Package leaflet: Information for the user

Epaclob 1 mg/ml and 2 mg/ml oral suspension

clobazam

Read all of this leaflet carefully before you starts 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, pharmacist or nurse.
- This medicine has been prescribed for you. 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Epaclob oral suspension is and what it is used for

Epaclob oral suspension contains clobazam which belongs to a group of medicines called benzodiazepines.
Clobazam works by having a calming effect on the brain.
Epaclob oral suspension is used to treat:
- Epilepsy (fits) (in combination with other treatments) in adults or children over 2 years of age, if standard treatment with one or more anticonvulsants has failed.

2. What you need to know before you take Epaclob oral suspension

Do not take Epaclob oral suspension:
- If you are allergic (hypersensitive) to clobazam, other benzodiazepine medicines or any of the other ingredients of this medicine (listed in section 6)
  Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- If you suffer from an illness that causes muscle weakness (called 'myasthenia gravis')
- If you have breathing problems
- If you stop breathing for short periods during sleep (called 'sleep apnoea syndrome')
- If you have severe liver problems
- If you are breast-feeding
- If you have ever had problems with drugs or alcohol dependence in the past
- if you are taking any medicinal or non-medicinal products containing cannabidiol, as it may increase the side effects of clobazam.

Clobazam is only to be used in children aged from 1 month to 2 years, in exceptional cases where the antiepileptic treatment is indispensable.

If you have kidney problem, careful observation is required whilst using clobazam, your doctor will decide whether to reduce the dose of Epaclob oral suspension.

If you are elderly, the dose might be reduced by your doctor.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Epaclob oral suspension.

Switching from tablet to oral suspension

You should be careful whilst switching from tablet to oral suspension as the doses are not identical. You might observe breathing problem or feel sleepy when switching to Epaclob oral suspension from tablet.

You might also observe an increase in frequency of epilepsy or new forms of epilepsy with Epaclob oral suspension. Please talk to your doctor if you experience this symptom.
Alcohol.

Don't take alcohol during treatment with Clobazam as there is an increased risk of experiencing side effects.

Amnesia (memory loss)
You may observe memory loss during treatment with Epaclob oral suspension when used in the normal dosage range. Most of these, however, occur only at higher doses.

Muscle weakness
Epaclob oral suspension may cause muscle weakness. Talk to your doctor if you have problems with controlling your movements (called 'spinal or cerebellar ataxia'). In severe muscle weakness (myasthenia gravis) Epaclob should not be used.

Dependence, tolerance and withdrawal
It is possible for you to become dependent on Epaclob oral suspension if you take it for a long period of time or with high dose, particularly if you have a history of heavy alcohol or drug use. This means that you may feel that you need to continue treatment with Epaclob oral suspension in order to feel well (known as psychological dependence). You should therefore take the drug for as short time as possible.

If you suddenly stop taking Epaclob oral suspension you may experience worsening of the symptoms you were originally being treated for, as well as mood changes, anxiety, sleep disturbance, headache, increased dreaming, tension, confusion, excitability, hallucinations, muscle pain, numbness of the limb tingling, sweating, tremor, nausea, sensitivity to light, increased sensitivity to sound, sensitivity to light or restlessness. This is known as withdrawal symptoms and can be avoided by slowly reducing your dose. If you are worried about dependence or withdrawal pleas talk to your doctor.

If you take Epaclob oral suspension for long periods of time for treatment of epilepsy it is possible that you may become tolerant to it, meaning that it will not be as effective as it was when you first started taking it. If you feel that Epaclob oral suspension is no longer helping to control your symptoms please talk to your doctor, they may suggest you take a short break from this medicine.

Breathing difficulties
Epaclob oral suspension may cause respiratory depression, particularly when administered at high doses. Tell your doctor if you have respiratory failure, your doctor will decide whether to reduce the dose. In case of severe respiratory disturbance, clobazam may not be used.

Kidney and liver failure
Report your doctor if your liver or kidneys do not work as well as they should. Your doctor will decide whether to reduce the dose of Epaclob oral suspension.

Elderly
Patients over 65 years may be affected by Epaclob more than younger patients. Drowsiness, dizziness, muscle weakness, increased risk of falling that could result in serious injury can occur. If you are over 65, your doctor may prescribe a lower dose and check your response to treatment. Please carefully follow the instructions of your doctor.

