

INDICATIONS AND USAGE

ROWEEPRA is an antiepileptic medicine (a medicine used to treat seizures in epilepsy). ROWEEPRA is used for:

Epilepsy a condition where the patients have repeated fits (seizures). ROWEEPRA is used for a form of epilepsy in which fits initially affect only one side of the brain, but could extend to larger areas on both sides of the brain (partial onset seizure with or without secondary generalization). ROWEEPRA has been given to you by your doctor to reduce the number of fits.

ROWEEPRA is used as an add-on to other antiepileptic medicines to treat:

- partial onset seizures with or without generalization in adults, adolescents, children and infants from one month of age;
- myoclonic seizures (short, shock-like jerks of a muscle or group of muscles) in adults and adolescents from 12 years of age with juvenile myoclonic epilepsy;
- primary generalized tonic-clonic seizures (major fits, including loss of consciousness) in adults and adolescents from 12 years of age with idiopathic generalized epilepsy (the type of epilepsy that is thought to have a genetic cause).

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Talk to your doctor before taking ROWEEPRA

- If you suffer from kidney problems, follow your doctor's instructions. They may decide if your dose should be adjusted.
- If you notice any slowdown in the growth or unexpected puberty develops in your child, please contact your doctor.
- A small number of people being treated with anti-epileptics such as ROWEEPRA have had thoughts of harming or killing themselves. If you have any symptoms of depression and/or suicidal thoughts, please contact your doctor.

ADVERSE REACTIONS

Like all medicines, ROWEEPRA can cause side effects, although not everybody gets them. The most frequently reported side effects are nasopharyngitis, somnolence (sleepiness), headache, fatigue and dizziness. At the beginning of the treatment or following dose increase, side effects such as sleepiness, tiredness and dizziness may be more common. These effects should decrease over time.

Very common: May affect more than 1 user in 10 people

- nasopharyngitis;
- somnolence (sleepiness), headache.

Common: May affect 1 to 10 users in 100 people

- anorexia (loss of appetite);
- depression, hostility or aggression, anxiety, insomnia, nervousness or irritability;
- convulsion, balance disorder (equilibrium disorder), dizziness (sensation of unsteadiness), lethargy (lack of energy and enthusiasm), tremor (involuntary trembling);
- vertigo (sensation of rotation);
- cough;
- abdominal pain, diarrhoea, dyspepsia (indigestion), vomiting, nausea;
- rash;
- asthenia/fatigue (tiredness).

Uncommon: May affect 1 to 10 users in 1000 people

- decreased number of blood platelets, decreased number of white blood cells;
- weight decrease, weight increase;
- suicide attempt and suicidal ideation, mental disorder, abnormal behaviour, hallucination, anger, confusion, panic attack, emotional instability/mood swings, agitation;
- amnesia (loss of memory), memory impairment (forgetfulness), abnormal coordination/ataxia (impaired coordinated movements), paraesthesia (tingling), disturbance in attention (loss of concentration);
- diplopia (double vision), vision blurred;
- elevated/abnormal values in a liver function test;
- hair loss, eczema, pruritus;
- muscle weakness, myalgia (muscle pain);
- Injury.

Rare: May affect 1 to 10 users in 10,000 people

- infection;
- decreased number of all blood cell types;
- severe allergic reactions (DRESS, anaphylactic reaction [severe and important allergic reaction], Quincke's edema [swelling of the face, lips, tongue and throat]);
- decreased blood sodium concentration;
- suicide, personality disorders (behavioral problems), thinking abnormal (slow thinking, unable to concentrate);

- uncontrollable muscle spasms affecting the head, torso and limbs, difficulty in controlling movements, hyperkinesia (hyperactivity);
- pancreatitis;
- liver failure, hepatitis;
- skin rash, which may form blisters and appears as small targets (central dark spots surrounded by a paler area, with a dark ring around the edge) (*erythema multiforme*), a widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (*Stevens–Johnson syndrome*), and a more severe form causing skin peeling in more than 30% of the body surface (*toxic epidermal necrolysis*).

Reporting of side effects

If you experience any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

USE IN SPECIFIC POPULATIONS

Children and adolescents

ROWEEPRA is not indicated for use in children and adolescents below 16 years on its own (monotherapy).

Pregnancy and breast-feeding

If you are pregnant or breastfeeding, think you may be pregnant, or are planning to become pregnant, ask your doctor for advice before taking this medicine.

ROWEEPRA should not be used during pregnancy unless the potential benefits justifies the potential risk to the baby. A risk of birth defects for your unborn child cannot be completely excluded. ROWEEPRA has shown unwanted reproductive effects in animal studies at dose levels higher than you would need to control your seizures. Breast-feeding is not recommended during treatment.

Driving and using machines

ROWEEPRA may impair your ability to drive or operate any tools or machinery, as it may make you feel sleepy. This is more likely at the beginning of treatment or after an increase in the dose. You should not drive or use machines until it is established that your ability to perform such activities is not affected.