Package leaflet: Information for the user

Clozapine Holsten 25 mg tablets
Clozapine Holsten 100 mg tablets

clozapine

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 [Nationally approved name] is and what it is used for

The active ingredient of [Nationally approved name] is clozapine which belongs to a group of medicines called antipsychotics (medicines that are used to treat specific mental disorders such as psychosis).

[Nationally approved name] is used to treat people with schizophrenia in whom other medicines have not worked.
Schizophrenia is a mental illness which affects how you think, feel and behave. You should only use this medicine if you have already tried at least two other antipsychotic medicines, including one of the newer atypical antipsychotics, to treat schizophrenia, and these medicines did not work, or caused severe side effects that cannot be treated.

[Nationally approved name] 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.

2. What you need to know before you take [Nationally approved name]

Do not take [Nationally approved name]

- If you are allergic to clozapine or any of the other ingredients of this medicine (listed in section 6).
- If you are not able to have regular blood tests

- If you have ever been told you have a low white blood cell count (e.g. leucopenia or agranulocytosis), especially if this was caused by medicines. This does not apply if you have had low white blood cell count caused by previous chemotherapy.
- If you had to stop using [Nationally approved name] previously because of severe side effects (e.g. agranulocytosis or heart problems).
- If you are being or have been treated with long-acting depot injections of antipsychotics.
- If you suffer from bone marrow disease or have ever suffered from bone marrow disease.
- If you suffer from uncontrolled epilepsy (seizures or fits).
- If you have an acute mental illness caused by alcohol or drugs (e.g. narcotics).
- If you suffer from reduced consciousness and severe drowsiness.
- If you suffer from circulatory collapse which may occur as a result of severe shock.
- If you suffer from any severe kidney disease.
- If you suffer from myocarditis (an inflammation of the heart muscle).
- If you suffer from any other severe heart disease.
- If you have symptoms of active liver disease such as jaundice (yellow colouring of the skin and eyes, feeling sick and loss of appetite).
- If you suffer from any other severe liver disease.
- If you suffer from paralytic ileus (your bowel does not work properly and you have severe constipation).
- If you use any medicine that stops your bone marrow from working properly.
- If you use any medicine that reduces the number of white cells in your blood.

If any of the above applies to you, tell your doctor or pharmacist and do not take [Nationally approved name].

[Nationally approved name] must not be given to anyone who is unconscious or in a coma.

Warnings and Precautions

The safety measures mentioned in this section are very important. You must comply with them to minimise the risk of serious life-threatening side effects.

Before you start treatment with [Nationally approved name], tell your doctor if you suffer from or have ever suffered from:

- blood clots or family history of blood clots, as medicines like these have been associated with formation of blood clots.
- glaucoma (increased pressure in the eye).
- diabetes. Elevated (sometimes considerably) blood sugar levels, has occurred in patients with or without diabetes mellitus in their medical history (see section 4).
- prostate problems or difficulty in urinating.
- any heart, kidney or liver disease.
- chronic constipation or if you are taking medicines which cause constipation (such as anticholinergics).
- galactose intolerance, total lactase deficiency or glucose-galactose malabsorption.
- controlled epilepsy.
- large intestine diseases.
- tell your doctor if you have ever had abdominal surgery.
- if you have had a heart disease or family history of abnormal conduction in the heart called “prolongation of the QT interval”.

- if you are at risk for having a stroke, for example if you have high blood pressure, cardiovascular problems or blood vessel problems in the brain.
- if you have ever developed a severe **skin rash** or **skin peeling**, **blistering** and/or **mouth sores** after taking [Nationally approved product name].
  This medicine can cause serious skin reactions. Stop using clozapine and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions

Tell your doctor immediately before taking the next [Nationally approved name] tablet:

- if you get signs of a **cold, fever, flu-like symptoms, sore throat or any other infection**. You will have to have an urgent blood test to check if your symptoms are related to your medicine.
- if you have a sudden rapid increase in body temperature, rigid muscles which may lead to unconsciousness (neuroleptic malignant syndrome) as you may be experiencing a serious side effect which requires immediate treatment.
- if you have **fast and irregular heart beat**, even when you are at rest, **palpitations, breathing problems, chest pain** or **unexplained tiredness**. Your doctor will need to check your heart and if necessary refer you to a cardiologist immediately.
- if you experience **nausea (feeling sick), vomiting (being sick)** and/or **loss of appetite**. Your doctor will need to check your liver.
- if you have **severe constipation**. Your doctor will have to treat this in order to avoid further complications.
- experience **constipation, abdominal pain, abdominal tenderness, fever, bloating** and/or **bloody diarrhoea**. Your doctor will need to examine you.
- if you develop signs and symptoms of **appendicitis**; these may include intense and worsening abdominal pain that begins near the navel and moves to the lower right side, made worse by movement, coughing or pressing the area. Other signs can include constipation, abdominal swelling malaise, mild fever, vomiting, loss of appetite or diarrhea. You will need an urgent medical examination by your doctor.

