1.3.2 Patient Information Leaflet

Patient Information Leaflet for QUETOSER

Read this leaflet carefully before QUETOSER is taken.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **QUETOSER** 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.
- If any of the side effects become serious, or you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

SCHEDULING STATUS: S5

PROPRIETARY NAMES (AND DOSAGE FORM)

QUETOSER 25 (film-coated tablets)

QUETOSER 100 (film-coated tablets)

QUETOSER 200 (film-coated tablets)

QUETOSER 300 (film-coated tablets)

WHAT QUETOSER CONTAINS

Each **QUETOSER 25** film-coated tablet contains quetiapine fumarate, equivalent to 25 mg quetiapine free base. It also contains lactose monohydrate, microcrystalline cellulose, sodium starch glycolate, povidone, dibasic calcium phosphate dihydrate, magnesium stearate, polyethylene glycol, hypromellose, titanium dioxide, iron oxide red and iron oxide yellow.

Each **QUETOSER 100** film-coated tablet contains quetiapine fumarate, equivalent to 100 mg quetiapine free base. It also contains lactose monohydrate, microcrystalline cellulose, sodium starch glycolate, povidone, dibasic calcium phosphate dihydrate, magnesium stearate, polyethylene glycol, hypromellose, titanium dioxide and iron oxide yellow.

Each **QUETOSER 200** film-coated tablet contains quetiapine fumarate, equivalent to 200 mg quetiapine free base. It also contains lactose monohydrate, microcrystalline cellulose, sodium starch glycolate, povidone, dibasic calcium phosphate dihydrate, magnesium stearate, polyethylene glycol, hypromellose, talc and titanium dioxide.

Each **QUETOSER 300** film-coated tablet contains quetiapine fumarate, equivalent to 300 mg quetiapine free base. It also contains lactose monohydrate, microcrystalline cellulose, sodium starch glycolate, povidone, dibasic calcium phosphate dihydrate, magnesium stearate, polyethylene glycol, hypromellose, talc and titanium dioxide.

WHAT QUETOSER IS AND WHAT IT IS USED FOR

QUETOSER belongs to a group of medicines called antipsychotics. It improves the symptoms of certain types of mental illness such as strange or frightening thoughts, feeling alone and confused, hallucinations (e.g. hearing unexplained voices) and changes in your behaviour (schizophrenia).

QUETOSER may also be used to treat people with an illness that affects their mood where they feel excessively excited. People with this condition may find that they are talkative and have racing thoughts or ideas, or that they need to sleep less than usual and may feel unusually irritable (manic phase of bipolar disorder).

QUETOSER is only available with your doctor's prescription.

BEFORE USING QUETOSER

Do not use QUETOSER if you

- are hypersensitive (allergic) to quetiapine or any of the ingredients of **QUETOSER**;
- are pregnant or breast-feeding;
- are a child or adolescent below the age of 18 years;
- have serious kidney and liver disease;
- are using any of the following medicines:
  - protease inhibitors (for HIV infection)
  - azole medicine (e.g. ketoconazole, fluconazole, itraconazole – for fungal infections)
  - medicines for infection (e.g. erythromycin or clarithromycin).

Take special care with QUETOSER

The presence of other medical problems may affect the use of **QUETOSER.** Talk to your doctor, pharmacist or healthcare professional before taking **QUETOSER** if you

- recently had a stroke or a heart attack, or if you have low blood pressure;
- have a kidney or liver problem;
- have ever had a seizure (fit);
- suffer from diabetes;
- have Alzheimer's disease or dementia (loss of brain function);
- have Neuroleptic Malignant Syndrome (NMS) – difficult or unusually fast breathing, fast heartbeat or irregular pulse, high fever, high or low (irregular) blood pressure, increased sweating, loss of bladder control, severe muscle stiffness, seizures, unusually pale skin, unusual tiredness or weakness.

Thoughts of suicide and worsening of your depression

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

Pregnancy and Breast-feeding

QUETOSER should not be used if you are pregnant or breast-feeding.

Effects on ability to drive and use machinery

QUETOSER may cause somnolence (sleepiness). You should exercise caution, not to drive, operate hazardous machinery or perform hazardous tasks.

Taking QUETOSER with food or drink

You can take **QUETOSER** with or without food. Be careful how much alcohol you drink, because the combined effect of **QUETOSER** and alcohol can make you feel sleepy.

Using other medicines with QUETOSER

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

Inform your doctor, pharmacist or other healthcare professional if you are using or receiving any of the following medicines:

- medicines for epilepsy (e.g. carbamazepine, phenytoin), anxiety and depression;
- medicines for high blood pressure;
- ketoconazole, fluconazole or itraconazole **(See "Do not use QUETOSER" above)**;
- erythromycin or clarithromycin **(See "Do not use QUETOSER" above)**;
- lithium;
- rifampicin (for tuberculosis);
- barbiturates for difficulty in sleeping;
- thioridazine (another antipsychotic medicine).

Before you begin using any new medicine (prescription or non prescription) or if you develop any new medical problem while you are using this medicine, check with your doctor, nurse, or pharmacist.

Important information about some of the ingredients of QUETOSER

QUETOSER contains lactose (a type of sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking **QUETOSER**.

