



## Package leaflet: Information for the user

### Perizam 1mg/ml Oral Suspension Clobazam

**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 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 doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet:**

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

## 1. What Perizam Oral Suspension is and what it is used for

The full name of your medicine is Perizam 1mg/ml Oral Suspension. In this leaflet the shorter name Perizam is used. It contains the active ingredient Clobazam.

Perizam belongs to a group of medicines called 'benzodiazepines'. It works by having a calming effect on the brain.

Perizam can be used for:

- symptomatic treatment of severe anxiety (short term use only)
- epilepsy (fits) in adults and children over 2 (together with other treatments)
- mental illness such as schizophrenia (together with other treatments).

## 2. What you need to know before you take Perizam Oral Suspension

#### **Do not take Perizam if:**

- you are allergic to clobazam or any of the other ingredients of this medicine (listed in section 6). The signs of an allergic reaction may include swelling of your face, lips, tongue or throat, difficulty breathing or swallowing, severe itching of your skin with raised lumps
- you have ever been addicted to drugs or alcohol
- you have an illness that causes muscle weakness ('myasthenia gravis')
- you have breathing problems
- you stop breathing for short periods while you sleep ('sleep apnoea syndrome')
- you have severe liver problems

- you are in the first 3 months of pregnancy, think you might be pregnant or are breast-feeding (see section 2 ‘Pregnancy, breast-feeding and fertility’)
  - the patient is under 2 years old, except if the doctor decides this is necessary.
- Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Perizam.

### Warnings and precautions

**Note:** Make sure that you receive the same clobazam medicine **every time** you collect your prescription unless your doctor has agreed to change to a different clobazam medicine. If the appearance of this medicine is not the same as usual or if the dosage instructions have changed, speak to your doctor or pharmacist as soon as possible to make sure you have the right medicine.

There have been very rare reports of potentially life-threatening skin rashes (Stevens-Johnson Syndrome, Toxic Epidermal Necrolysis) with the use of Perizam. Symptoms of which may include: flu-like symptoms followed by a painful red or purplish rash that spreads and blisters. If you develop any of the above you must stop taking this medicine and inform your doctor straight away (see Section 4).

Talk to your doctor or pharmacist before taking Perizam if:

- you have problems with controlling your movements (‘spinal or cerebellar ataxia’)
- you have depression, irrational fears or obsessions
- you have kidney problems
- you sometimes believe things which are not true (delusions) or see things which are not there (hallucinations)
- you have ever become dependent upon another drug or alcohol. Alcohol should not be taken during treatment with Perizam as there is an increased risk of experiencing side effects
- you are over 65. This is due to increased sensitivity to adverse reactions in elderly such as drowsiness, dizziness and muscle weakness. There is also an increased risk of fall that might result in serious injury
- you have difficulty digesting medicines. Some patients liver may not metabolise (break down) medicines adequately. In these patients the medicine may remain in the body for a longer period of time. This may result in side effects. If you are known to poorly metabolise certain medicines please speak to your doctor.

Drowsiness, difficulties breathing, coma and death may occur if Perizam is taken together with opioids. Perizam and opioids should only be used concomitantly, when other treatment options are inadequate. Please tell your doctor about all opioid medicines you are taking and follow your doctor’s dosage recommendations closely.

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking Perizam.

### Suicidal thoughts

Tell your doctor straight away if you start thinking about suicide or harming yourself. Some patients have had suicidal thoughts while taking medicines containing clobazam, especially if they were also depressed.

**Dependence, withdrawal and tolerance**

You may become dependent on Perizam if you take it for a long period of time, especially if you regularly drink a lot of alcohol or use drugs. This means that you may feel that you need to continue the treatment with Perizam in order to feel well ('psychological dependence').

If you suddenly stop taking Perizam you may get:

- worsening of the symptoms you were originally being treated for
- mood changes, feeling anxious, restless, depressed or confused
- sleep problems
- loss of appetite.

These are known as 'withdrawal symptoms' and can be avoided by slowly reducing your dose. Talk to your doctor or pharmacist if you are worried about 'psychological dependence' or 'withdrawal symptoms'.

