Package leaflet: Information for the user

Clonazepam XGX Pharma 1 mg/ml concentrate for solution for injection/infusion
clonazepam

Read all of this leaflet carefully before you or your child receive 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 doctor or pharmacist.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Clonazepam is and what it is used for

This medicine contains the active substance clonazepam, which belongs to a group of medicines known as benzodiazepines. These medicines have anticonvulsant and relaxing effects.

This medicine is used for various forms of epilepsy, including status epilepticus, for adults and adolescents from 12 years of age.

2. What you need to know before you use Clonazepam

Do not use Clonazepam
- if you are allergic to clonazepam, any other benzodiazepine (such as diazepam or nitrazepam), or any of the other ingredients of this medicine (listed in section 6)
- if you have severe breathing problems since this medicine can make breathing difficulties worse
- if you have severe liver problems
- if you are addicted to medicines, drugs or alcohol
- in children under 12 years of age

Clonazepam should not be given to patients who are in coma.

Warnings and precautions
Talk to the doctor or nurse before receiving Clonazepam if you:
- have ever had depression or tried to harm or kill yourself
- are pregnant, breast-feeding or think you may be pregnant (see Pregnancy and breast-feeding section)
- have ever had drug or alcohol problems or if you have consumed alcohol or drugs just before receiving this medicine
- have mild to moderate liver problems
- have a lung condition causing breathing problems as this medicine could make your breathing worse. Your dose will be adjusted in accordance with your respiratory condition
- feel weak, unstable, or shaky because this medicinal product affects the central nervous system (CNS)
- have a rare hereditary blood disorder called “porphyria”
- are older since you will have an increased risk of side effects
- have severe muscle weakness (myasthenia gravis)
- have withdrawal symptoms

Anterograde amnesia may occur with the use of benzodiazepines at therapeutic doses and the risk increases with higher doses.

During treatment with benzodiazepines, paradoxical reactions such as restlessness, agitation, irritability, aggression, anxiety, delusions, anger, nightmares, hallucinations, psychosis, inappropriate behaviour, and other behavioural disorders have been reported. Paradoxical reactions may be a class effect of benzodiazepines. If this occurs during treatment with this medicine, gradual discontinuation of treatment should be considered. Paradoxical reactions are more common in children and the elderly.

Children
This medicine must not be used in children under 12 years of age.

Other medicines and Clonazepam
Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines. If you have any doubt about whether any medicine you are taking may affect the use of Clonazepam, please speak to your doctor.

The effects of Clonazepam may be intensified by medicines such as:
- antiepileptic medicines for treating epilepsy e.g., phenytoin, phenobarbital, carbamazepine, lamotrigine and valproate
- St. John's wort (used for mild depression and mild anxiety)
- medicines used to treat absence seizures (valproic acid)
- medicines that cause drowsiness and sleepiness (CNS depressants)
- opioids (strong pain killers, medicines for replacement therapy and some cough medicines) since it may increase the risk of severe side effects.

If Clonazepam is combined with one of these drugs, it is usually necessary to adjust the dosage to achieve the optimum effect of the medicines.

Clonazepam and alcohol
Do not drink alcohol during treatment with this medicine. This is because it may make you feel very sleepy and cause problems with your breathing.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask the doctor or pharmacist for advice before giving this medicine.

Pregnancy
Since ingredients of this medicine crosses the placenta there is a risk that the baby can be affected by this medicine. Therefore, this medicine should be used with caution during pregnancy.

Breast-feeding
Clonazepam passes into breast milk and there is a risk that the baby can be affected. Therefore, breast-feeding should be discontinued during the treatment with this medicine.

Driving and using machines
This medicine has an impact on the ability to drive, use machines or any activities that requires increased attention since it can slow down your reactions. Driving should therefore be avoided after receiving this medicine, especially during the first days after treatment before you know how the medicine affects you.

