

Versacloz™

Clozapine

50 mg/mL oral suspension

What is in this leaflet

Please read this leaflet carefully before you start taking Versacloz.

This leaflet answers some common questions about Versacloz. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Versacloz against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What Versacloz is used for

Versacloz suspension belongs to the group of medicines known as antipsychotics. This group of medicines is mainly used in the treatment of schizophrenia. Schizophrenia is a mental illness with disturbances in thinking, feelings and behaviour.

This medicine is only used in patients with schizophrenia for whom other antipsychotic medicines have not worked or have caused severe side effects.

This medicine is thought to work by correcting the chemical imbalances in the brain, which may cause mental illness. Your doctor may have prescribed it for another reason.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

This medicine is available only with a doctor's prescription.

There is no evidence that this medicine is addictive.

Versacloz is not recommended for use in children or adolescents under the age of 16, as there is not enough information on its use in that age group.

Before you take Versacloz

When you must not take it

Do not take this medicine if you have an allergy to:

- the active ingredient, clozapine
- any of the other ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction to this medicine may include:

- breathing problems such as shortness of breath, wheezing, difficulty breathing
- skin rash, itching or hives
- swelling of the face, lips, tongue or other parts of the body

If you think that you are allergic to Versacloz, ask your doctor for advice before taking this medicine.

Do not take this medicine if you have a low white blood cell count, or if you have previously had a low white blood cell count caused by the use of a medicine.

Versacloz can cause agranulocytosis. With this condition, the number of white blood cells (which are needed to fight infections) is reduced. If you have a low white blood cell count or have had one in the past, you must not take this medicine.

Do not take Versacloz if you are unable to have regular blood tests.

Before starting this medicine and during your therapy, checks will be required to monitor the

levels of various components in your blood. Your doctor will tell you when these tests are needed.

Do not take Versacloz if you have or have had any of the following medical conditions:

- any blood disorder that may lower your red blood cell or platelet count.
- a low white blood cell count (e.g., leucopenia or agranulocytosis), especially if this was caused by medicines.
- symptoms of active liver disease such as jaundice (yellowing of the skin and eyes, feeling sick, loss of appetite) or liver failure.
- problems with your kidneys
- inflammation of heart muscle (myocarditis) or any other heart disorder
- uncontrolled epilepsy (fits or seizures)
- paralytic ileus, a condition where your bowel does not work properly, and
- severe constipation or obstruction
- bone marrow disorder
- acute mental illness caused by alcohol or another drug.
- circulatory collapse which may occur as a result of severe shock.

Versacloz must not be given to anyone who is unconscious or in a coma.

Do not take this medicine if the expiry date (EXP) shown on the outer container, on the bottle has passed. Do not use if the suspension show signs of deterioration or if the packaging shows signs of tampering.

If you take this medicine after the expiry date has passed, it may not work as well or you may feel unwell.

If you are not sure whether you should start taking this medicine, talk to your doctor or pharmacist.

Before you start to take it

Tell your doctor if:

1. you have allergies to:

- any other medicines
- any other substances such as foods, preservatives or dyes

2. you have or have had any medical conditions, especially the following:

- heart disease or a family history of heart disease or disorders.
- chest pain which maybe a symptom of heart attack or inflammation of the heath muscle.
- family history of an abnormal conduction in the heart called 'prolongation of QT interval'.
- neuroleptic malignant syndrome (NMS) - a reaction to some medicines with a sudden increase in body temperature, sweating, fast heart heartbeat, muscle stiffness and fluctuating blood pressure, which may lead to coma.
- a condition called tardive dyskinesia characterised by uncontrollable twitching or jerking of the arms or legs.
- diseases of liver or kidneys or family history of liver and kidney problems
- glaucoma (raised pressure in the eye)
- enlargement of the prostate or prostate problems or difficulty urinating
- fits or epilepsy that is under control.
- seizures, drowsiness, fainting, muscle weakness, which may lead to falls.
- diabetes
- chronic constipation or abdominal pain
- large intestine diseases
- stroke
- anticholinergic effects -confusion and excitement especially in the elderly
- dementia
- blood clots or family history of blood clots, as medicines like these have been associated with the formation of blood clots.
- any other medical condition

Your doctor may want to take special precautions if you have any of these conditions.

