

SERONIA

quetiapine (as fumarate)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about SERONIA.

It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

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

Talk to your doctor or pharmacist if you have any concerns about taking this medicine.

Keep this leaflet with your medicine.

You may need to read it again.

What SERONIA is used for

SERONIA is used to treat:

- schizophrenia
- acute mania associated with Bipolar 1 Disorder.

Schizophrenia and Bipolar 1 Disorder are mental illnesses with disturbances in thinking, feelings and behaviour.

SERONIA belongs to a group of medicines called antipsychotics. These medicines work by improving the symptoms of certain types of mental illnesses.

Your doctor may have prescribed SERONIA for another reason. Ask your doctor if you have any questions about why SERONIA has been prescribed for you.

SERONIA is not recommended for use in children as there have been no studies of its effects in children.

SERONIA is available only with a doctor's prescription.

There is no evidence that SERONIA is addictive.

Before you take it

When you must not take it

Do not take SERONIA if you are allergic to medicines containing quetiapine or any of the ingredients listed at the end of this leaflet.

Do not take SERONIA if the expiry date (Exp.) printed on the pack has passed.

Do not take SERONIA if the packaging is torn or shows signs of tampering.

Before you start to take it

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

Tell your doctor if you are pregnant or plan to become pregnant.

It is not known whether SERONIA is safe during pregnancy. Your doctor will discuss the risks and benefits of taking SERONIA.

Tell your doctor if you are breastfeeding or wish to breastfeed.

It is recommended that you do not breastfeed while taking SERONIA.

Tell your doctor if you have, or have had, any medical conditions, especially the following:

- heart problems
- problems with your circulation
- liver problems
- diabetes (or a family history of diabetes)

- seizures or fits
- any condition that affects blood flow to the brain
- dementia or related behavioural disorders (especially in the elderly).

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

If you have not told your doctor about any of the above, tell them before you start taking SERONIA.

Taking other medicines

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

Some medicines may be affected by SERONIA, or may affect how well it works. These include:

- medicines for anxiety or depression
- lorazepam - a medicine to help you sleep
- medicines for epilepsy
- medicines for high blood pressure
- antibiotics such as rifampicin and erythromycin
- ketoconazole, an antifungal agent
- glucocorticoids - medicine used to treat inflammation
- medicines for HIV
- thioridazine, used to treat schizophrenia.

Your doctor can tell you what to do if you are taking any of these medicines.

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

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

How to take it

How much to take

Your doctor will decide what dose of SERONIA you should take and how long you need to take it.

The total daily dose is slowly increased depending on your condition. The usual dose may be between 150 mg and 800 mg a day. Some people may need a different dose. Your dose will depend on your response.

If you are elderly, or have liver problems, your doctor will adjust your dose to suit you.

Follow all directions given to you by your doctor and pharmacist carefully.

How to take SERONIA

Swallow the tablets with a glass of water. Do not split, chew, or crush the tablets.

SERONIA is taken twice a day.

If you forget to take it

If it is almost time for your next dose (within 6 hours), skip the dose you missed and take your next dose when you are meant to.

Otherwise, take the missed dose as soon as you remember, and then go back to taking your tablets as you would normally.

Do not take a double dose to make up for the dose you missed.

Ask your doctor or pharmacist if you are not sure what to do.

If you take too much (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much SERONIA. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too much SERONIA, you may feel drowsy, dizzy and have fast heart beats.

While you are taking it

Things you must do

Tell all the doctors, dentists and pharmacists who are treating you that you are taking SERONIA.

Before starting any new medicine, tell your doctor or pharmacist that you are taking SERONIA.

Tell your doctor if you become pregnant while taking SERONIA.

Visit your doctor regularly so they can check on your progress.

Tell your doctor immediately, or go to the nearest hospital if you have any of the following suicidal thoughts or other mental/mood changes:

- thoughts of talks of death or suicide
- thoughts or talk of self-harm or harm to others
- any recent attempts of self-harm
- increase in aggressive behaviour, irritability or agitation
- worsening of depression

Things you must not do

Do not stop taking SERONIA, or lower the dose, without checking with your doctor.

