

FINAL PATIENT INFORMATION LEAFLET

Seroquel® XR Tablets

Read this entire leaflet carefully before you start taking Seroquel XR.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

SCHEDULING STATUS:

S 5

PROPRIETARY NAME (and dosage form):

Seroquel® XR 50; 150; 200; 300; 400 (Tablet)

The active substance is quetiapine.

1. WHAT SEROQUEL XR CONTAINS:

50 mg XR prolonged-release tablet:

Each tablet contains quetiapine fumarate equivalent to 50 mg of quetiapine free base.

150 mg XR prolonged-release tablet:

Each tablet contains quetiapine fumarate equivalent to 150 mg of quetiapine free base.

200 mg XR prolonged-release tablet:

Each tablet contains quetiapine fumarate equivalent to 200 mg of quetiapine free base.

300 mg XR prolonged-release tablet:

Each tablet contains quetiapine fumarate equivalent to 300 mg of quetiapine free base.

400 mg XR prolonged-release tablet:

Each tablet contains quetiapine fumarate equivalent to 400 mg of quetiapine free base.

The other ingredients in SEROQUEL XR are:

Microcrystalline cellulose, sodium citrate, lactose monohydrate, magnesium stearate, hydroxypropyl methycellulose, polyethylene glycol 400, titanium dioxide, and iron oxide.

2. WHAT SEROQUEL XR IS USED FOR:

SEROQUEL XR belongs to a group of medicines called antipsychotics.

SEROQUEL XR can be used to treat schizophrenia, bipolar disorder and depression.

Your doctor may continue to give you SEROQUEL XR when you are feeling better to prevent your symptoms from returning.

3. BEFORE YOU TAKE SEROQUEL XR:

Do not take SEROQUEL XR:

- If you have ever had an allergic reaction to SEROQUEL XR or to any of its ingredients.

Take special care with SEROQUEL XR:

- If you go into a hospital let the medical staff know you are taking SEROQUEL XR

Before taking SEROQUEL XR tell your doctor, pharmacist or other health care professional:

- If you have any health problems.
- If you have low blood pressure or have had a stroke.
- If you, or a family member, have a history of any problems with the way your heart beats or have a history of heart disease or heart problems or if you are taking any medicines that may have an impact on the way your heart beats.
- If you have diabetes.
- If you have any problems with your liver.
- If you know that you had a low white blood cell count in the past, which may or may not have been caused by other medicines.
- If you have ever had a seizure (fit).

While you are taking SEROQUEL XR tell your doctor, pharmacist or other health care professional:

- If you feel “light-headed” and think you have low blood pressure.
- If you experience involuntary movements of your facial muscles and tongue, or your hand and leg muscles (tardive dyskinesia).
- If you feel you have a fever, feel confused or drowsy, muscle stiffness or changes in your blood pressure or heartbeats (neuroleptic malignant syndrome).

In clinical studies with this medicine and other medicines of this type, an increased risk of death has been reported in elderly patients with dementia and behavioural disturbances. SEROQUEL XR is not approved for this use.

SEROQUEL XR is not approved for children or adolescents less than 18 years of age.

Thoughts of suicide and worsening of your depression or other mental illnesses

If you are depressed and/or have other mental illnesses you may sometimes have thoughts of harming or killing yourself. These may be increased when first starting treatment, since these medicines all take time to work, usually about 2 weeks but sometimes longer.

You may be more likely to think like this if:

- You have previously had thoughts about killing or harming yourself.
- You are a child, teenager or young adult. Information from clinical trials has shown an increased risk of suicidal thoughts and/or suicidal behavior in children, teenagers, or young adults aged less than 25 years with psychiatric conditions who were treated with an antidepressant.

If you have thoughts of harming or killing yourself at any time, contact your doctor or go to a hospital straight away.

You may find it helpful to tell a relative or close friend that you are depressed or have other mental illnesses, and ask them to read this leaflet. You might ask them to tell you if they think your depression or mental illness is getting worse, or if they are worried about changes in your behaviour.

Taking SEROQUEL XR with food and drink

If you drink alcohol, please mention this to your doctor before you start to take SEROQUEL XR. SEROQUEL XR can be taken with or without food.