3. you are pregnant or are thinking of becoming pregnant during treatment with Versacloz.

There is limited information on the safety of clozapine in pregnancy. Your doctor will discuss the risks and benefits of taking this medicine during pregnancy.

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.

4. Make sure you use a contraceptive to prevent pregnancy during treatment with Versacloz.

Some women taking some antipsychotic medications have irregular or no periods. If you are female and you have been affected in this way, your periods may return when your medication is changed to clozapine.

5. you are breast-feeding or plan to breast-feed.

It is recommended that you do not breast-feed while taking Versacloz, as clozapine may pass into breast milk and affect your baby.

6. you smoke and how often you have drinks containing caffeine (e.g., coffee, tea, cola).

Nicotine and caffeine can affect the amount of clozapine in your body. Sudden changes in your usual smoking or coffee drinking habits can also change the effects of this medicine.

7. you will be in a hot environment or you do a lot of vigorous exercise.

Clozapine may make you sweat less; causing your body to overheat.

8. you are lactose intolerant.

This medicine contains lactose.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

You should also tell any health professional who is prescribing a new medication for you that you are taking Versacloz.

Some medicines and Versacloz may interfere with each other. These include:

- medicines that may decrease the number of blood cells produced by your body.
- other medicines for schizophrenia, mental disorders, depression or mood swings such as lithium, paroxetine, sertraline, fluoxetine, citalopram, MAO inhibitors, perazine, fluvoxamine
- medicines used to treat anxiety and sleep disturbances such as benzodiazepines.
- epilepsy medicines e.g., phenytoin, carbamazepine, valproic acid
- warfarin or heparin - medicines used to prevent blood clots.
- strong pain killers e.g., morphine
- St John's wort (*Hypericum perforatum*) - a herbal remedy
- antihistamines - medicines used to control and prevent symptoms of allergies such as hay fever.
- anticholinergic medicines used to relieve stomach cramps, spasms and travel sickness.
- Parkinson's disease medicines
- high blood pressure medicines
- medicines used to treat a fast or irregular heartbeat e.g., digoxin.
- medicines used for stomach ulcers e.g., cimetidine, omeprazole.
- medicines used to treat bacterial infections e.g., erythromycin, rifampicin.
- medicines used to treat fungal and viral infections.
- nicotine in medicines used to help you quit smoking e.g., nicotine patches or chewing gum.
- atropine - a medicine which may be used in some eye drops or cough preparations.
- adrenaline - a drug used in emergency situations.
- oral contraceptives (birth-control tablets)

These medicines may be affected by Versacloz or may affect how well Versacloz work. Your doctor will advise you.

Your doctor and pharmacist may have more information on medicines to be careful with or avoid while taking this medicine.

How to take Versacloz

Your dose of Versacloz has been determined for you by your doctor. The dose will depend on how you respond to the medicine, other medicines you are taking, and other medical conditions that you may have. The dose may be altered from time to time.

Carefully follow all directions given to you by your doctor. Their directions may differ from the information contained in this leaflet.

If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

How much to take

Your doctor will determine the most appropriate dose for you.

Take Versacloz exactly as prescribed by your doctor.

If you have heart, kidney or liver disease, epilepsy or you are elderly; your doctor may start you on a lower dose and gradually increase the dose to prevent unwanted effects.

Do not exceed the prescribed dose. If you think the dose is too weak or too strong, talk to your doctor.

How to take it

The total daily amount of Versacloz is usually divided into two doses. However, if your total dose is 200 mg or less, your doctor may allow you to take the whole amount in one dose, usually in the evening.

Versacloz suspension may be taken alone or in water if required.

When to take it

Take your medicine at about the same time each day.

Taking your suspension at the same time each day will have the best effect. It will also help you to remember when to take the medicine. It does not matter if you take this medicine before or after food.

