

Package leaflet: Information for the patient

Zurzuvaе 20 mg hard capsules
Zurzuvaе 25 mg hard capsules
Zurzuvaе 30 mg hard capsules
(zuranolone)

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your nurse, doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your nurse, doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Zurzuvaе is and what it is used for
2. What you need to know before you take Zurzuvaе
3. How to take Zurzuvaе
4. Possible side effects
5. How to store Zurzuvaе
6. Contents of the pack and other information

1. What Zurzuvaе is and what it is used for

What Zurzuvaе is

Zurzuvaе is an antidepressant medicine used to treat postnatal depression. It should be taken after giving birth by adults aged 18 years or older.

What Zurzuvaе is used for

Postnatal depression is depression that begins during pregnancy or soon after giving birth.

Symptoms can include low mood or sadness, sleep disturbances, changes in weight, difficulty in concentrating, feelings of worthlessness, loss of interest in favourite activities, and feelings of being slowed down or anxiety.

Postnatal depression may interfere with the mother-baby relationship and have serious effects on the newborn baby and other family members.

How Zurzuvaе works

Zurzuvaе increases the activity of GABA (gamma-aminobutyric acid) on receptors in the brain. GABA is involved in the regulation of mood. By increasing the activity of GABA, Zurzuvaе may help the parts of the brain affected by depression. Typically, **symptoms start to improve by the third day of the 14-day Zurzuvaе treatment course.**

2. What you need to know before you take Zurzuvaе

Do not take Zurzuvaе

- if you are allergic to zuranolone or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Zurzuvaе can **reduce awareness and alertness**. It is important to **discuss these possible effects with your nurse, doctor or pharmacist before taking Zurzuvaе**.

- Do not drive for at least 12 hours after taking each Zurzuvaе dose. You may not be able to tell on your own how much Zurzuvaе is affecting you and whether you are safe to drive.
- Zurzuvaе may also cause sleepiness, slow thinking, trouble remembering, confusion, and dizziness during the day. These effects may interfere with your daily activities. Do not perform potentially dangerous activities if you feel any of these effects.
Tell your doctor if you notice any of these signs.

Talk to your doctor before taking Zurzuvaе if you think any of these apply:

- if you have **kidney** problems
- if you have **liver** problems
- if you have abused or been addicted to **alcohol, illegal drugs or prescribed medicines** –
- if you have had **depression, mood problems or suicidal thoughts** or behaviour. (See below – Depression getting worse).

Depression getting worse

For some people starting treatment for depression, their depressive symptoms may get worse before they start to feel better:

- Tell your doctor straight away if your depression gets worse
- Go to the nearest hospital immediately if you have thoughts of harming or killing yourself at any time.

You may find it helpful to talk to a relative or a close friend if you are depressed and ask them if they think your depression is getting worse or if they are worried about your behaviour. You might ask them to read this leaflet.

Ask your doctor if other medicines you are taking prevent you from taking Zurzuvaе.

Children and adolescents

This medicine is not for children and adolescents under 18 years of age. Zurzuvaе has not been tested in this age group.

Other medicines and Zurzuvaе

Tell your nurse, doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is because Zurzuvaе can affect the way some medicines work and some medicines can have an effect on Zurzuvaе. Only take other medicines while you are on Zurzuvaе if your doctor tells you that you can.

In particular, tell your nurse, doctor or pharmacist if you are taking:

- medicines that may increase the level of Zurzuvaе in your blood. These include those used to treat:
 - **fungal infections**, such as ketoconazole, posaconazole, voriconazole, itraconazole
 - **bacterial infections**, such as the antibiotics clarithromycin, josamycin, telithromycin, troleandomycin

- **HIV infection**, such as ritonavir, elvitegravir, indinavir, saquinavir, telaprevir, danoprevir, lopinavir, nelfinavir, boceprevir
- **cancer**, such as ceritinib, idelalisib, ribociclib, tucatinib.
- medicines that can affect the nervous system, such as:
 - **painkillers like opioids** (such as methadone, tramadol, morphine, oxycodone, codeine)
 - **sleep aids** like benzodiazepines (such as diazepam, lorazepam), and nonbenzodiazepine hypnotics (such as zolpidem, zopiclone).
 - **Antidepressants causing drowsiness** (such as amitriptyline, clomipramine, dosulepin, doxepin, mianserin, mirtazapine, trazodone, trimipramine)
 - **medicines used to treat seizures, nerve pain or anxiety** (such as gabapentin and pregabalin)
- medicines that may reduce how well Zuruvae works, such as:
 - **rifampin** (antibiotic)
 - **St. John's Wort** (herbal remedy taken for depression)
 - **phenobarbital** (also known as barbiturates, used for epilepsy or sleep problems)
 - **efavirenz** (used for HIV infection),
 - **carbamazepine** (used to treat seizures).

Talk to your nurse, doctor or pharmacist before taking Zuruvae, if any of the above apply to you (or you are not sure).

Zuruvae with alcohol

Do not drink alcohol or take products containing alcohol while taking Zuruvae without talking to your doctor. Taking alcohol while on this medicine may make side effects such as drowsiness and sleepiness worse.

