

OKEDI®

(Risperidone prolonged-
release suspension for
injection)


INFORMATION **FOR PATIENTS**

Helping you get the most
from your treatment

This guide intends to further complement information contained in the patient information leaflet (PIL) for patients who have been prescribed OKEDI®

Read the contents of the PIL as this guide is not intended as a substitute for the PIL.





WELCOME TO YOUR OKEDI® PATIENT BOOKLET

The aim of **this booklet is to give you more information about OKEDI® and explain important aspects of this medicine which has been prescribed for you.** This can help you understand more about your medication and treatment goals.

The information in this booklet **can help you when you are having conversations with healthcare professionals. If you have any questions now, or in the future, you should always ask them.** When we say 'healthcare professional' in this booklet we mean the doctors, nurses or pharmacists involved in treating you. If you wish, a healthcare professional can go through this booklet with you and help explain what it all means.

There is also a patient information leaflet that is provided with the OKEDI® pack. **You should take the time to carefully read this leaflet as it contains important information concerning this medication.**

There are some blank pages at the end of this booklet, which you can use to write any notes or other information that is important to you. These might be things that you have talked about with your healthcare professionals which you want to remember or questions you want to ask at your next appointment.



WHAT IS THIS BOOKLET FOR?



Warnings and precautions



Do NOT use OKEDI® if you are allergic (hypersensitive) to risperidone, poly-(D, L-lactide-coglycolide) or dimethyl sulfoxide.



Talk to your doctor or pharmacist BEFORE taking OKEDI® if:

- ✓ **You have a heart problem.** Examples include an irregular heart rhythm or if you are prone to low blood pressure or if you are using medicines for your blood pressure. OKEDI® may cause low blood pressure. Your dose may need to be adjusted
- ✓ **You know of any factors which would favour you having a stroke**, such as high blood pressure, cardiovascular disorder or blood vessel problems in the brain.
- ✓ **You have ever experienced involuntary movements** of the tongue, mouth and face.
- ✓ **You have ever had a condition whose symptoms include high temperature, muscle stiffness, sweating or a lowered level of consciousness** (also known as Neuroleptic Malignant Syndrome).

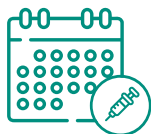
- ✓ **You have Parkinson's disease.**
- ✓ **You have dementia.**
- ✓ **You know that you have had low levels of white blood cells in the past** (which may or may not have been caused by other medicines).
- ✓ **You are diabetic.**
- ✓ **You have epilepsy.**
- ✓ **You are a man and you have ever had a prolonged or painful erection.**
- ✓ **You have problems controlling your body temperature** or overheating.
- ✓ **You have kidney problems.**
- ✓ **You have liver problems.**
- ✓ **You have an abnormally high level of the hormone prolactin** in your blood **or if you have a tumour**, which is possibly dependent on prolactin.
- ✓ **You or someone else in your family has a history of blood clots**, as antipsychotics have been associated with formation of blood clots.



If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before using oral risperidone or OKEDI®.



Warnings and precautions



During Treatment

- ✓ Dangerously low numbers of a certain type of white blood cell needed to fight infection in your blood has been seen very rarely with patients taking risperidone.

Your doctor may therefore check your white blood cell counts before and during treatment.

- ✓ Even if you have previously tolerated oral risperidone, rarely allergic reactions occur after receiving injections of OKEDI®.

Seek medical attention right away if you experience a rash, swelling of your throat, itching, or breathing problems as these may be signs of a serious allergic reaction.

- ✓ OKEDI® may cause you to gain weight. Significant weight gain may adversely affect your health.

Your doctor should regularly measure your body weight.

- ✓ Diabetes mellitus or worsening of pre-existing diabetes mellitus have been seen with patients taking OKEDI®.

Your doctor should therefore check for signs of high blood sugar. In patients with pre-existing diabetes mellitus blood glucose should be monitored regularly.

- ✓ OKEDI® commonly raises levels of a hormone called "prolactin". This may cause side **effects such as menstrual disorders or fertility problems in women, breast swelling in men.**

If such side effects occur, evaluation of the prolactin level in the blood is recommended.

- ✓ During an operation on the eye for cloudiness of the lens (cataract), problems may arise that may lead to eye damage.

If you are planning to have an operation on your eye, make sure you tell your eye doctor that you are taking this medicine.