If you forget to take it

If it is almost time for your next dose (within 4 hours), skip the dose you missed and take your next dose when you are meant to. Otherwise take it as soon as you remember, and then go back to taking your medicine as you would normally.

If you miss a dose of Versacloz, do not take a double dose to make up for the missed dose.

If you have stopped taking Versacloz for more than 2 days, do not start taking it again before you contact your doctor.

To prevent unwanted side effects, your doctor will probably restart you on Versacloz at a lower dose and increase it gradually back to your normal dose.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

How long to take it

Take this medicine until your doctor tells you to stop. Your doctor will check your progress and decide how long to continue your treatment. This medicine helps to control your condition but does not cure it. It is important to keep taking your medicine **even if you feel well.**

Do not lower the dosage, even if you are feeling better, unless your doctor tells you to do so.

Your condition may worsen if you suddenly stop taking it. Your doctor will gradually reduce the amount you take each day before stopping the medicine completely.

Do not let yourself run out of over the weekend or on holidays. If you have any concerns, talk to your doctor.

While you are taking Versacloz

Things you must do

You must have strict and regular blood tests while taking this medicine. This medicine can

cause agranulocytosis. This is a condition where the number of white blood cells (which are necessary to fight infection in your body) may be reduced. Severe cases of agranulocytosis have resulted in deaths. Only regular blood tests can tell the doctor if you are at risk of agranulocytosis. Therefore, agranulocytosis can be detected early, and if this medicine is stopped as soon as possible, the white blood cell numbers should return to normal.

After starting on this medicine, you must have a blood test at least once a week for the first 18 weeks of treatment (this is when the risk of agranulocytosis is greatest), thereafter at least once a month for as long as you are taking this medicine, and for one month after stopping.

Your doctor will advise if blood tests are required more often. These tests will tell the doctor if the white blood cell count is dropping.

There are some situations where you may need to have blood tests more often (e.g., twice a week). Your doctor will talk to you about this.

If the number of your white blood cells falls below a safe level, this medicine must be stopped immediately and you must never take any medicines containing clozapine again.

Other monitoring

If you suffer from diabetes (a high level of sugar in the blood) your doctor may regularly check your level of sugar in the blood.

Contact your doctor immediately if:

- you develop a **fast or irregular heartbeat** that is present even when you are resting, accompanied by **rapid breathing, shortness of breath, dizziness or lightheadedness, or chest pain**. These symptoms could be signs of myocarditis, an inflammation of the heart muscle, or another heart condition.
- **you have muscle weakness, fever, fast or irregular heartbeat and excessive sweating**. These are symptoms of a very rare condition called Neuroleptic Malignant Syndrome (NMS) - a reaction to some medicines, which can cause a **sudden increase in body temperature**.
- you have **uncontrolled movements of the tongue, jaw (such as puffing at the cheeks, chewing movements, puckering of the**

mouth), face and mouth. These are symptoms of a very rare condition called tardive dyskinesia - a condition more likely to happen during long term treatment, especially in older women.

- you develop a **sore throat, mouth ulcers, fever, any "flu-like" symptoms** such as **swollen glands** or other signs of infection as these symptoms may be an early sign of agranulocytosis. Flu-like symptoms may also be a sign of myocarditis.

If you become pregnant while taking this medicine, tell your doctor immediately.

Be sure to keep all of your doctor's appointments so that your progress can be checked.

Tell any other doctors, dentists, and pharmacists who are treating you that you are taking Versacloz or if you are about to be started on any new medicines or if you plan to have surgery

Things you must not do

Do not give the medicine to anyone else even if their symptoms seem similar or they have the same condition as you.

Do not take this medicine to treat any other complaints unless your doctor tells you to.

You might get withdrawal reactions if you stop Versacloz abruptly such as sweating, headache, nausea (feeling sick), vomiting (being sick) and diarrhoea. Those signs may be followed by more serious side effect so do not stop taking Versacloz without asking your doctor.