Clonazepam contains benzyl alcohol, ethanol, and propylene glycol

Benzyl alcohol
This medicine contains 31 mg benzyl alcohol in each ampoule. Benzyl alcohol may cause allergic reactions. Ask your doctor or pharmacist for advice if you are pregnant, breast-feeding or if you have a

liver or kidney disease. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called “metabolic acidosis”).

Ethanol
This medicine contains 158 mg of alcohol (ethanol) in each ampoule which is equivalent to 158 mg/ml. The amount in one dose of this medicine is equivalent to 4 ml beer or 2 ml wine.

The amount of alcohol in this medicine is not likely to have an effect in adults and adolescents.

The alcohol in this medicine may alter the effects of other medicines. Talk to your doctor or pharmacist if you are taking other medicines.

If you are pregnant or breast-feeding, talk to your doctor or pharmacist before taking this medicine.

If you are addicted to alcohol, talk to your doctor or pharmacist before taking this medicine.

If this medicine is given slowly over 2 hours, the effects of alcohol may be reduced.

Propylene glycol
This medicine contains 805 mg propylene glycol in each ampoule which is equivalent to 805 mg/ml.

If you are pregnant or breast-feeding, do not take this medicine unless recommended by your doctor. Your doctor may carry out extra checks while you are taking this medicine.

If you suffer from a liver or kidney disease, do not take this medicine unless recommended by your doctor. Your doctor may carry out extra checks while you are taking this medicine.

3. How to use Clonazepam

The dose is individual and depends on your or your child’s age and how the medicine works for you. It is possible for the doctor or nurse to dilute the medicine with sodium chloride (salt) and/or glucose before giving it to you, to ensure that you get the dose your need. The medicine will be slowly injected/infused (via a drip) directly into a vein. The medicine can also be injected into a muscle if the doctor finds it necessary.

If you use more Clonazepam than you should
Since this medicine is given at the hospital, it is unlikely that the wrong dose will be given. However, if you get too much medicine, you may experience symptoms such as drowsiness, loss of coordination, difficulty with speech, involuntary eye movements, absence of reflexes, slowed breathing, low blood pressure, difficulty breathing or unconsciousness. Tell your doctor or nurse right away if you think you have been given too much.

If you stop receiving Clonazepam
If treatment with this medicine is stopped suddenly, there is a risk of provoking tonic clonic seizures, status epilepticus or withdrawal symptoms. Withdrawal symptoms include tremors, restlessness, sleep disturbances, anxiety, headache, difficulty concentrating, sweating, muscle and abdominal pains, confusion and in rare cases delirium and convulsions.

Treatment with this medicine should only be stopped in consultation with a doctor.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Contact your doctor immediately if you experience any of these potentially serious side effects:

Rare *(may affect up to 1 in 1 000 people):*
- bleeding from the skin and mucous membranes and bruising due to low levels of platelets in the blood (thrombocytopenia)

Very rare *(may affect less than 1 in 10 000 people):*
- severe acute allergic reactions (anaphylactic reaction) with symptoms such as generalized itching and hives, swelling, wheezing and difficulty breathing, fainting, and/or other allergy symptoms.

Not known *(cannot be estimated from the available data):*
- epilepsy
- heart failure including cardiac arrest
- breathing difficulties
- vein inflammation or thrombosis

Other side effects:

Common *(may affect up to 1 in 10 people):*
- impaired concentration
- sleepiness
- delayed response
- low level of muscle tone
- dizziness
- fatigue (tiredness, apathy)
- muscle weakness
- problems with coordination of movement and walking (ataxia)
- rapid involuntary movements of the eyes

Rare *(may affect up to 1 in 1 000 people):*
- sexual desire disorder
- headache
- nausea, upper abdominal pain
- nettle rash, itching, rash, transient hair loss, pigmentation changes
- inability to retain urine (incontinence)
- inability of a man to maintain an erection (erectile dysfunction)