HOW TO USE QUETOSER

Always take **QUETOSER** 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 **QUETOSER** is too strong or too weak, you should talk to your doctor or pharmacist.

Do not share medicines prescribed for you with any other person.

The starting dose will be decided by your doctor and will depend on what type of illness you have. Follow your doctor's instructions about when and how to take your tablets (usually twice a day). Ask your doctor, nurse or pharmacist if you are not sure.

The dose can range from 150 mg to 800 mg each day, depending on your individual illness and needs.

If you are elderly, or you have problems with your liver or kidneys, your doctor may decide to give you a reduced dose.

Swallow your tablets whole with a drink of water.

Do not stop taking your tablets even if you are feeling better, unless your doctor tells you.

What if you have taken too many tablets

You may experience an increase in side effects and their frequency. In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre. Take this leaflet and any remaining tablets with you, so that the doctor knows what you have taken.

*If you stop taking **QUETOSER***

If you suddenly stop taking **QUETOSER**, you may feel sick (nausea), you may be unable to sleep (insomnia), or you may experience being sick (vomiting), headache, diarrhoea, dizziness or irritability. Your doctor may suggest that you reduce the dose gradually before stopping treatment.

POSSIBLE SIDE EFFECTS

QUETOSER may cause unwanted effects. Check with your doctor, pharmacist or healthcare professional if any of these unwanted effects persist or become bothersome. Do not be alarmed by the list below, you may not get any of them.

If any of the following happens, stop taking **QUETOSER** and contact your doctor immediately or go to the nearest hospital, as you may need urgent medical attention:

- fits (seizures);
- allergic reactions (hypersensitivity);
- swelling of the hands, feet, ankles, face, lips, mouth, or throat which may cause difficulty in swallowing or breathing (angio-oedema);

- severe and serious allergic skin reactions with rash, fever, and blistering (Stevens-Johnson syndrome);
- involuntary movements of the tongue and face (tardive dyskinesia);
- Neuroleptic Malignant Syndrome (NMS) – difficult or unusually fast breathing, fast heartbeat or irregular pulse, high fever, high or low (irregular) blood pressure, increased sweating, loss of bladder control, severe muscle stiffness, seizures, unusually pale skin, unusual tiredness or weakness;
- jaundice (yellowing of the skin and eyes);
- inflammation of the liver (hepatitis);
- painful and/or prolonged erection (priapism);
- chest pain and/or changes in the way your heart beats, e.g. if you notice it beating faster;
- 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.

Other possible side effects include blood disorders (symptoms include fever, chills or sore throat); abnormal dreams; nightmares; dizziness; feeling sleepy; low blood pressure when standing (which may result in dizziness or feeling faint); constipation; dry mouth; indigestion; increased weight gain; swelling of feet and lower legs; decreased strength and energy; high blood sugar; worsening of pre-existing diabetes; abnormal muscle movements (including difficulty starting muscle movements, shaking, feeling restless or muscle stiffness without pain); trouble in speaking or swallowing; anxiety; dry eyes; blurred vision; ear pain; high or low blood pressure; difficulty in breathing; sore throat; stuffy or runny nose; abdominal pain; decreased appetite; diarrhoea; skin rash; muscle pain; urine infections, swelling of breasts and unexpected secretion of milk; flu-like symptoms; increased sweating; headache; back pain; fever.

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

STORAGE AND DISPOSAL INFORMATION

Store in the original packaging at or below 25 °C. Keep the blisters in the carton until required for use. The bottles must be tightly closed.

Do not store your medicine in the bathroom.

Do not use **QUETOSER** after the expiry date printed on the label, container or blister.

Return any expired or unused medicine to your pharmacist for safe disposal. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

STORE ALL MEDICINES OUT OF THE REACH AND SIGHT OF CHILDREN.

PRESENTATION

QUETOSER is packed in:

- Clear PVC/PCTFE and Aluminium blister strips in a cardboard carton, or
- White opaque HDPE bottle with white opaque polypropylene ribbed cap with induction seal and silica gel sachet as desiccant

in the following pack sizes:

QUETOSER 25: 60's, 100's and 500's

QUETOSER 100: 90's, 100's and 500's

QUETOSER 200: 60's, 90's, 100's and 500's

QUETOSER 300: 60's, 90's, 100's and 500's

IDENTIFICATION OF QUETOSER

QUETOSER 25: Peach, round, biconvex, film-coated tablet, debossed with "25" on one side and a "P" logo on the other side.

QUETOSER 100: Yellow, round, biconvex, film-coated tablet, debossed with "100" on one side and a "P" logo on the other side.

QUETOSER 200: White, round, biconvex, film-coated tablet, debossed with "200" on one side and a "P" logo on the other side.

QUETOSER 300: White, capsule-shaped, biconvex, film-coated tablet, debossed with "300" on one side and a "P" logo on the other side.

REGISTRATION NUMBERS

QUETOSER 25: 43/2.6.5/0800

QUETOSER 100: 43/2.6.5/0801

QUETOSER 200: 43/2.6.5/0802

QUETOSER 300: 43/2.6.5/0803

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATES OF REGISTRATION

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