If you take Perizam for epilepsy for a long period of time then it is possible that you may become 'tolerant' to it. This means that it will not work as well as it did when you first started taking it. Talk to your doctor if you feel that Perizam is no longer helping to control your symptoms - they may suggest that you take a short break from this medicine.

**Children under 2 years**

Epilepsy (fits): Perizam should only be taken by children under 2 years if the doctor decides this is necessary.

**Other medicines and Perizam**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription and herbal medicines. This is because Perizam can affect the way some other medicines work. Also, some other medicines can affect the way Perizam works.

In particular tell your doctor or pharmacist if you are taking any of the following:

- medicines for epilepsy such as phenytoin, carbamazepine or valproic acid
- medicines for depression such as trazodone, 'SSRI's' (such as fluoxetine or citalopram), 'tricyclic anti-depressants' (such as amitriptyline or nortriptyline) or 'MAOIs' (such as phenelzine or moclobemide)
- medicines for serious mental health problems called 'neuroleptics' such as chlorpromazine, haloperidol, clozapine and pimazide
- painkillers such as medicines containing codeine, dihydrocodeine or morphine
- sleeping tablets such as zolpidem or temazepam
- medicines for anxiety such as diazepam or lorazepam
- muscle relaxants such as baclofen
- antihistamines that make you feel sleepy such as chlorphenamine, promethazine or diphenhydramine
- lithium, used for a serious mental health problem called 'bipolar disorder' (mood changes between a state of high excitability or exaggerated emotions and depression)
- cimetidine, used to treat stomach ulcers and heartburn
- omeprazole, used to treat symptoms of acid reflux such as heartburn or acid regurgitation
- ticlopidine, an antiplatelet medication used in patients with an increased risk of stroke

- fluconazole, used in the treatment of fungal conditions
- dextromethorphan, used to relieve dry irritating coughs
- nebivolol, medicines used to treat high blood pressure.

When taking Perizam you should not start taking any different medicines containing clobazam unless your doctor tells you to. If you do, it may cause breathing difficulties and sleepiness.

Concomitant use of Perizam and opioids increases the risk of drowsiness, difficulties breathing, coma and death. Follow your doctor's dosage recommendations closely.

If you are not sure if any of the above apply to you talk to your doctor or pharmacist.

### **Operations**

If you are going to have an operation or dental work, tell your doctor or dentist that you are taking Perizam. This is because they may need to change the amount of medicine (anaesthetic or muscle relaxant) they give to you.

### **Perizam with alcohol**

Do not drink alcohol while taking Perizam. This is because alcohol can change the way Perizam works.

### **Pregnancy, breast-feeding and fertility**

Do not take Perizam if:

- you are in the first 3 months of pregnancy or think you may be pregnant
- you are breast-feeding. This is because Perizam may pass into the mother's breast milk.

Talk to your doctor before taking this medicine if you are more than 3 months pregnant or plan to become pregnant.

- Your doctor may give you this medicine during later pregnancy or during labour. If this happens, there is a risk of having a baby with low body temperature, floppiness, breathing or feeding problems.
- If this medicine is taken regularly in late pregnancy, your baby may get withdrawal symptoms. In this case the newborn should be closely monitored during the postnatal period.

In fertility studies, no effects on fertility were observed in animals.

### **Driving and using machines**

You may feel sleepy or have concentration or memory problems after taking this medicine. You may also experience double vision or you may react more slowly to things. If this happens, do not drive or use any tools or machines.

The medicine can affect your ability to drive as it may make you feel sleepy or dizzy.

- Do not drive while taking this medicine until you know how it affects you.
- It is an offence to drive if this medicine affects your ability to drive.
- However, you would not be committing an offence if:
  - The medicine has been prescribed to treat a medical or dental problem
  - You have taken it according to the instructions given by the prescriber or in the information provided with the medicine
  - It was not affecting your ability to drive safely.

Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine.