Not known *(cannot be estimated from the available data):*
- hypersensitivity
- emotional disorders, mood changes, confusion, loss of direction, depression, paradoxical reactions to a medication (the inability to rest or relax, irritability, aggression, nervous excitement , nervousness, unfriendliness behaviour, anxiety, sleep disorders, delusion, anger, nightmares and abnormal dreams, perception of something not present (hallucination), condition of being abnormally or extremely active (hyperactivity), psychoses, inappropriate behaviour and other behavioural side effects)
- inability to transfer information from short-term memory to long-term memory and amnesia which may be associated with inappropriate behaviour
- addiction and withdrawal symptoms
- double vision
- difficulty speaking (organic speech disorder)
- risk of falls and fracture

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

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 carton after EXP and on the ampoule after EXP. The expiry date refers to the last day of that month.

Store below 25°C. Do not freeze. Keep the ampoules in the outer carton in order to protect from light.

Stability for up to 2 hours at room temperature (25 ± 2°C) and refrigerator (2 – 8°C) has been shown for diluted intravenous infusion in 0.9 % sodium chloride, 0.45 % sodium chloride + 2.5 % glucose, 5 % glucose and 10 % glucose.

From a microbiological point of view the product should be used immediately after dilution.

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 protect the environment.

6. Contents of the pack and other information

What Clonazepam contains
- The active substance is clonazepam.
  Each ml of Clonazepam (one ampoule) contains 1 mg of clonazepam.
- The other ingredients are anhydrous ethanol, benzyl alcohol, glacial acetic acid, propylene glycol.

What Clonazepam looks like and contents of the pack
A colourless or slightly yellowish-greenish solution (sterile concentrate).
10 ampoules of amber transparent borosilicate glass are packed in a carton box. Ampoules are packed in two plastic trays, before placement in the carton box.

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The following information is intended for healthcare professionals only:

Please read the summary of product characteristic for full information.

Slow intravenous injection
Slow intravenous injection should be used for acute treatment, not for long term treatment. The solution of one ampoule of the product containing 1 mg of the active substance can be used only after dilution with 1.0 ml water for injection to prevent local irritation at the injection site. The solution for injection should be prepared immediately before administration.

Intravenous injection should be administered slowly, with constant monitoring of EEG, respiration, and blood pressure.

Intravenous infusion
The solution for infusion should be used for long term treatment and prepared immediately before administration. It should be administered slowly, with constant monitoring of EEG, respiration, and blood pressure.

Intramuscular injection
Only in exceptional cases, where intravenous administration is not possible, intramuscular (IM) route of administration should be used, due to the slow absorption rate following IM administration. For intramuscular injection product should not be diluted since administration will be more painful.

Dilution and stability
Stability for up to 2 hours at room temperature (25 ± 2°C) and refrigerator (2 – 8°C) has been shown for diluted intravenous infusion in

- 0.9 % NaCl
- 0.45 % NaCl + 2.5 % glucose
- 5 % glucose
- 10 % glucose

From a microbiological point of view the product should be used immediately after dilution.

Any potential change of colour of the solution for injection and intravenous infusion of the product Clonazepam has no impact on the activity or properties of the product.

The use of PVC infusion sets and infusion fluid bags and made of PVC for the preparation of solutions of this medicinal product is not recommended due to the considerable reduction in clonazepam content during storage. If the medicine is diluted in 0.9 % NaCl solution, 0.45 % NaCl solution + 2.5 % glucose solution, 5 % glucose solution and 10 % glucose solution, stored at room temperature (25 ± 2°C) in packages containing PVC, it should be used within 1 hour in relation to the loss of the active substance because of sorption on PVC.

Incompatibilities
Do not prepare Clonazepam infusions using sodium bicarbonate solution.

Do not store the solution in PVC bags, the active substance clonazepam is absorbed by PVC leading to a reduction in clonazepam concentration by up to 50 %, especially where prepared bags are stored for 24 hours or more, in warm ambient conditions, or where long tubing sets or slow rates of infusion are used. PVC-containing bags and infusion sets should be avoided when infusing clonazepam. When infusing clonazepam caution should be exercised when switching between PVC and non-PVC-containing bags and infusion sets.