Zuruvae with food and drink

Avoid grapefruit or grapefruit juice while taking Zuruvae.

Pregnancy

Zuruvae may cause harm to an unborn baby. Do not take Zuruvae if you are pregnant.

Use reliable contraception during treatment and for 7 days afterwards. Speak to your nurse or doctor about suitable methods of contraception for you.

Tell your doctor straight away if, during treatment with Zuruvae **you become pregnant or think you are pregnant.**

Breast-feeding

Zuruvae passes into breast milk. You and your doctor should discuss the risks and benefits of taking Zuruvae during breast-feeding. **Tell your doctor straight away if you are breast-feeding or plan to breast-feed.**

Driving and using machines

Do not drive or take part in any potentially dangerous activities such as operating machinery for at least 12 hours after taking Zuruvae (see above section Warnings and precautions).

Zuruvae contains sodium

This medicine contains less than 1mmol sodium (23mg) per tablet, that is to say essentially 'sodium free'.

3. How to take Zurzuvae

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Recommended dose

The recommended dose is 50 mg (two 25 mg capsules) taken once daily in the evening. Take it every day for 14 days as a single course of treatment.

Do not stop taking Zurzuvae until you finish your 14-day treatment course, even if you feel better. Typically, symptoms start to improve by the third day of Zurzuvae treatment.

Your doctor may reduce your dose to 40 mg (two 20 mg capsules) taken once daily in the evening if you have trouble with side effects.

If you have any moderate or severe kidney related problems or severe liver problems, your doctor will prescribe a dose of 30 mg (one capsule) taken once daily in the evening.

How to take Zurzuvae capsules

- Swallow Zurzuvae capsules whole without chewing or opening it.
- **Take Zurzuvae with food containing fat.** Typical fat containing foods include nuts, peanut butter, avocado, eggs, and cheese.
- **Avoid grapefruit or grapefruit juice while taking Zurzuvae** (see Zurzuvae with food and drink).

If you take more Zurzuvae than you should

If you take more Zurzuvae than you should, seek medical help immediately, either by calling your doctor, or going to the nearest hospital emergency (A&E) department. Do not drive yourself because you may start to feel sleepy. Always take the labelled medicine container with you to show the doctor, even if there are no capsules left.

If you forget to take Zurzuvae

If you forget to take Zurzuvae, **skip the missed dose** and take the next dose at your regular time the next day. **Do not take a double dose to make up for forgetting a dose.** Continue taking Zurzuvae once daily until the remainder of the prescription is completed.

If you stop taking Zurzuvae

Treatment with Zurzuvae can be stopped without needing to gradually reduce the dose.

If you have any further questions on the use of this medicine, ask your nurse, doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects may happen with this medicine.

Very common (may affect more than 1 in 10 people)

- drowsiness or sleepiness
- dizziness.

Common (may affect up to 1 in 10 people)

- loose stools (diarrhoea)
- lack of energy
- trouble remembering information
- trembling or shaking
- feeling confused.

Tell your nurse, doctor, or pharmacist if you notice any of the side effects above.

Reporting of side effects

If you get any side effects, talk to your nurse, doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card scheme 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.

5. How to store Zurzuvae

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the bottle or blister after EXP.

The expiry date refers to the last day of that month.

Store below 25 °C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Zurzuvae contains

The active substance is zuranolone.

Each hard capsule of Zurzuvae 20 mg contains 20 mg zuranolone.

Each hard capsule of Zurzuvae 25 mg contains 25 mg zuranolone.

Each hard capsule of Zurzuvae 30 mg contains 30 mg zuranolone.

The other ingredients are:

Capsule contents: colloidal silicon dioxide; croscarmellose sodium; mannitol (E421); microcrystalline cellulose (E460); silica, colloidal anhydrous; sodium stearyl fumarate.

Capsule shell: gelatin (E441); red iron oxide (E172); titanium dioxide (E171); yellow iron oxide (E172).

Capsule print (black ink): ammonium hydroxide (E527); black iron oxide (E172); propylene glycol (E1520); shellac glaze (E904).

What Zurzuvae looks like and contents of the pack

Zurzuvaе 20 mg hard capsules are hard capsules with a light-orange cap and an ivory to light-yellow body, printed with “S-217 20 mg” in black ink.

Zurzuvaе 25 mg hard capsules are hard capsules with a light-orange cap and light-orange body, printed with “S-217 25 mg” in black ink.

Zurzuvaе 30 mg hard capsules are hard capsules with an orange cap and light-orange body, printed with “S-217 30 mg” in black ink.

The capsules are provided in bottle packs containing:

- 14 or 28 hard capsules of Zurzuvaе 20 mg, or
- 14 or 28 hard capsules of Zurzuvaе 25 mg, or
- 14 hard capsules of Zurzuvaе 30 mg

The capsules are provided in blister packs containing:

- 28 hard capsules of Zurzuvaе 20 mg, or
- 28 hard capsules of Zurzuvaе 25 mg

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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