Serious skin problems
Epaclob may cause serious skin reactions. You should talk to your doctor if you develop any rash unless it is clearly not drug related.

Depression and Suicidal thoughts
Some patients have experienced suicidal thoughts whilst taking medicines containing clobazam, particularly if they are already depressed. If you are depressed, have irrational fears and obsessions, have started experiencing thoughts of suicide or harm towards yourself, please tell your doctor **immediately**.

Psychotic reactions and 'paradoxical' reactions
It is known that with the use of clobazam restlessness, agitation, irritability, aggression, delusions, rage, nightmares, hallucinations, deceptive thoughts (psychosis), inappropriate behaviour and other adverse behavioural effects may occur. If this happens you should stop taking Epaclob oral suspension and contact your doctor. These reactions are more common in children and elderly patients.

Poor metabolism
Some patient's 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.

Children from 1 month to 2 years:
Epaclob oral suspension should only be taken by children under 2 years if the doctor decides this is necessary.

Drowsiness, difficulties breathing, coma and death may occur if Epaclob 1mg/ml and 2mg/ml oral suspension is taken together with opioids. [invented name] oral suspension 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.

Other medicines and Epaclob Oral Suspension
Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might use any other medicines. At higher doses of clobazam, the concomitant use of other drugs may increase or decrease its effect., these include :

- Medicines for epilepsy (such as phenytoin, carbamazepine or valoproic acid, stiripentol)
- Medicines for depression (such as trazodone, selective serotonin reuptake inhibitors-'SSRIs' (such as fluoxetine or citalopram), tricyclic anti-depressants (such as amitriptyline or nortriptyline) or monoamine oxidase inhibitors-'MAOIs' (such as phenelzine or moclobemide)
- Medicines for severe mental illness called 'neuroleptics' (such as chlorpromazine, haloperidol and clozapine)
- Painkillers (such as medicines containing codeine, dihydrocodeine or morphine)
- Sleeping tablets (such as zolpidem)
- Tranquilisers (such as diazepam, temazepam or lorazepam)
- Muscle relaxants (such as baclofen)
- Antihistamine that make you sleepy (such as chlorphenamine, promethazine or diphenhydramine)
- Lithium – used for a mental illness called 'bipolar disorder' (mood changes between a state of high excitability emotions and depression)
- Cimetidine (used to treat ulcers and heartburn)
- Antibiotic erythromycin
- Omeprazole - used to treat the 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
- Fluvoxamine, paroxetine (medicines for depression)
- Dextromethorphan - used to relieve dry, irritating coughs
- Nebivolol - medicine used to treat high blood pressure
- Pimozide - medicine used to treat mental disorder
- Cannabidiol-containing products (medicinal or non-medicinal products).

Concomitant use of Epaclob and opioids (strong pain killers, medicines for substitution therapy and some cough medicines) increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening. Because of this, concomitant use should only be considered when other treatment options are not possible.
However if your doctor does prescribe Epaclob together with opioids the dose and duration of concomitant treatment should be limited by your doctor.
Please tell your doctor about all opioid medicines you are taking, and follow your doctor's dose recommendation closely. It could be helpful to inform friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.

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

Anaesthetics
If you are going to have an anaesthetic, tell your doctor or anaesthetist you are taking Epaclob Oral Suspension. This is because your doctor may need to change the amount of anaesthetic or muscle relaxants given to you.

Epaclob oral suspension with food, drink and alcohol
Do not drink alcohol while you are taking Epaclob oral suspension. This is because alcohol can change the way Epaclob oral suspension works.

Pregnancy ,breast-feeding and fertility
Pregnancy

Use of this medicine is not recommended during pregnancy and in women of childbearing potential not using contraception.

If you discover that you are pregnant or are planning to have a baby, consult your doctor right away to re-assess the need for treatment. Do not stop taking <invented name> without talking to your doctor.

A large amount of data has not shown evidence of malformations associated with the use of benzodiazepines. However, some studies have shown a potentially increased risk of cleft lip and palate in newborn babies compared to that in the general population.

Cleft lip and palate (sometimes called “harelip”) is a deformation at birth caused by incomplete fusion of the palate and upper lip.

Reduced fetal movement and fetal heart rate variability may occur after taking Clobazam during the second and/or third trimester of pregnancy.