Medical check-ups and blood tests
Before you start taking this medicine, your doctor will ask about your medical history and do a blood test to ensure that your white blood cells count is normal. It is important to find this out, as your body needs white blood cells to fight infections.

Make sure that you have regular blood tests before you start treatment, during treatment and after you stop treatment with [Nationally approved name].
- Your doctor will tell you exactly when and where to have the tests. [Nationally approved name] may only be taken if you have a normal blood count.
- This medicine can cause a serious decrease in the number of white cells in your blood (agranulocytosis). Only regular blood tests can tell the doctor if you are at risk of developing agranulocytosis (see section 4).
- During the first 18 weeks of treatment, tests are needed once a week. Afterwards, tests are needed at least once a month for the following 34 weeks.
- After 12 months of treatment, blood tests must be performed every 12 weeks for a year, and then yearly, if decrease in the number of white cells in your blood is not detected.
- If there is a decrease in the number of white blood cells, you will have to stop clozapine treatment immediately. Your white blood cells should then return to normal.
- You will need to have blood tests for another 4 weeks after the end of clozapine treatment in case of complete discontinuation caused by haematological reasons (i.e. agranulocytosis) or in case of duration of monitoring < 2 years and/or in presence of history of neutropenia that had not led to treatment interruption.

Your doctor will also do a physical examination before starting treatment. Your doctor may do an electrocardiogram (ECG) to check your heart, but only if this is necessary for you, or if you have any special concerns.
If you have a liver disorder you will have regular liver function tests as long as you continue to take this medicine.
If you suffer from high levels of sugar in the blood (diabetes) your doctor may regularly check your level of sugar in the blood.
This medicine may cause alteration in blood lipids. This medicine may cause weight gain. Your doctor may monitor your weight and blood lipid level.

If this medicine makes you feel light-headed, dizzy or faint, be careful when getting up from a sitting or lying position as this may increase the possibility of falling.

If you have to undergo surgery or if for some reason you are unable to walk around for a long time, discuss with your doctor the fact that you are taking this medicine. You may be at risk of thrombosis (blood clotting within a vein).

Children and adolescents under 16 years
If you are under 16 years of age you should not use [Nationally approved name] as there is not enough information on its use in that age group.

Older people (aged 60 years and over)
Older people (aged 60 years and over) may be more likely to have the following side effects during treatment with this medicine: faintness or light-headedness after changing position, dizziness, fast heart beat, difficulty in passing urine, and constipation.

Tell your doctor or pharmacist if you suffer from a condition called dementia.

Other medicines and [Nationally approved name]
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription or herbal therapies. You might need to take different amounts of your medicines or to take different medicines.

Do not take [Nationally approved name] together with medicines that stop the bone marrow from working properly and/or decrease the number of blood cells produced by the body, such as:
- carbamazepine, a medicine used in epilepsy.
- certain antibiotics: chloramphenicol, sulphonamides such as co-trimoxazole.
- certain painkillers: pyrazolone analgesics such as phenylbutazone.
- penicillamine, a medicine used to treat rheumatic joint inflammation.
- cytoxic agents, medicines used in chemotherapy.
- long-acting depot injections of antipsychotic medicines.

These medicines increase your risk of developing agranulocytosis (lack of white blood cells).

Taking [Nationally approved name] at the same time as another medicine may affect how well [Nationally approved name] and/or the other medicine works. Tell your doctor if you plan to take, if you are taking (even if the course of treatment is about to end) or if you have recently had to stop taking any of the following medicines:
- medicines used to treat depression such as lithium, fluvoxamine, tricyclic antidepressants, MAO inhibitors, citalopram, paroxetine, fluoxetine, and sertraline.
- other antipsychotic medicines used to treat mental illnesses such as perazine.
- benzodiazepines and other medicines used to treat anxiety or sleep disturbances.