**Perizam contains liquid maltitol, sodium methyl and sodium propyl parahydroxybenzoate, sodium and propylene glycol.**

- Liquid maltitol (0.3g/ml) - a type of sugar. If your doctor has told you that you cannot tolerate some sugars, talk to your doctor before taking this medicine.
- Sodium methyl parahydroxybenzoate and sodium propyl parahydroxybenzoate. These may cause an allergic reaction. This allergy may happen some time after starting the medicine.
- Sodium: This medicine contains 2.3mg sodium (main component of cooking/table salt) in each ml. This is equivalent to 0.12% of the recommended maximum daily dietary intake of sodium for an adult. This should be taken into account by patients on a low salt diet.
- This medicine contains 2.35 mg propylene glycol in each ml. If your baby is less than 4 weeks old, talk to your doctor or pharmacist before giving them this medicine, in particular if the baby is given other medicines that contain propylene glycol or alcohol.

### 3. How to take Perizam Oral Suspension

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

Perizam is usually given for 2 to 4 weeks. After that your doctor will decide whether you should keep taking this medicine.

#### Taking this medicine

- This medicine contains 1 milligram (mg) of clobazam in each 1 millilitre (ml) of suspension.
- Take this medicine by mouth.
- This product must not be mixed with other medicinal products or beverages.
- Always shake the bottle before using it.
- Always use the syringe supplied with the pack.
- Perizam can be taken with or without food.

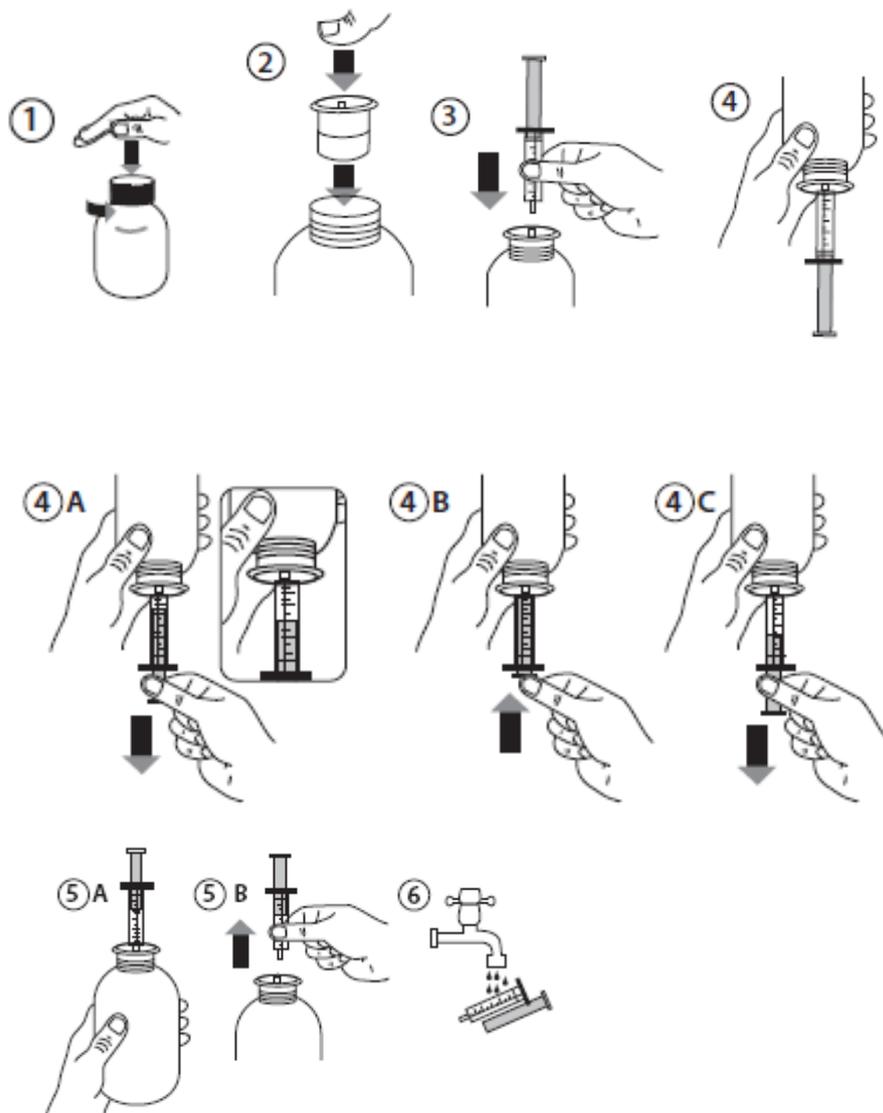
#### Measuring your dose

Instructions for use of the syringe.

