Quetiapine Rosemont 20mg/ml Oral Suspension

Package Leaflet: Information for the User

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

1. What this medicine is and why you are using it

Quetiapine Rosemont Oral Suspension is used to treat depression and schizophrenia. It contains the active substance quetiapine.

2. What you need to know before you use it

Talk to your doctor or pharmacist before taking quetiapine if:

- you are breast-feeding.
- you have or have had a condition where you can't completely empty your bladder (urinary retention), have an enlarged prostate, a history of blood clots in the legs or arms, or a history of blood clots in people with low blood platelets (thrombocytopenia). There is a higher risk of blood clots in these conditions. Blood clots can occur as a complication of medicines like this one. The risk may increase if you take high doses of quetiapine, have a blood clotting disorder, have low blood platelets (thrombocytopenia), have had a stroke or have a heart problem. See "Side effects" for the risks of blood clots.
- you have or have had a condition where you can't completely empty your bladder (urinary retention), have an enlarged prostate, or you, or someone in your family has a history of blood clots.
- you have or have had a condition that can affect how your blood clots (thrombocytopenia, myelodysplasia, myelofibrosis, aplastic anaemia). These conditions can be caused by this type of medicine.

3. How to use and how much to use

Always take this medicine exactly as prescribed. Your doctor may tell you to take different doses at certain times. Follow all the instructions shown on the label. The number of doses and the amount to be taken at each dose is shown in the package leaflet. Take the medicine by mouth.

4. Possible side effects

The most common side effects of this medicine are:

- feeling sleepy (this may go away with time, as you keep taking quetiapine) (may lead to falls)
- dizziness (may lead to falls), headache, dry mouth
- constipation along with persistent abdominal pain, or constipation which has not responded to treatment, as this may lead to a bowel obstruction
- feeling dizzy
- sweating
- fever
- chest pain
- shortness of breath
- feeling nervous
- high blood pressure
- increased blood creatine phosphokinase (a substance from the muscles)
- increased liver enzymes
- changes in the amount of thyroid hormones in your blood
- increased cholesterol or sugar in the blood
- blood clots in the veins especially in the legs (symptoms include swelling, pain and redness in the leg) which may travel through blood vessels.

Some rare side effects of this medicine are:

- rapid swelling of the skin, usually around the eyes, lips and throat (angioedema)
- uncontrollable movements, mainly of your face and tongue
- uncontrollable jerking movements of your face
- unusual bleeding
- a long-standing and painful erection (priapism)
- fever, severe muscle stiffness, sweating or a lowered level of consciousness (a disorder called “neuroleptic malignant syndrome”)
- increased blood creatine phosphokinase (a substance from the muscles)
- a combination of fever, severe muscle stiffness, sweating or a lowered level of consciousness (a disorder called “neuroleptic malignant syndrome”)
- a rapid increase in the number of certain types of blood cells
- a decrease in the amount of red blood cells, kidney problems
- changes in the levels of certain of your blood cells
- increased blood pressure
- decreased amount of white blood cells in your blood
- high blood sugar (diabetes)
- numbness or tingling in your hands or feet
- rapid and forceful heart beats

Side effects that normally do not need medical attention (usually do not require stopping the medicine) include:

- feeling dizzy
- feeling nervous
- feeling sleepy
- feeling drowsy
- feeling tired
- dry mouth
- increased salivary gland activity
- constipation
- flatulence
- indigestion
- belching
- heartburn
- weight gain
- dizziness
- sweating
- nausea
- vomiting
- increased saliva
- increased stomach acid
- increased urination
- increased thirst

Stop taking this medicine and see your doctor or pharmacist straight away if you get side effects that are serious or get worsened by taking this medicine or if you get any side effects that you think may be serious.

4. Instructions for use of the cup (for doses above 5ml)

7. Remove the syringe from the adaptor. Put the end of the syringe into your mouth (Figure 4).

6. Fill the syringe with a small amount of solution by pulling the plunger down (Figure 2).

5. Turn the bottle the right way up.

4. Wash the dosing cup with water and let it dry before you use it again.

3. Dose is exactly level with the lip of the cup (Figure 3).

2. The dose mark is exactly level with the lip of the cup.

1. Once a day - at bedtime.

3. Fill the syringe with a small amount of solution by pulling the plunger down (Figure 2).

2. Turn the bottle the right way up.

1. Wash the dosing cup with water and let it dry before you use it again.

4. Instructions for use of the cup (for doses above 5ml)

7. Remove the syringe from the adaptor. Put the end of the syringe into your mouth (Figure 4).

6. Fill the syringe with a small amount of solution by pulling the plunger down (Figure 2).

5. Turn the bottle the right way up.

4. Wash the dosing cup with water and let it dry before you use it again.

3. Dose is exactly level with the lip of the cup (Figure 3).

2. The dose mark is exactly level with the lip of the cup.

1. Once a day - at bedtime.

3. Fill the syringe with a small amount of solution by pulling the plunger down (Figure 2).

2. Turn the bottle the right way up.

1. Wash the dosing cup with water and let it dry before you use it again.

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2. The dose mark is exactly level with the lip of the cup.

3. Fill the syringe with a small amount of solution by pulling the plunger down (Figure 2).

4. Turn the bottle the right way up.

5. Wash the dosing cup with water and let it dry before you use it again.

6. Contents of the pack and other information

6. Do not use quetiapine if you notice anything wrong with the medicine. Talk to your pharmacist.

5. Do not use 28 days after you first open it. Take it back to the pharmacy.

4. Store in a refrigerator (2 – 8°C).

3. Do not take the medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking quetiapine.

2. Do not take quetiapine if you are breastfeeding.

1. Do not use quetiapine if you are breast-feeding.

1. Take this medicine exactly as prescribed. Your doctor may tell you to take different doses at certain times. Follow all the instructions shown on the label. The number of doses and the amount to be taken at each dose is shown in the package leaflet. Take the medicine by mouth.

4. Don't stop taking your medicine even if you feel better, unless your doctor tells you to.

3. Do not use quetiapine if you are pregnant or may become pregnant.

2. Do not use quetiapine if you are pregnant or may become pregnant.

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2. For 5ml to 25ml doses, pour the medicine into the dosing cup to the required level. If the dose is more than 25ml, use the syringe provided.

6. Turn the bottle the right way up.

1. To open the bottle, press the cap down and turn it anti-clockwise (Figure 1)."