- narcotics and other medicines which can affect your breathing.
- medicines used to control epilepsy such as phenytoin and valproic acid.
- medicines used to treat high or low blood pressure such as adrenaline and noradrenaline.
- warfarin, a medicine used to prevent blood clots.
- antihistamines, medicines used for colds or allergies such as hay fever.
- anticholinergic medicines, which are used to relieve stomach cramps, spasms and travel sickness.
- medicines used to treat Parkinson's disease.
- digoxin, a medicine used to treat heart problems.
- medicines used to treat a fast or irregular heart beat.
- some medicines used to treat stomach ulcers, such as omeprazole or cimetidine.
- some antibiotic medicines, such as erythromycin and rifampicin.
- some medicines used to treat fungal infections (such as ketoconazole) or viral infections (such as protease inhibitors, used to treat HIV infections).
- atropine, a medicine which may be used in some eye drops or cough and cold preparations.
- adrenaline, a medicine used in emergency situations.
- hormonal contraceptives (birth-control tablets).

This list is not complete. Your doctor and pharmacist have more information on medicines to be careful with or to avoid while taking [Nationally approved name]. They will also know if the medicines you are taking belong to the listed groups. Speak to them.

[Nationally approved name] with food, drink and alcohol
Do not drink alcohol during treatment with this medicine.
Tell your doctor if you smoke and how often you have drinks containing caffeine (coffee, tea, cola). Sudden changes in your smoking habits or caffeine drinking habits can also change the effects of this medicine.

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. Your doctor will discuss with you the benefits and possible risks of using this medicine during pregnancy. Tell your doctor or pharmacist immediately if you become pregnant during treatment with [Nationally approved name].

The following symptoms may occur in newborn babies, of mothers that have used clozapine in the last trimester (last three months of their pregnancy): shaking, muscle stiffness and/or weakness, sleepiness, agitation, breathing problems, and difficulty in feeding. If your baby develops any of these symptoms you may need to contact your doctor.

Some women taking some medicines to treat mental illness have irregular or no periods. If you have been affected in this way, your periods may return when your medicine is changed to [Nationally approved name]. This means you should use effective contraception.

Do not breast-feed during treatment with this medicine. Clozapine, the active substance of [Nationally approved name], may pass into your milk and affect your baby.

Driving and using machines
This medicine might cause tiredness, drowsiness and seizures, especially at the beginning of treatment. You should not drive or operate machines while you have these symptoms.

[Nationally approved name] contains lactose
[Nationally approved name] contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take [Nationally approved name]

In order to minimise the risk of low blood pressure, seizures and drowsiness it is necessary that your doctor increases your dose gradually. Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

It is important that you do not change your dose or stop taking this medicine without asking your doctor first. Continue taking the tablets for as long as your doctor tells you. If you are 60 years or older, your doctor may start you on a lower dose and increase it more gradually because you might be more likely to develop some unwanted side effects (see section 2 “Before you take [Nationally approved name]”).

If the dose you are prescribed cannot be achieved with this strength tablet, other strengths of this medicinal product are available to achieve the dose.

The tablet can be divided into equal doses.

Treatment of schizophrenia
The usual starting dose is 12.5 mg (one half of a 25 mg tablet) once or twice on the first day followed by 25 mg once or twice on the second day. Swallow the tablet with water. If tolerated well, your doctor will then gradually increase the dose in steps of 25-50 mg over the next 2-3 weeks until a dose up to 300 mg per day is reached. Thereafter, if necessary, the daily dose may be increased in steps of 50 to 100 mg half-weekly or, preferably, at weekly intervals.

The effective daily dose is usually between 200 mg and 450 mg, divided into several single doses per day. Some people might need more. A daily dose of up to 900 mg is allowed. Increased side effects (in particular seizures) are possible at daily doses over 450 mg. Always take the lowest effective dose for you. Most people take part of their dose in the morning and part in the evening. Your doctor will tell you exactly how to divide your daily dose. If your daily dose is only 200 mg, then you can take this as a single dose in the evening. Once you have been taking [Nationally approved name] with successful results for some time, your doctor may try you on a lower dose. You will need to take this medicine for at least 6 months.