Pregnancy and breastfeeding

Before taking SEROQUEL XR, tell your doctor if you are pregnant, trying to become pregnant or are breastfeeding.

If you are pregnant or breastfeeding your baby while taking SEROQUEL XR please consult your doctor, pharmacist or other health care professional for advice.

Driving and using machinery

Your tablets may make you feel sleepy. This may disappear while you continue taking your tablets. Even so, you should not drive or use machinery until you know how these tablets affect you.

Taking other medicines with SEROQUEL XR

Tell your doctor or pharmacist if you are taking, or about to stop taking, any other medicines including those which you may have bought. In particular, tell your doctor if you are taking, or about to stop taking medicines for:

- anxiety, depression
- epilepsy (such as phenytoin, carbamazepine or sodium valproate)
- high blood pressure
- Human Immunodeficiency Virus (protease inhibitors)

Or if you are taking:

- barbiturates (for sleeplessness)
- a medicine called thioridazine (an antipsychotic)
- medicines that have an impact on the way your heart beats, for example medicines that can cause an imbalance in electrolytes (low levels of potassium or magnesium) such as diuretics (water pills) or certain antibiotics (medicines to treat infections).

Ask your doctor if you are not sure. Tell your doctor if you are taking, or about to stop taking medicines for infection e.g.:

- rifampicin (for tuberculosis)
- ketoconazole (for fungal infections)
- erythromycin (an antibiotic)

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of SEROQUEL XR with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other health care professional for advice.

4. HOW TO TAKE SEROQUEL XR:

Always take SEROQUEL XR exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

If you have the impression that the effect of SEROQUEL XR is too strong or too weak, talk to your doctor or pharmacist.

Your doctor may adjust your daily dose of SEROQUEL XR, typically between 50 mg and 800 mg depending on your individual treatment and needs.

SEROQUEL XR is to be taken once a day either with or without food.

- Swallow your tablets whole with a drink of water.
- Do not split, chew or crush the tablets.

SEROQUEL XR prolonged-release tablets come in different strengths, and each strength is a different colour. Therefore don't be surprised if the colour of your tablets differs from time to time.

- Do not share your medicines prescribed for you with any other person.
- Do not stop taking your tablets even if you are feeling better unless your doctor tells you to.

If you take more SEROQUEL XR than you should

If you take more than the recommended number of tablets, you are likely to feel drowsy, sleepy, light-headed (low blood pressure) and have rapid heart beat.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.

If you forget to take SEROQUEL XR

If you miss a dose, take the dose as soon as you remember. Then take the next dose at the usual time. Do not take a double dose.

Effects when treatment with SEROQUEL XR is stopped

If you stop taking SEROQUEL XR abruptly you may experience nausea, vomiting or insomnia.

5. POSSIBLE SIDE-EFFECTS:

SEROQUEL XR can have side-effects.

Not all side-effects reported for SEROQUEL XR are included in this leaflet. Should your general health worsen while taking SEROQUEL XR, please consult your doctor, pharmacist or other health care professional for advice.

Contact your doctor immediately or go to the nearest hospital if any of the following events happen to you (these are also described below). These events are rare and sometimes seen with medicines used to treat mental illness.

- Very marked drowsiness
- Reduced consciousness
- Fits (seizures)
- Priapism (long-lasting and painful erection)
- Involuntary movements, mainly of your face or tongue (Tardive dyskinesia).

Tell your doctor if any of the following side-effects bothers you:

Side-effects that are very common (more than 10 of every 100 patients are likely to have them):

- Dizziness (may lead to falls)
- Feeling sleepy (this may go away whilst you continue taking your tablets and may also lead to falls)
- Dry mouth
- Headache (this may or may not be caused by taking SEROQUEL XR)
- Weight gain
- Discontinuation symptoms (i.e. symptoms which occur upon stopping SEROQUEL XR) include vomiting, dizziness, nausea, headache, diarrhoea, insomnia and irritability.

Gradual withdrawal over a period of at least 1 to 2 weeks is advisable.