If you are taking a large dose, you may have to measure the dose with the syringe more than one time. It may be helpful to write on a piece of paper the amount of times you have to use the syringe. Each time you take the dose, tick off a dose on the paper.

- Open the bottle: press the cap and turn it anticlockwise (Figure 1).
- Insert the syringe adaptor into the bottle neck (Figure 2).
- Take the syringe and put it in the adaptor opening (Figure 3).
- Turn the bottle upside down (Figure 4).
- Fill the syringe with a small amount of solution by pulling the piston down (Figure 4A). Then push the piston upward in order to remove any possible bubbles (Figure 4B). Finally, pull the piston down to the graduation mark corresponding to the quantity in millilitres (ml) prescribed by your doctor (Figure 4C).
- Turn the bottle the right way up (Figure 5A).

- Remove the syringe from the adaptor (Figure 5B). Put the end of the syringe into your mouth and push the plunger slowly back in to take the medicine.
- Wash the syringe with water and let it dry before you use it again (Figure 6).
- Close the bottle with the plastic screw cap - leave the syringe adaptor in the bottle.



### How much to take

If low doses are required, the 1mg/ml strength product is the most suitable presentation. If high doses are required, the 2mg/ml strength product is the most suitable presentation.

### Adults

- The usual dose is 20mg (20ml) to 30mg (30ml) each day. This can be taken as 2 separate doses or as a single dose at night.
- Your doctor may increase your dose to up to 60mg (60ml) each day.
- Your doctor may lower the dose to suit you.

**Children (2 years and over)**

- The usual starting dose is 0.1mg/kg each day.
- Your doctor will then change the dose according to your child's weight.

**Elderly**

- The usual dose for anxiety is 10mg (10ml) to 20mg (20ml) each day.

**If you take more Perizam than you should**

- If you take more Perizam than you should, talk to your doctor or go to the nearest hospital straight away. Take the medicine pack with you. Do not drive yourself because you may start to feel sleepy.

**If you forget to take Perizam**

- If you forget a dose, skip the missed dose. Then wait until the next dose is due.
- Do not take a double dose to make up for a forgotten dose.

**If you stop taking Perizam**

Keep taking this medicine until your doctor tells you to stop. Do not stop taking this medicine just because you feel better.

- When your doctor says you can stop taking Perizam, you need to do this gradually. Your doctor will help you to do this.
- Stopping this medicine suddenly can cause withdrawal effects (see section 2 'Dependence, withdrawal and tolerance'). Talk to your doctor or pharmacist if this happens.

If you have any further questions on the use of this medicine, ask your 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:

**Stop taking Perizam and see a doctor or go to a hospital straight away if you notice the following serious side effect - you may need urgent medical treatment:**

- allergic reaction - the signs may include swelling of your face, lips, tongue or throat, difficulty breathing or swallowing, severe itching of your skin with raised lumps.

Stop taking Perizam and see a doctor or go to a hospital straight away if you notice the symptoms listed above.

**Tell your doctor straight away if you have any of the following side effects:****Common side effects (may affect up to 1 in 10 people):**

- Feeling irritable or restless.

**Uncommon side effects (may affect up to 1 in 100 people):**

- Poor memory while taking Perizam (amnesia) or showing unusual behaviour.
- Nightmares.

- Feeling anxious.
- Believing things which are not true (delusions).
- Increased possibility of tripping or falling, especially in elderly patients.

**Not known (frequency cannot be estimated from available data):**

- Sleeping problems that get worse after taking this medicine.
- Sensing things which are not there (hallucinations).
- Being less aware of your environment, especially in the elderly.
- Feeling suicidal.
- Blistering or bleeding of the skin around the lips, eyes, mouth, nose and genitals. Also flu-like symptoms and fever. This may be something called 'Stevens-Johnson Syndrome'.
- A severe blistering rash where layers of the skin may peel off to leave large areas of raw exposed skin over the body. Also a feeling of being generally unwell, fever, chills and aching muscles. This is something called 'Toxic Epidermal Necrolysis' (TEN). Both Stevens Johnson Syndrome and TEN can be fatal.