Warnings and precautions



Other medicines and OKEDI®

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including any medicines bought of the counter.



It is especially important to talk to your doctor or pharmacist if you are taking any of the following:

- **Medicines that work on your brain** such as to help you calm down (benzodiazepines) or some medicines for pain (opiates), medicines for allergy (some antihistamines), as **OKEDI® may increase the sedative effect of all of these.**
- **Medicines that may change the electrical activity of your heart**, such as medicines for malaria, heart rhythm problems, allergies (antihistamines), some antidepressants or other medicines for mental problems.
- **Medicines that cause a slow heartbeat.**

- **Medicines that cause low blood potassium** (such as certain diuretics).
- **Medicines to treat raised blood pressure.** OKEDI® can lower blood pressure.
- **Medicines for Parkinson's disease** (such as levodopa).
- **Medicines that increase the activity of the central nervous system** (psychostimulants, such as methylphenidate).
- **Water tablets** (diuretics) **used for heart problems or swelling of parts of your body due to accumulation of too much fluid** (such as furosemide or chlorothiazide). OKEDI® taken by itself or with furosemide, may have an increased risk of stroke or death in elderly people with dementia.



The following medicines may reduce the effect of risperidone:

- **Rifampicin** (a medicine for treating some infections)
- **Carbamazepine, phenytoin** (medicines for epilepsy)



The following medicines may increase the effect of risperidone:

- **Quinidine** (used for certain types of heart disease)
- **Antidepressants** (such as paroxetine, fluoxetine, tricyclic antidepressants)
- **Medicines known as beta-blockers** (used to treat high blood pressure)
- **Phenothiazines** (such as medicines used to treat psychosis or to calm down)
- **Cimetidine, ranitidine** (blockers of the acidity of stomach)
- **Itraconazole and ketoconazole** (medicines for treating fungal infections)
- **Certain medicines used in the treatment of HIV/AIDS**, such as ritonavir
- **Verapamil**, a medicine used to treat high blood pressure and/or abnormal heart rhythm
- **Sertraline and fluvoxamine**, medicines used to treat depression and other psychiatric disorders. If you start or stop taking such medicines, you may need a different dose of risperidone.



If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before using oral risperidone or OKEDI®.



OKEDI® with food, drink and alcohol

You should avoid drinking alcohol when using OKEDI®.



Children and adolescents

Do not give this medicine to children and adolescents under 18 years old.



Pregnancy, breast-feeding and fertility

- If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, **ask your doctor or pharmacist for advice before taking this medicine.** Your doctor will decide if you can use it.
- **The following symptoms may occur in newborn babies, of mothers that have used risperidone 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.**
- OKEDI® can **raise** your levels of a hormone called “prolactin” that **may impact fertility** (see section 4 Possible side effects).



Driving and using machines

Dizziness, tiredness and vision problems may occur during treatment with OKEDI®. **Do not drive or use any tools or machines without talking to your doctor first.**



What is a Depot or Long-Acting Injectable (LAI) medicine?

It is a medicine, which is given by injection and slowly releases the medicine over a period of several weeks or months. In the case of OKEDI[®], it contains risperidone.

It is important to know that the active ingredient in this injection is risperidone and is the same active ingredient as the risperidone you have been taking in tablet form.

The key difference is the route through which it enters your body.



What is important about having this LAI medicine?

You only need to have the medicine once every 28 days, unlike risperidone tablets which have to be taken every day.

This could mean you are less likely to forget your medicine, so less likely to become unwell.



OKEDI[®] and you

OKEDI[®] contains the active substance risperidone which belongs to the group of medicines called antipsychotics.

OKEDI[®] is used in adult patients to treat schizophrenia.

OKEDI[®] is intended for patients who have shown they can tolerate oral (e.g., tablets) risperidone and it has been effective in treating their schizophrenia.



OKEDI[®] can help alleviate the symptoms of your illness and reduce the chances of your symptoms coming back.

The recommended dose is 75 mg every 28 days, but a higher dose of 100 mg every 28 days may be necessary for some people. You and your healthcare team will decide on the dose of OKEDI[®] that is right for you. This dose will be determined on your prior current dose of oral risperidone.