Treatment of severe thought disturbances in patients with Parkinson’s disease
The usual starting dose is 12.5 mg (one half of a 25 mg tablet) in the evening. Swallow the tablet with water. Your doctor will then gradually increase the dose in steps of 12.5 mg, not faster than two steps a week, up to a maximum dose of 50 mg by the end of the second week. Increases in the dosage should be stopped or postponed if you feel faint, light-headed or confused. In order to avoid such symptoms your blood pressure will be measured during the first weeks of treatment.

The effective daily dose is usually between 25 mg and 37.5 mg, taken as one dose in the evening. Doses of 50 mg per day should only be exceeded in exceptional cases. The maximum daily dose is 100 mg.
Always take the lowest effective dose for you.

If you take more [Nationally approved name] than you should
If you think that you may have taken too many tablets, or if anyone else takes any of your tablets, contact a doctor immediately or call for emergency medical help.

The symptoms of overdose are:

Drowsiness, tiredness, lack of energy, unconsciousness, coma, confusion, hallucinations, agitation, incoherent speech, stiff limbs, trembling hands, seizures (fits), increased production of saliva, widening of the black part of the eye, blurred vision, low blood pressure, collapse, fast or irregular heart beat, shallow or difficult breathing.

If you forget to take [Nationally approved name]
If you forget to take a dose, take it as soon as you remember. If it is almost time for your next dose, leave out the forgotten tablets and take the next dose at the right time. Do not take a double dose to make up for a forgotten dose. Contact your doctor as soon as possible if you have not taken any [Nationally approved name] for more than 48 hours.

If you stop taking [Nationally approved name]
Do not stop taking [Nationally approved name] without asking your doctor, because you might get withdrawal reactions. These reactions include sweating, headache, nausea (feeling sick), vomiting (being sick) and diarrhoea. **If you have any of the above signs, tell your doctor straight away. These signs may be followed by more serious side effects unless you are treated immediately.** Your original symptoms might come back. A gradual reduction in dose in steps of 12.5 mg over one to two weeks is recommended, if you have to stop treatment. Your doctor will advise you on how to reduce your daily dose. If you have to stop [Nationally approved name] treatment suddenly, your will have to be checked by your doctor.
If your doctor decides to re-start the treatment with this medicine and your last dose of [Nationally approved name] was over two days ago, this will be with the starting dose of 12.5 mg.

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.

Some side effects can be serious and need immediate medical attention:
Tell your doctor immediately before taking the next [Nationally approved name] tablet if you experience any of the following:

Very common *(may affect more than 1 in 10 people)***:**
- if you have **severe constipation**. Your doctor will have to treat this in order to avoid further complications.
- fast heart beat.

Common *(may affect up to 1 in 10 people):*
- if you get signs of a **cold, fever, flu-like symptoms, sore throat or any other infection**. You will have to have an urgent blood test to check if your symptoms are related to your medicine.
- if you experience seizures.
- sudden fainting or sudden loss of consciousness with muscle weakness (syncope).

Uncommon (may affect up to 1 in 100 people):
- if you have a sudden rapid increase in body temperature, rigid muscles which may lead to unconsciousness (neuroleptic malignant syndrome) as you may be experiencing a serious side effect which requires immediate treatment.
- light-headedness, dizzyness or fainting, when getting up from a sitting or lying position as it may increase the possibility of falling.

Rare *(may affect up to 1 in 1,000 people):*

- if you get signs of a respiratory tract infection or pneumonia such as fever, coughing, difficulty breathing, wheezing.
- severe, burning, upper abdominal pain extending to the back accompanied by nausea and vomiting due to inflammation of the pancreas.
- fainting and muscle weakness due to a significant drop in blood pressure (circulatory collapse).
- difficulty in swallowing (which may cause inhalation of food).
- if you experience **nausea (feeling sick), vomiting (being sick)** and/or **loss of appetite**. Your doctor will need to check your liver.
- signs of becoming obese or increasing obesity.
- interruption in breathing with or without snoring during sleep.

Rare (*may affect up to 1 in 1,000 people)* or **very rare** *(may affect up to 1 in 10,000 people)*:
- if you have **fast and irregular heart beat**, even when you are at rest, **palpitations, breathing problems, chest pain** or **unexplained tiredness**. Your doctor will need to check your heart and if necessary refer you to a cardiologist immediately.

