank holidays?

When a bank holiday interrupts your normal blood monitoring day, your doctor will make arrangements for a blood sample to be collected the day before or after the holiday. If the bank holiday is longer than a day, special arrangements will be made to collect and send your sample to the laboratory. If there is no recent blood result available, you cannot be given your Clozaril[®].

Who makes Clozaril[®]?

Clozaril[®] is made by Viatrix. The Clozaril[®] Patient Monitoring Service is run by Viatrix.



Useful Contacts

Your doctor, nurse or pharmacist will be able to answer further questions about your illness and the treatments, including Clozaril[®]. They will also be able to discuss any questions you may have about the information in this booklet.

A number of charities and support organisations are able to provide further information, help and advice. They include:

Rethink

Offer support through a wide range of services in order to improve the quality of life of people affected by severe mental illness.

t: 0300 5000 927 or 0121 522 7007
w: www.rethink.org
e: info@rethink.org

Hafal

Providing support across Wales.

t: 01792 816 600/832 400
w: www.hafal.org
e: hafal@hafal.org

Support in Mind Scotland (NSF Scotland)

Provides help for people affected by mental illness through support and information groups, telephone and written advice and other services.

t: 0131 662 4359
w: www.supportinmindscotland.org.uk
e: info@supportinmindscotland.org.uk

SANE

Established to improve the quality of life for people affected by mental illness SANE aims to raise awareness and respect, to undertake research and to provide help and information to those suffering from mental health problems, their families and carers.

t: 020 3805 1790
w: www.sane.org.uk
e: info@sane.org.uk

MIND

Literature and phone-line support for people in mental distress and their families. Advice, campaigns, local services, legal advice.

180 local Mind associations in England and Wales.

Mind Infoline: 0300 123 3393
Text: www.hafal.org
w: www.mind.org.uk
e: info@mind.org.uk

Making Space

Organisation providing information and services to improve the long term welfare of people with mental health problems and their carers.

t: 01925 571 680
w: www.makingspace.co.uk
e: enquiries@makingspace.co.uk

CARERS UK

t: 020 7378 4999
w: www.carersuk.org
e: info@carersuk.org
Carers UK's helpline: 0808 808 7777 (Monday to Wednesday, 9am-6pm)
e: advice@carersuk.org



Samaritans

t: 116 123
w: www.samaritans.org
e: admin@samaritans.org

Parkinsons UK

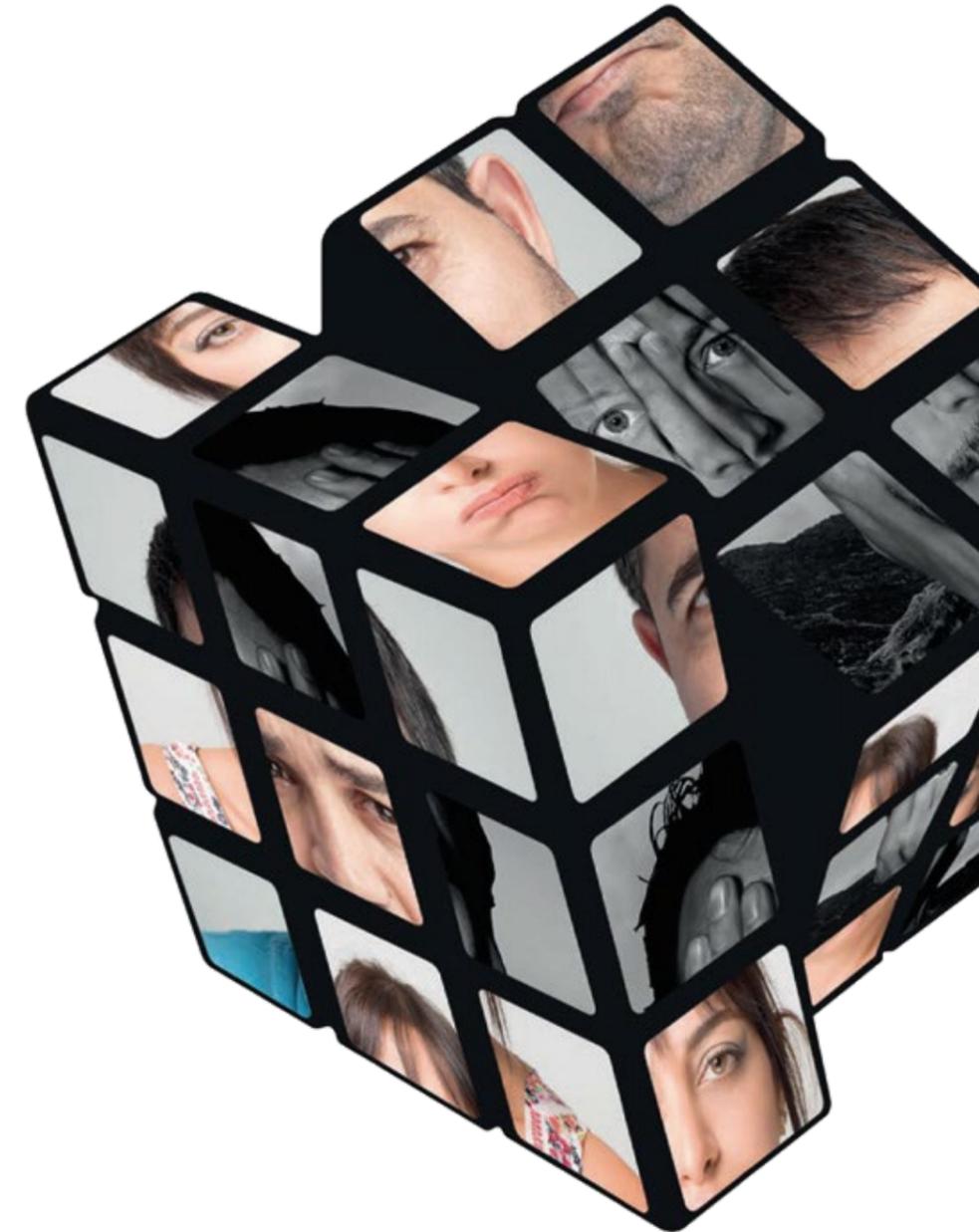
Organisation providing information and support for people with Parkinson's Disease, their friends, relatives and carers.

Helpline: 0808 800 0303
w: www.parkinsons.org.uk
e: hello@parkinsons.org.uk

Royal College of Psychiatrists (RC PSYCH)

This is an organisation for Psychiatrists, however it also has a wide range of mental health information leaflets. These are free to access and are in sometimes provided in foreign languages.

t: 020 7235 2351
w: www.rcpsych.ac.uk



Reporting of side effects:

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet. Please report side effects with any medicine or vaccine to the medicines regulator MHRA through the Yellow Card Scheme.

It is easiest and quickest to report side effects online via the Yellow Card website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

Alternatively, prepaid Yellow Cards for reporting are available by writing to FREEPOST YELLOW CARD (no other address details necessary), by emailing yellowcard@mhra.gov.uk, by telephoning the Commission on Human Medicines (CHM) free phone line: 0800-731-6789, or by downloading and printing a form from the Yellow Card section of the MHRA website. You can also report side effects direct to the marketing authorisation holder at cpms@viatris.com