- **If you are already stabilised with oral risperidone you can be switched on to OKEDI[®].**
- **If you are currently treated with an antipsychotic other than risperidone, but have taken risperidone in the past, you should begin taking oral risperidone for at least 6 days before beginning treatment with OKEDI[®].** This is to confirm tolerability and responsiveness to risperidone.
- **If you have never taken any form of risperidone before, you should begin taking oral risperidone for at least 14 days before beginning treatment with OKEDI[®].** Again, this is to confirm tolerability and responsiveness to risperidone.
- **If you are currently treated with a different risperidone injection your doctor will advise you when to start OKEDI[®].**

How is OKEDI® administered?

OKEDI® is an injectable medicine that is given by your doctor or nurse every 28 days.

The injection can be administered into either your upper arm or buttocks. You can choose which injection site you prefer.

The monthly injections should be switched between the right and left sides of the body (left/right arm, left/right buttock).

OKEDI® has a slow-release formula. **The injection uses a patented technology** that allows for both a **rapid and then prolonged release of medicine**.

How long will OKEDI® take to start working?

After you receive the injection, **the risperidone will be start to be released and will continue to work over the following 28 days**.

Will the OKEDI® injection be painful?

As with all injections, you might experience some pain when it is administered. **Generally, the injection pain reported in patients who have been given OKEDI® has been mild to moderate and tended to lessen over time**.

You can have the injection in your upper arm or your buttocks (you can discuss this with a healthcare professional).

What if my symptoms come back?

If you start to notice your symptoms returning, you start to feel unwell, or you notice some of your relapsing patterns of behaviour, then **speak to a healthcare professional as soon as possible**.



My healthcare team:



Healthcare teams can vary from patient to patient. It is important that **you know each member of your healthcare team**.

My Doctor/Psychiatrist/Consultant:

My Community Psychiatric Nurse (CPN):

My Primary Nurse:

My Social Worker:

My Pharmacist:

My Depot/LAI Clinic Address:

Telephone number:

If you have any questions or concerns about your treatment, **it is important to talk with your healthcare team so you can work together to move forward**.

What happens if I stop taking OKEDI®?

There are many other alternative antipsychotics treatments for schizophrenia if you or a health care professional decide that OKEDI® is not the treatment for you.

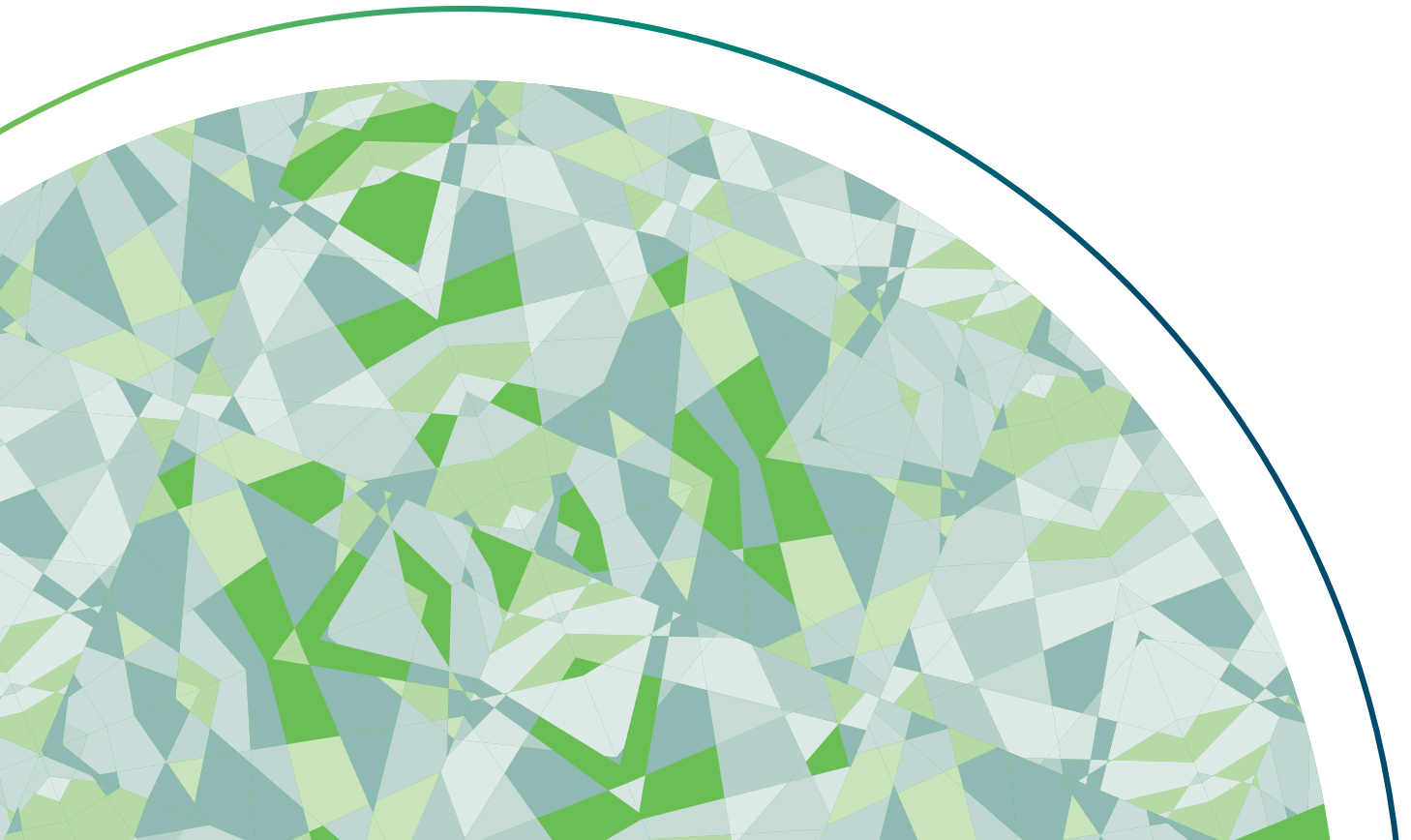
This should be discussed with your healthcare team. They will listen to your concerns and agree with you the best treatment plan moving forward.