Things to be careful of

Be careful driving or operating machinery until you know how this medicine affects you. You may feel tired, drowsy, dizzy or you may feel faint while taking this medicine, especially during the early stages of treatment. If you have any of these symptoms, do not drive, operate machinery or do any tasks where you need to be alert.

If this medicine makes you feel dizzy, light-headed or faint, be careful when getting up from

a sitting or lying position. This medicine may lower your blood pressure, especially at the start of treatment. Getting up slowly and flexing leg muscles and toes to get the blood circulating can usually prevent these symptoms. When getting out of bed, dangle your legs over the side for a minute or two before standing up.

Be careful when drinking alcohol or when taking antihistamines (medicines used for hay fever, allergies or colds), sleeping tablets or tablets to relieve pain while taking this medicine. Clozapine can increase drowsiness caused by alcohol and by medicines affecting your nervous system.

Clozapine may cause weight gain or affect your blood lipid levels. Your doctor may monitor your weight and blood lipid levels.

Tell your doctor if you will be in a hot environment or you do a lot of vigorous exercise. Clozapine may affect the way your body controls temperature, and it may prevent sweating even in very hot weather. Exercise, hot baths or saunas may make you feel dizzy or faint while you are taking this medicine.

Tell your doctor if you smoke and how much coffee you drink.

Smoking and caffeine can affect how Versacloz affects your body. Sudden changes in your usual smoking or coffee drinking habits can also change the effects of Versacloz and how much Versacloz you need.

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766) or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much Versacloz.

The most common signs and symptoms of clozapine overdose include drowsiness, confusion and coma; light-headedness; shallow breathing or breathing more slowly; fast or irregular heartbeat and dribbling. Occasionally, fits have also been reported.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Versacloz.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the adverse effects.

If you are over 60 years old, you may have an increased chance of getting side effects. You may be more likely to get some of the side effects of clozapine, such as rapid heartbeat, dizziness or light-headedness due to low blood pressure, constipation and difficulty urinating.

Do not be alarmed by this list of possible adverse effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

Very common (affects more than 1 in 10 people):

- tiredness and drowsiness
- dizziness, fainting, light-headedness
- constipation (if it seems to be getting worse, check with your doctor immediately)
- excessive saliva
- fast heartbeat

Common (affects up to 1 in 10 people):

- nausea, vomiting
- headache
- dry mouth
- weight gain
- blurred vision
- tremor, stiffness, restlessness
- increased or decreased sweating
- high blood pressure
- faintness or light-headedness after changing position.
- problems in passing or holding urine.
- changes in the way your body reacts to temperature changes.
- speech disorders (e.g., slurred speech)
- changes in ECG heart machine
- abnormalities in liver function tests

- High level of white blood cells (leukocytosis), high level of a specific type of white blood cell (eosinophilia)

Uncommon (affects up to 1 in 100 people):

- lack of white blood cells (agranulocytosis)
- speech disorders (e.g., stuttering)
- falls

Rare (affects up to 1 in 1,000 people):

- low level of red blood cells (anaemia)
- high level of sugar in the blood, diabetes mellitus
- restlessness, agitation
- confusion, delirium
- difficulty in swallowing

Very rare (affects up to 1 in 10,000 people):

- abdominal discomfort, heartburn
- swelling of the glands in the cheeks
- very high levels of triglycerides or cholesterol in the blood
- obsessive thoughts and compulsive repetitive behaviours

Other side effects

- skin reactions, including rash or itching.
- profuse sweating, headache, nausea, vomiting and diarrhoea.
- 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 (restless legs syndrome)
- symptoms of low blood pressure such as light-headedness, dizziness, fainting, blurred vision, unusual fatigue, cold and clammy skin or nausea
- stuffy nose
- diarrhoea, abdominal discomfort, heartburn
- muscle pain
- night-time bedwetting
- ejaculatory disorder if you are a male
- skin discolouration

If any of the following happen, tell your doctor immediately or go to your nearest Accident & Emergency department or clinic:

Very common (affects more than 1 in 10 people):

- constipation is very common, however, tell your doctor immediately if you have severe constipation. Your doctor will have to treat this to avoid further complications

Common (affects 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 Versacloz.
- if you experience seizures (fits).