If Epaclob is taken at the end of pregnancy or during childbirth, your baby may show drowsiness (sedation), muscle weakness (hypotonia or floppy infant syndrome), a drop in body temperature (hypothermia), difficulty feeding (problems suckling causing poor weight gain) and breathing problems (respiratory depression sometimes severe).

If taken regularly in late pregnancy, your baby may get withdrawal symptoms such as agitation or shaking. In this case the newborn should be closely monitored during the postnatal period.
Breastfeeding

As clobazam, the active substance in Epaclob oral suspension, is excreted into breast milk, you must not use Epaclob oral suspension during breast-feeding**.**

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Driving and using machines

Clobazam has major influence on the ability to drive and use 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. Do not drive or use any tools or machines if you are affected in this way.

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

Epalcob contains sorbitol, sodium methyl parahydroxybenzoate, sodium propyl parahydroxybenzoate, sodium and propylene glycol

- this medicine contains 250 mg sorbitol in each ml of suspension. Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine. Sorbitol may cause gastrointestinal discomfort and mild laxative effect.

- this medicine contains 2.06 mg sodium methyl hydroxy benzoate and 0.224 mg sodium propyl hydroxy benzoate in each ml of suspension. May cause allergic reactions (possibly delayed), and exceptionally, bronchospasm.
- this medicine contains 3.33 mg of sodium (main component of cooking/table salt) in each ml of suspension: This is equivalent to 10% of the recommended maximum daily dietary intake of sodium for an adult.
- this medicine contains 4.825 mg propylene glycol in each ml of suspension. If your child is less than 5 years old, talk to your doctor or pharmacist before giving them this medicine, in particular if they use other medicines that contain propylene glycol or alcohol. If you are pregnant or breast-feeding, do not take this 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.

If you have any concerns over whether this medicine is suitable for you, talk to your doctor, pharmacist or nurse.

3. How to take Epaclob oral suspension

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

Epaclob oral suspension is usually given for 2 to 4 weeks. Then every 4 weeks thereafter your doctor will determine the need for continued treatment. Check with your doctor or pharmacist if you are not sure.

When you are taking Epaclob oral suspension you should not change to any different Epaclob containing medicines except under your doctor's supervision.

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.

<u>The recommended dose is</u>
Adults and adolescents

- The starting dose is 5-15 mg each day gradually increasing as necessary.
- Your doctor may increase your dose to up to 60 mg each day.
- Your doctor may lower the dose to suit you.

Use in Children (2-16 years)

- The starting dose is 5 mg each day for children aged 6 years and above or 0.1 mg/kg/day for younger patients and gradually increasing as necessary after every 7 days.
- The usual maintenance dose of 0.3 to 1 mg/kg per day. This can be taken in divided doses or as a single dose at night.
- Your doctor will then adjust the dose according to your child's need.

Clobazam is generally not suitable for use in children under the age of 2 years. It may however be used under specialist medical care.

In patients with liver or kidney disease and in elderly patients lower initial doses are required, with a gradual increase under careful observation of your doctor (see section "Warnings and precautions").

Method of administration
This product may settle during storage. **Please shake well before use.**
Your doctor, pharmacist or nurse will show you how to administer this medicine. The box containing this medicine will contain a 5ml dosing syringe, a dosing adaptor and a 30ml dosing cup.

5ml syringe- each numbered increment is 1ml equivalent to 1mg of Epaclob 1mg/ml oral suspension and 2mg of Epaclob 2mg/ml oral suspension. The smaller increments are 0.2ml or 0.2mg of Epaclob 1mg/ml oral suspension and 0.4mg of Epaclob 2mg/ml oral suspension.

30ml dosing cup- each numbered increment is 5ml - equivalent to 5mg of Clobzam 1mg/ml oral suspension and 10mg of Epaclob 2mg/ml oral suspension.

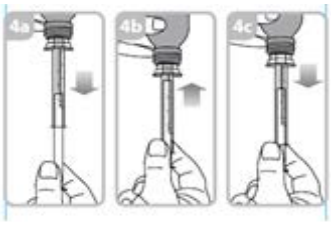
Instructions are provided overleaf for using the dosing syringe. If you have any questions about the dose you should use or how to use the syringe, you should ask your pharmacist.

Instructions for use:
Open the bottle: press the cap and turn it anticlockwise (figure 1)

Holding the bottle, take the plastic syringe adaptor from the box and insert the adaptor into the bottle neck (figure 2). Ensure it is well fixed.