Side-effects that are common (1 to 10 of every 100 patients are likely to have them):

- Rapid heart beat
- Constipation
- Indigestion
- Feeling weak
- Swelling of arms or legs
- Fainting (may lead to falls)
- Stuffy nose
- Low blood pressure in standing position, which may result in dizziness or feeling faint (may lead to falls)
- Blurred vision
- Abnormal dreams and nightmares

- Irritability
- Feeling more hungry
- You may have abnormal muscle movements, including difficulty starting muscle movements, shaking, restlessness or muscle stiffness without pain
- Disturbance in speech and language
- Urinary tract infection (bladder infection) (this may or may not be caused by taking SEROQUEL XR).

Side-effects that are uncommon (less than 1 of every 100 patients are likely to have them):

- Allergic reactions that may include weals and swelling of the skin
- Fits (seizures)
- Restless legs (unpleasant sensations in the legs)
- Difficulty swallowing
- Involuntary movements, mainly of your face or tongue (Tardive dyskinesia).

Side-effects that are rare (less than 1 of every 1 000 patients are likely to have them):

- Fever
- Very marked drowsiness
- Muscle stiffness
- Marked increases in blood pressure or heartbeats
- Reduced consciousness
- Men and women to have swelling of breasts and unexpectedly produce breast milk
- Priapism (long-lasting and painful erection).

Side-effects that are very rare (less than 1 of every 10 000 patients are likely to have them):

- Anaphylaxis (severe form of allergic reaction; may include severe difficulty breathing and shock).

The following side-effects can also occur with SEROQUEL XR, and may be seen when a blood test is taken:

- Decrease in the amount of white blood cells. These changes will normally disappear when stopping the treatment of SEROQUEL XR.
- “Eosinophilia” - an increase in one type of white blood cells, which is sometimes seen in allergic reactions.
- ‘Thrombocytopenia’ - a decrease in platelets, which are cells that help you stop bleeding if you get a cut.
- Increase in the amount of liver enzymes. These changes will normally disappear when continuing the treatment of SEROQUEL XR.
- Changes in the amount of fatty substances (lipid levels such as triglycerides and cholesterol) in the blood.
- Increase in the amount of “creatine phosphokinase” - a substance in the muscles.
- Increase in the amount of sugar (glucose) in the blood.
- Increase in the amount of hormone prolactin in the blood. Rarely this may lead to:
 - Men and women to have swelling of breasts and unexpectedly produce breast milk.
 - Women to have no monthly period or irregular periods.

If you notice any side-effects not mentioned in this leaflet, please inform your doctor or pharmacist as soon as possible.

6. STORING AND DISPOSING OF SEROQUEL XR:

Store at or below 30°C.

Do not remove the blister from the outer carton until required for use.

Keep all medicines out of reach and sight of children. Your tablets could harm them.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect your environment.

Do not take your tablets after the expiry date on the container. Return all out of date tablets to your pharmacist.

7. PRESENTATION OF SEROQUEL XR:

The tablets are packed into opaque PVC/PCTFE aluminium foil blister strips with each strip containing 10 tablets. The blisters are packed in cartons of 10, 60 or 100 tablets.

8. IDENTIFICATION OF SEROQUEL XR:

SEROQUEL XR 50:

Peach, film-coated, capsule-shaped, biconvex, marked tablet with 'XR 50' on one side and plain on the other.

SEROQUEL XR 150:

White, film-coated, capsule-shaped, biconvex, marked tablet with 'XR 150' on one side and plain on the other.

SEROQUEL XR 200:

Yellow, film-coated, capsule-shaped, biconvex, marked tablet with 'XR 200' on one side and plain on the other.

SEROQUEL XR 300:

Pale yellow, film-coated, capsule-shaped, biconvex, marked tablet with 'XR 300' on one side and plain on the other.

SEROQUEL XR 400:

White, film-coated, capsule-shaped, biconvex, marked tablet with 'XR 400' on one side and plain on the other.

9. REGISTRATION NUMBERS:

SEROQUEL XR 50: 42/2.6.5/0573

SEROQUEL XR 150: 44/2.6.2/0973

SEROQUEL XR 200: 42/2.6.5/0574

SEROQUEL XR 300: 42/2.6.5/0575

SEROQUEL XR 400: 42/2.6.5/0576

10. NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:


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11. DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET:

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