Uncommon (affects 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
- sore throat, mouth ulcers, fever, any "flu-like" symptoms such as swollen glands or other signs of infection as these symptoms may be an early sign of agranulocytosis.

Rare (affects 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.
- 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 a fast and irregular heartbeat, 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.
- signs of loss of blood sugar control such as excessive thirst, passing large amounts of urine, dry mouth and skin
- 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.
- signs of becoming obese or increasing obesity

- develop a fast or irregular heartbeat that is present even when you are resting, accompanied by rapid breathing, shortness of breath, dizziness or lightheadedness, or chest pain. These symptoms could be signs of **myocarditis**, an inflammation of the heart muscle, or another heart condition.
- interruption in breathing with or without snoring during sleep
- 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

Very rare (affects 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 to avoid further complications.
- spontaneous bleeding or bruising, which might be signs of a decrease in numbers of blood platelets.
- 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.
- nausea, vomiting, fatigue, weight loss which may be symptoms of inflammation of the kidney
- if you have uncontrolled movements of the tongue, jaw (such as puffing at the cheeks, chewing movements, puckering of the mouth), face and mouth.

These are **serious** side effects. You may need urgent medical treatment.

Other side effects not listed above may occur in some patients. Tell your doctor or pharmacist if you notice anything else that is making you unwell.

After taking Versacloz

Storage

Keep your medicine in the original container until it is time to take them.

If you take the suspension out of the original container they will not keep well.

Keep your suspension in a cool dry place away from light where the temperature stays at or below 25°C. Do not refrigerate or freeze Versacloz. Recap the bottle tightly following each use. Discard any remaining suspension 100 days after opening.

Heat and dampness can destroy medicines, so do not store Versacloz in the bathroom or near a sink. Do not leave it in the car or on a windowsill.

As with all medicines, you should store them out of the reach of children. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or it has passed its expiry date, ask your pharmacist what to do with any unused medicine.

Product description

What it looks like

Versacloz 50 mg/mL - a free-flowing yellow suspension.

Versacloz 50 mg/mL Suspension is available in a bottle containing 100 mL.

Your doctor will determine the quantity provided to you by the pharmacy.

Ingredients

Active ingredient(s)

clozapine

Inactive ingredients

glycerol, hydrochloric acid, monobasic sodium phosphate dihydrate, povidone, purified water, sodium hydroxide, sodium methyl hydroxybenzoate, sodium propyl hydroxybenzoate, sorbitol, xanthan gum.

Sponsor details

Versacloz is supplied in New Zealand by:

Douglas Pharmaceuticals Ltd

P O Box 45 027

Auckland 0651

New Zealand

Phone: (09) 835 0660

Date of preparation

10 March 2021

(based on data sheet dated 23 February 2021)

Dispensing Instructions



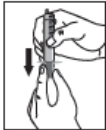
1. Shake the bottle until the suspension is thoroughly mixed.



2. Push down and turn the cap to open the bottle.



3. Push the bottle adaptor into the top of the bottle.



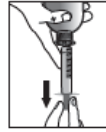
4. Fill the oral dispenser (syringe) with air.



5. Insert the oral dispenser into the opening of the bottle adaptor. Expel all the air from the oral dispenser into the bottle.



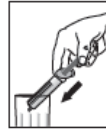
6. Turn the bottle upside down.



7. Withdraw the prescribed amount of Versacloz Oral Suspension.



8. Turn the bottle upright and remove oral dispenser. Expel any large bubbles.



9. Swallow Versacloz Oral Suspension directly from the oral dispenser or add the suspension to a glass with 200 ml of water. Stir and drink the entire mixture right away.



10. Wash the oral dispenser in warm soapy water after each use and rinse well with water. Leave to air dry.



11. Close the bottle with cap provided. The bottle adaptor does not need to be removed before closing.