What are the side effects of OKEDI® treatment?

All medications can cause side effects. They will vary in frequency and severity from one person to another.

The following table lists some of the more commonly seen side effects and any action you might need to take if you do experience them.

If you think you might be experiencing a side effect to this medicine, you should tell your healthcare professional team.





Possible Side Effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.



Contact a doctor or go to your nearest emergency department immediately if you experience the following uncommon side effect (may affect up to 1 in 100 people):

- ✔ **Experience tardive dyskinesia** (twitching or jerking movements that you cannot control in your face, tongue, or other parts of your body).



Contact a doctor or go to your nearest emergency department immediately if you experience any of the following rare side effects (may affect up to 1 in 1,000 people):

- ✔ **Experience 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 breathing.

- ✔ **Experience fever, muscle stiffness, sweating or a lowered level of consciousness** (a disorder called “Neuroleptic Malignant Syndrome”).
- ✔ **Are a man and experience prolonged or painful erection.** This is called priapism.
- ✔ **Experience severe allergic reaction characterised by fever, swollen mouth, face, lip or tongue, shortness of breath, itching, skin rash or drop in blood pressure** (anaphylactic reaction or angioedema). Even if you have previously tolerated oral risperidone, rarely allergic reactions occur after receiving injections of OKEDI.
- ✔ **Have a dark red or brown urine or notable decreased urination along with muscle weakness or trouble moving arms and legs.** These may be signs of rhabdomyolysis (a rapid damage of your muscles).
- ✔ **Have weakness or lightheadedness, fever, chills or sores in the mouth.** These may be signs of very low number of granulocytes (a type of white blood cell to help you against infection).



Possible Side Effects

The following other side effects may also happen:

Very common (may affect more than 1 in 10 people)	Common (may affect more than 1 in 10 people)	Uncommon (may affect more than 1 in 100 people)	Rare (may affect more than 1 in 1,000 people)	Very rare (may affect more than 1 in 10,000 people)	Not known
Difficulty falling or staying asleep.	Pneumonia (lung infection), bronchitis (infection of the main airways of the lungs), sinus infection, urinary tract infection, ear infection, flu, flu-like symptoms, sore throat, cough, stuffy nose, fever, eye infection or "pink eye"	Bladder infection, tonsillitis, fungal infection of nails, infection of the deeper layers of the skin, viral infection, inflammation of the skin caused by mites	Infection.	Life threatening complications of uncontrolled diabetes.	Stevens Johnson syndrome/toxic epidermal necrolysis
	Parkinsonism: movement disorders that may include slow or impaired movements, sensation of stiffness or tightness of the muscles, and sometimes even a sensation of movement "freezing up" and then restarting. Other signs include a slow shuffling walk, tremor while at rest, increased saliva and/or drooling, and a loss of expression on the face	Raised levels of a hormone called "prolactin" found in a blood test. Symptoms of high prolactin occur uncommonly and may include in men breast swelling, difficulty in getting or maintaining erections, decreased sexual desire. In women they may include leakage of milk from the breasts, menstrual disorders, missed menstrual periods, lack of ovulation, fertility problems.	Decrease or increase in white blood cells in your blood, decrease in platelets (blood cells that help you stop bleeding), anaemia or haematocrit decreased (decrease in red blood cells), blood creatine phosphokinase enzyme increased, increased liver enzymes in your blood		
Headache	Weight gain, increased or decreased appetite.	Low blood pressure, drop in blood pressure after standing, flushing, brain ischemia (insufficient blood flow to the brain)	Not responsive to stimulation, catatonia (not moving or responding while awake), low level of consciousness, sleep walking, sleep-related eating disorder, trouble breathing during sleep (sleep apnoea), fast shallow breathing, lung infection caused by inhaling food into the breathing passages, lung congestion, breathing passage disorder, voice disorder, crackly lung sounds, lack of emotion, inability to reach orgasm.		
	Sleep disorder, irritability, depression, anxiety, feeling sleepy or less alert.	Diabetes, high blood sugar, excessive drinking of water, increased cholesterol in your blood, weight loss, anorexia, high blood triglycerides (a fat)	Mania (elated mood), confusion, decreased sexual drive, nervousness, nightmares		
	Dystonia (involuntary contraction of muscles that cause slow repetitive movements or abnormal postures), dyskinesia (another condition which affects involuntary muscle movements including repetitive, spastic or writhing movements, or twitching).	Fainting, convulsion (fits), sensation of spinning (vertigo), tinnitus, ear pain			
	Tremor (shaking), muscle spasms, bone or muscle pain, back pain, joint pain, fall	A restless urge to move parts of your body, balance disorder, abnormal coordination, poor attention, problems with speech, loss or abnormal sense of taste, reduced sensation of skin to pain and touch, a sensation of tingling, pricking, or numbness on the skin	Blood vessel problems in the brain, coma due to uncontrolled diabetes, involuntary shaking of the head.		
	Blurry vision.				
	Urinary incontinence (involuntary leakage of urine).				



Possible Side Effects (cont.)

The following other side effects may also happen:

Very common (may affect more than 1 in 10 people)	Common (may affect more than 1 in 10 people)	Uncommon (may affect more than 1 in 100 people)	Rare (may affect more than 1 in 1,000 people)	Very rare (may affect more than 1 in 10,000 people)	Not known
	<p>Rapid heart rate, high blood pressure, shortness of breath.</p>	Irregular and often rapid heart rate, slow heart rate, abnormal electrocardiogram (test that measures the electrical activity of the heartbeat), palpitations (a fluttering or pounding feeling in your chest), an interruption in conduction between the upper and lower parts of the heart	Glaucoma (increased pressure within the eye), problems with movement of your eyes, eye rolling, eyelid margin crusting/ inflammation, eye problems during cataract surgery.		
	<p>Abdominal pain, abdominal discomfort, vomiting, nausea, dizziness, constipation, diarrhoea, indigestion, dry mouth, toothache.</p>	Congestion of breathing passages, wheezing (coarse/whistling sound during breathing), nose bleeds	Inflammation of the pancreas, blockage in the bowels.		
	<p>Rash, skin redness, reaction at the injection site (including discomfort, pain, redness or swelling), swelling of the body, arms or legs, chest pain, lack of energy and strength, fatigue, pain.</p>	Abnormal posture, joint stiffness, joint swelling, muscle weakness, neck pain, walking abnormality, thirst, feeling unwell, chest discomfort or general discomfort, feeling "out of sorts"	Swollen tongue, chapped lips, dandruff, jaundice (yellowing of the skin and the eyes), hardening of the skin.		
		Stomach or intestinal infection or irritation, fecal incontinence, difficulty swallowing, excessive passing of gas or wind, frequent passing of urine, inability to pass urine, pain when passing urine	Breast enlargement, breast engorgement (hard, swollen, painful breasts from too much breast milk production).		
		Loss of menstrual periods or other problems with your cycle, leakage of milk from the breasts, sexual dysfunction, breast pain or discomfort, vaginal discharge, erectile dysfunction, ejaculation disorder, development of breast in men	Decreased body temperature, coldness in arms and legs.		
		Hives, thickening of skin, skin disorder, intense itching of the skin, hair loss, eczema (patches of skin become inflamed, itchy, cracked, and rough), dry skin, skin discoloration, acne, seborrheic dermatitis (red, scaly, greasy, itchy, and inflamed skin), skin lesion	Symptoms of drug withdrawal (also in newborns).		
		Oversensitivity of the eyes to light, dry eye, increased tears			
		Allergic reaction, chills.			