Take the syringe and put it in the adaptor opening (figure 3). Turn the bottle upside down.

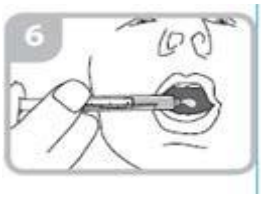
Fill the syringe with a small amount of suspension by pulling the piston down (figure 4a), then push the piston upward in order to remove any possible bubble (figure 4b). Pull the piston down to the graduation mark corresponding to the quantity in milliliters (ml) prescribed by your doctor (figure 4C).



Turn the bottle the right way up.

Remove the syringe from the adaptor (figure 5)

Administer the contents of the syringe into the mouth by pushing the piston to the bottom of the syringe (figure 6) and ensure the medicine is swallowed.



Remove the adaptor from the bottle and close the bottle with the plastic screw cap.

Wash the adaptor and the syringe with warm water. Dry them with a clean paper towel and replace them into the box with your medicine.

If you take more Epaclob oral suspension than you should
If you take more Epaclob oral suspension than you should, tell your doctor or go to your nearest hospital casualty department **immediately,** also take the medicine pack with you**. Do not** drive yourself because you may start to feel sleepy.

If you forget to take Epaclob oral suspension
If you have missed a dose take it as soon as your remember unless it is almost time for the next one then carry on as before. **Do not** take a double dose to make up for a forgotten dose.

If you stop taking Epaclob oral suspension
Do not stop taking your medicine without telling your doctor as he may **gradually** reduce your dose before stopping it completely. **If stopped suddenly, you may have unpleasant side effects** including stress (anxiety), confusion, or depression. You may also lose your appetite and have difficulty sleeping (see Section 2 'Dependence, tolerance and withdrawal').

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

3. Possible side effects

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

Serious Side Effects:

Tell your doctor **immediately** 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 [invented name] oral suspension (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 the 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'.

If you get any of the above side effects, your doctor may decide that your treatment needs to be stopped.

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.
- Dry mouth, constipation.
- Loss of appetite, feeling sick (nausea).

Uncommon side effects (may affect up to 1 in 100 people):
• Loss of sexual drive when used for long time or with high doses and is reversible.
• Memory difficulties, confusion.
• Double vision.
• Skin rash.
• Weight gain.

Not known (frequency cannot be estimated from available data):
• Becoming dependent on [invented name] oral suspension ('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.**

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance Earlsfort Terrace, IRL - Dublin 2, Tel: +353 1 6764971, Fax: +353 1 6762517, Website: www.hpra.ie
e-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

4. How to store Epaclob oral suspension

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

Do not use this medicine after the expiry date stated on the bottle label and carton after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C. Use within 28 days of opening.

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

5. Contents of the pack and other information

What Epaclob oral suspension contains

- The active substance (the ingredient that makes the oral solution work) is Epaclob.

Epaclob 1 mg/ml oral suspension
Each ml contains 1 mg/ml of Epaclob

Epaclob 2 mg/ml oral suspension
Each ml contains 2 mg/ml of Epaclob

The other ingredients are sorbitol (E420), xanthan gum (E415), acesulfame potassium (E950), raspberry flavour, sodium propyl hydroxybenzoate (E217), sodium methyl hydroxybenzoate (E219), disodium hydrogen phosphate dehydrate, sodium dihydrogen phosphate dehydrate and purified water.

What Epaclob oral suspension looks like and contents of the pack
Epaclob oral suspension is an off white viscous suspension with an odour of raspberry supplied in an amber glass bottle.
The contents may settle during storage and should be shaken before use.
Pack sizes are 100ml, 150ml and 250 ml.
A 30 ml polypropylene dosing cup and a 5 ml syringe are supplied with this pack.
Not all pack sizes may be marketed.

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The medicinal product is authorised in the Member States of the EEA under the following names:
Germany: Epaclob® 1 mg/ml Suspension zum Einnehmen; Epaclob 2 mg/ml Suspension zum Einnehmen
Denmark: Silocalm®
Spain: Silocalm® 1 mg/ml suspensión oral; Silocalm 2 mg/ml suspensión oral
Italy: Epaclob® 1mg/ml e 2 mg/ml sospensione orale
Ireland: Epaclob® 1mg/ml oral suspension; Epaclob 2 mg/ml oral suspension

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