Very rare *(may affect up to 1 in 10,000 people):*
- if you are a man and experience persistent painful erection of the penis. This is called priapism. If you have an erection which lasts more than 4 hours immediate medical treatment may be needed in order to avoid further complications.
- spontaneous bleeding or bruising, which might be signs of a decrease in numbers of blood platelets.
- symptoms due to uncontrolled blood sugar (such as nausea or vomiting, abdominal pain, excessive thirst, excessive urination, disorientation or confusion).
- abdominal pain, cramping, swollen abdomen, vomiting, constipation and failure to pass gas which may be signs and symptoms of bowel obstruction.
- loss of appetite, swollen abdomen, abdominal pain, yellowing of the skin, severe weakness and malaise. These symptoms may be signs that you are starting to develop a liver disorder that may advance to fulminant liver necrosis.
- nausea, vomiting, fatigue, weight loss which may be symptoms of inflammation of the kidney

Not known *(frequency cannot be estimated from the available data)*
- if you experience crushing chest pain, sensation of chest tightness, pressure or squeezing (chest pain may radiate to the left arm, jaw, neck and upper abdomen), shortness of breath, sweating, weakness, light headedness, nausea, vomiting and palpitations (symptoms of heart attack). You should seek emergency medical treatment immediately.
- if you experience chest pressure, heaviness, tightness, squeezing, burning or choking sensation (signs of insufficient blood flow and oxygen to the heart muscle). Your doctor will need to check your heart.
- intermittent “thumping,” “pounding,” or “fluttering” sensation in the chest (palpitations).
- rapid and irregular heartbeats (atrial fibrillation). There may be occasional heart palpitations, fainting, shortness of breath, or chest discomfort. Your doctor will need to check your heart.
- symptoms of low blood pressure such as light-headedness, dizziness, fainting, blurred vision, unusual fatigue, cold and clammy skin or nausea.
- if you get signs of blood clots in the veins especially in the legs (symptoms include swelling, pain and redness in the leg), which may travel through blood vessels to the lungs causing chest pain and difficulty in breathing.
- proven or strongly suspected infection along with fever or low body temperature, abnormally rapid breathing, rapid heart rate, change in responsiveness and awareness, drop in blood pressure (sepsis).
- if you experience profuse sweating, headache, nausea, vomiting and diarrhoea (symptoms of cholinergic syndrome).
- if you experience severely decreased urine output (sign of kidney failure).

- if you experience an allergic reaction (swelling mainly of the face, mouth and throat, as well as, the tongue, which may be itchy or painful).
- loss of appetite, swollen abdomen, abdominal pain, yellowing of the skin, severe weakness and malaise. This may indicate possible liver disorders that involve replacement of normal liver tissue with scar tissue leading to loss of liver function, including those liver events leading to life-threatening consequences such as liver failure (which may lead to death), liver injury (injury of liver cells, bile duct in the liver, or both) and liver transplant.
- burning upper abdominal pain, particularly between meals, early in the morning, or after drinking acidic drinks; tarry, black, or bloody stools; bloating, heartburn, nausea or vomiting, early feeling of fullness (intestinal ulceration of stomach and/or gut) which may lead to death.
- severe abdominal pain intensified by movement, nausea, vomiting including vomiting blood (or liquid with what looks like coffee grounds); abdomen becomes rigid with (rebound) tenderness spreading from point of perforation across the abdomen; fever and/or chills (intestinal perforation of stomach and/or gut or ruptured bowel) which may lead to death.
- constipation, abdominal pain, abdominal tenderness, fever, bloating, bloody diarrhoea. This may indicate possible megacolon (enlargement of the intestines) or intestinal infarction/ischaemia/necrosis, which may lead to death. Your doctor will need to examine you.
- sharp chest pain with shortness of breath and with or without coughing.
- increased or new muscle weakness, muscle spasms, muscle pain. This may indicate possible a muscle disorder (rhabdomyolysis). Your doctor will need to examine you.
- sharp chest or abdominal pain with shortness of breath and with or without coughing or fever.
- Extremely intense and serious skin reactions, such as drug rash with eosinophilia and systemic symptoms (DRESS syndrome), have been reported during use of Clozapine Holsten. The adverse reaction of the skin may appear as rashes with or without blisters. Skin irritation, oedema and fever and flulike symptoms may occur. Symptoms of DRESS syndrome usually appear approximately 2–6 weeks (possibly up to 8 weeks) after treatment begins.
- inflammation of the appendix (**appendicitis**).
- blood cancer (haematological malignancy).
  A small increased risk of developing blood cancer has been observed in patients taking clozapine, especially in cases of longer treatment. Symptoms could include:
  - unexplained fever
  - swollen glands,
  - persistent infections during the treatment
  - weight loss
  - extreme tiredness
  - redness
  - night sweats
  - easy bruising or bleeding

If any of the above apply to you, please tell your doctor immediately before taking the next [Nationally approved name] tablet.