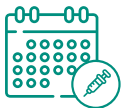


Reporting Side Effects

If you get any side effects from OKEDI[®], talk to your healthcare professional team. This includes any side effects not listed in this booklet.

You can also report side effects yourself directly via the 'Yellow Card' Scheme, **but always ensure you speak with your healthcare professional team as well.** Website: www.mhra.gov.uk/yellowcard or search for Mhra Yellow Card in the Google Play or Apple App Store.

By reporting side effects, you can help provide more information on the safety of this medicine.



What if I miss my next appointment for my OKEDI[®]?

It is important not to miss your appointments (every 28 days) when you are supposed to receive your OKEDI[®] injections.

If you cannot keep your appointment, make sure to contact your healthcare professionals right away to discuss another date when you can come in for your injection.



It is important that you don't miss your appointment for your injection without first discussing this with your healthcare professionals.



Reminders



It is important not to miss your appointments when you are due to receive your OKEDI[®] injections. **These appointments will be once every 28 days.**

Some helpful tips to remember your next appointment:



When you have your injection, **ask your healthcare professional to give you the time and date of your next appointment.**



Write the date of your next appointment on a card that you can keep in your purse or wallet. **Or write it in the notes and calendar section of this booklet.**



Use alerts on your phone's calendar to remind you when your next injection appointment is.



You can also, **ask a support worker, CPN or a friend/member of your family to set reminders for your appointments.**



Staying well



Medication is not the only thing in your life that can help keep you well. Keeping active and eating a balanced diet can have a positive impact on your wellbeing.

You should try to **eat a healthy and balanced diet** and consume the right amount of food and drink to achieve and maintain a healthy body weight.

Regular exercise can reduce your risk of major illnesses, such as coronary heart disease, stroke, type 2 diabetes and cancer and lower your risk of early death by up to 30%. Evidence also shows it can also improve your mental wellbeing.

Choose an activity that you enjoy and can be consistent with. This can be anything from taking a walk, going for a swim, or joining a local sports team.

Ask your healthcare professional team if they can provide guidance on activities/sports in your local area that you can get involved with.

<https://www.nhs.uk/live-well/>

The NHS website provides very useful information on improving your mental and physical wellbeing.



Will I need to have any tests while I am taking OKEDI®?

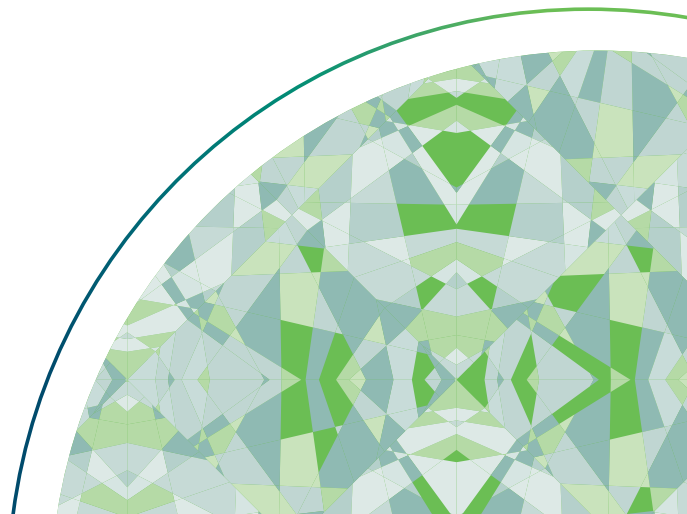
It is equally important to look after both your mental health and your physical health.



National guidance recommends that everyone taking treatment for schizophrenia should have their **blood pressure, pulse, weight, overall physical health checked, and blood tested regularly.**

This might be done if you are in hospital or when you first start on treatment for schizophrenia. Your healthcare team can arrange for these tests to be completed

These tests are important to ensure that this treatment is appropriate for you to continue. If there are any concerns, your team will let you know and advise you about what to do next.





ROVI Biotech Ltd.

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