Stopping SERONIA suddenly may cause nausea, vomiting or insomnia. Discuss any changes of dose with your doctor.

Do not use SERONIA to treat any other conditions unless your doctor tells you to.

Do not give SERONIA to anyone else, even if they have the same condition as you.

Things to be careful of

Be careful driving or operating machinery until you know how SERONIA affects you. SERONIA may cause drowsiness or dizziness in some people. If any of these occur, do not drive, operate machinery or do anything else that could be dangerous.

Be careful when getting up from a sitting or lying position if it makes you feel light-headed. Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure.

Be careful when drinking alcohol while taking SERONIA.

Combining SERONIA and alcohol can make you more sleepy or dizzy.

Avoid drinking large quantities of grapefruit juice.

This medicine may be affected by grapefruit juice.

Side effects

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

Like all other medicines, SERONIA may have unwanted side effects in some people. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

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

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

- feeling sleepy
- feeling dizzy or faint
- increase in weight
- swelling of the hands, ankles or feet
- abnormal dreams/ nightmares
- feeling weak
- fainting
- dry mouth
- constipation
- indigestion
- runny or stuffy nose.

These are all mild side effect of SERONIA.

If any of the following happen, stop taking SERONIA and tell your doctor immediately, or go to Accident and Emergency at the nearest hospital:

- abnormal muscle movements, including difficulty starting muscle movements, shaking, restlessness or muscle stiffness without pain
- uncontrolled movements of the tongue, mouth, cheeks or jaw
- a sudden increase in body temperature, with sweating, or a fast heart beat
- very fast breathing
- muscle stiffness
- fits (seizures)
- severe allergic reaction (may include severe difficulty breathing, shock, swelling of the face, lips tongue or other parts of the body, skin rash, hayfever, or you may feel faint).

These are very serious side effects. If you have them, you may have had a serious reaction to SERONIA. You may need urgent medical attention or hospitalisation.

All of these side effects are rare or very rare.

Occasionally, SERONIA may be associated with changes in your liver or blood, which may require your doctor to do certain blood tests.

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

After using SERONIA

Storage

Keep your medicine where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Keep your tablets in a cool dry place where the temperature stays below 25°C.

Do not store SERONIA or any other medicine in the bathroom or near a sink.

Do not leave it in the car or on window sills. Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking SERONIA, or your tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

SERONIA comes in 5 strengths of tablets:

- SERONIA 25 - round orange tablet marked 'QT' on one side and '>' on the other
- SERONIA 100 - round yellow tablet marked 'QT' over '100' on one side and '>' on the other
- SERONIA 200 - round white tablet marked 'QT' over '200' on one side and '>' on the other
- SERONIA 300 - capsule shaped white tablet marked 'QT' over '300' on one side and '>' on the other.

SERONIA 100 are available as packs of 90. SERONIA 25, 150, 200 and 300 are in packs of 60 tablets.

Ingredients

The active ingredient in SERONIA is quetiapine fumarate.

- each SERONIA 25 tablet contains 25 mg of quetiapine
- each SERONIA 100 tablet contains 100 mg of quetiapine
- each SERONIA 200 tablet contains 200 mg of quetiapine
- each SERONIA 300 tablet contains 300 mg of quetiapine

The tablets also contain:

- microcrystalline cellulose
- calcium hydrogen phosphate
- povidone
- lactose
- magnesium stearate
- Opadry II 85F63196 Orange (SERONIA 25 only)
- Opadry II 85F62513 Yellow (SERONIA 100 only)
- Opadry II 85F18378 White (SERONIA 200 and SERONIA 300 only).

The tablets do not contain gluten, sucrose, tartrazine or any other azo dyes.

Supplier

Aspen Pharma Pty Ltd
34-36 Chandos Street
St Leonards NSW 2065
Australia

Australian Registration Numbers:

SERONIA 25 - AUST R 143704
SERONIA 100 - AUST R 143710
SERONIA 200 - AUST R 143716
SERONIA 300 - AUST R 143717

This leaflet was last revised in April 2012.