Other side effects:

Very common (may affect more than 1 in 10 people):
Drowsiness, dizziness, increased production of saliva.

Common (may affect up to 1 in 10 people):
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, 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).

Uncommon (may affect up to 1 in 100 people):
Lack of white blood cells (agranulocytosis), speech disorders (e.g. stuttering).

Rare (may affect up to 1 in 1,000 people):
Low level of red blood cells (anaemia), restlessness, agitation, confusion, delirium, irregular heart beat, inflammation of the heart muscle (myocarditis) or the membrane surrounding the heart muscle (pericarditis), fluid collection around the heart (pericardial effusion), high level of sugar in the blood, diabetes mellitus, blood clot in the lungs (thromboembolism), inflammation of the liver (hepatitis), liver disease causing yellowing of the skin/dark urine/itching, raised levels of an enzyme called creatinine phosphokinase in the blood.

Very rare (may affect up to 1 in 10,000 people):
Increase in numbers of blood platelets with possible clotting in the blood vessels, uncontrollable movements of mouth/tongue and limbs, obsessive thoughts and compulsive repetitive behaviours (obsessive compulsive symptoms), skin reactions, swelling in front of the ear (enlargement of saliva glands), difficulty in breathing, very high levels of triglycerides or cholesterol in the blood, disorder of the heart muscle (cardiomyopathy), stopped heart beat (cardiac arrest), sudden unexplained death.

Not known (frequency cannot be estimated from the available data)
Changes in brain waves machine (electroencephalogram/EEG), diarrhoea, stomach discomfort, heartburn, stomach discomfort after a meal, muscle weakness, muscle spasms, muscle pain, stuffy nose, nocturnal bedwetting, sudden, uncontrollable increase in blood pressure (pseudophaeochromocytoma), uncontrolled bending of the body to one side (pleurothotonus), ejaculatory disorder if you are a male, in which semen enters the bladder instead of ejaculating through the penis (dry orgasm or retrograde ejaculation), rash, purplish-red spots, fever or itching due to inflammation of blood vessel, inflammation of the colon resulting in diarrhoea, abdominal pain, fever, change in skin colour, “butterfly” facial rash, joint pain, muscle pain, fever and fatigue (lupus erythematous), restless legs syndrome (irresistible urge to move your legs or arms, usually accompanied by uncomfortable sensations during periods of rest, especially in the evening or at night and temporarily relieved by movement).

In elderly people with dementia, a small increase in the number of people dying has been reported for patients taking antipsychotics compared with those not taking antipsychotics.

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 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 [Nationally approved name]

This medicine does not require any special storage conditions.
Keep this medicine out of the sight and reach of children.
Do not use this medicine after the expiry date which is stated on the carton and on the blister after “EXP”. The expiry date refers to the last day of that month.
Do not use this medicine if you notice the pack is damaged or shows signs of tampering.

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 to protect the environment.

6. Contents of the pack and other information

What [Nationally approved name] contains

The active substance is clozapine.

25 mg: Each tablet contains 25 mg clozapine.
100 mg: Each tablet contains 100 mg clozapine.

The other ingredients are lactose monohydrate, maize starch, povidone K30, silica colloidal anhydrous, magnesium stearate and talc.

What [Nationally approved name] looks like and contents of the pack

25 mg: Pale yellow to yellow, round, approximately 6.0 mm in diameter, uncoated tablets, debossed on one side with “FC” and “1” on either side of breakline and plain on other side.
The tablet can be divided into equal doses.

100 mg: Pale yellow to yellow, round, approximately 10.0 mm in diameter, uncoated tablets, debossed on one side with “FC” and “3” on either side of breakline and plain on other side.
The tablet can be divided into equal doses.

[Nationally approved name] are available in Aluminium - PVC/PVDC blister packs.
Pack sizes:
25 mg: 7, 14, 20, 28, 30, 50, 60, 100 or 500 tablets in blister
100 mg: 14, 28, 30, 50, 60, 84, 100 or 500 tablets in blister

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
[To be completed nationally]

This medicinal product is authorised in the Member States of the EEA under the following names:
[To be completed nationally]

This leaflet was last approved in 04/2026