If you get any of the above side effects, your doctor may decide that your treatment needs to be stopped. These side-effects are more likely to happen in elderly people and children.

Tell your doctor or pharmacist if any of the following side effects get serious or lasts longer than a few days, or if you notice any side effects not listed in this leaflet.

**Very common side effects (may affect more than 1 in 10 people):**

- Difficulty in staying awake or alert

**Common side effects (may affect up to 1 in 10 people):**

- Feeling sleepy or dizzy.
- Feeling agitated or being aggressive.
- Depression.
- Headache.
- Short attention span.
- Difficulty in speaking.
- Shaking fingers (tremor).
- Problems with walking or other movement problems.
- Perizam having less effect than normal (especially in long term use).
- Dry mouth, constipation.
- Loss of appetite, feeling sick (nausea).

**Uncommon side effects (may affect up to 1 in 100 people):**

- Loss of sexual drive.
- Memory difficulties, confusion.
- Double vision.

- Skin rash.
- Weight gain.

**Not known (frequency cannot be estimated from available data):**

- Becoming dependent on Perizam ('physical or mental dependence') (especially in long term use).
- A feeling of being out of touch with reality and being unable to think or judge clearly (psychosis).
- Feeling angry.
- Changes in the way you walk.
- Breathing problems.
- Sensitivity to sunlight.
- Itchy, lumpy rash (urticaria).
- Muscle spasms or muscle weakness.
- Reacting to things more slowly than usual.
- Rapid uncontrollable movement of the eyes.
- Learning problems.
- Abnormally low body temperature.

If you take this medicine for a long time, you are more likely to get the following side effects: anxiety, confusion, depression, loss of appetite and difficulty sleeping.

Use of Perizam may lead to a physical addiction. Stopping Perizam suddenly may lead to side effects. Dependence on Perizam may occur. Talk to your doctor if you feel you have developed a dependence on Perizam.

**Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

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**5. How to store Perizam Oral Suspension**

- Keep this medicine out of the sight and reach of children.
- Do not store above 25°C.
- Do not use 28 days after you first open it. Take it back to the pharmacy.

- Do not use this medicine after the expiry date (month, year) which is stated on the label after EXP. The expiry date refers to the last day of that month.
- Do not use Perizam if you notice anything wrong with the medicine. Talk to your doctor or pharmacist.
- 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 Perizam contains**

- The active substance is clobazam. Each ml of oral suspension contains 1mg of clobazam.
- The other ingredients are aluminium magnesium silicate, citric acid monohydrate (E330), di-sodium hydrogen phosphate dihydrate, simethicone emulsion, sucralose (E955), polysorbate 80 (E433), masking flavour (contains propylene glycol (E1520)), raspberry flavour, xanthan gum (E415), sodium propyl hydroxybenzoate (E217), sodium methyl hydroxybenzoate (E219), liquid maltitol (E965) and purified water.

### **What Perizam looks like and contents of the pack**

Perizam is an off-white suspension. It comes in a brown glass bottle holding 150ml of suspension with a 5ml syringe and bottle adaptor. The bottle adaptor is not pre-fitted.

### **The Marketing Authorisation Holder and Manufacturer is**

#### **Marketing Authorisation Holder:**

Perrigo Pharma International DAC, The Sharp Building, Hogan Place, Dublin 2, Ireland. Tel: +353 (0) 1 709 4000

#### **Manufacturer:**

Jenson R+ (Ireland) Ltd, 2 Dublin Landing, N Wall Quay, North Dock, Dublin 1, D01 V4A3, Ireland.

This medicinal product is authorised in the Member States of the EEA under the following names:

|         |                                    |
|---------|------------------------------------|
| UK      | Perizam 1mg/ml Oral Suspension     |
| Ireland | Perizam 1mg/ml Oral Suspension     |
| France  | Likozam 1 mg/ml suspension buvable |

**This leaflet was last revised in 12/2020.**