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Package leaflet:
Information for the user

Clobazam Milpharm 10 mg Tablets

clobazam

This medicine contains clobazam, which can cause dependence, tolerance and addiction. You can get withdrawal symptoms if you stop taking it or reduce the dose suddenly. If this medicine is being used for the treatment of epilepsy you must continue to take this medicine as instructed by your doctor.

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, pharmacist, or nurse.
- 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 Clobazam Milpharm is and what it is used for
2. What you need to know before you take Clobazam Milpharm
3. How to take Clobazam Milpharm
4. Possible side effects
5. How to store Clobazam Milpharm
6. Contents of the pack and other information

1. What Clobazam Milpharm is and what it is used for

This medicine has been prescribed for you for:
- Severe anxiety over a short time
- Epilepsy (fits) over a longer time
- Mental illness such as schizophrenia (in combination with other treatments)

It contains clobazam which belongs to a class of medicines called benzodiazepines.

This medicine has been prescribed to you and should not be given to anyone else.

Benzodiazepines can cause dependence, tolerance and addiction, and you may get withdrawal symptoms if you stop taking it or reduce the dose suddenly. Your prescriber should have explained how long you will be taking it for and, when it is appropriate to stop, how to do this safely. When your treatment is stopped, it is usually done gradually over a period which is specific to you and may occur over a period of weeks to months. If this medicine is being used for the treatment of epilepsy you must continue to take it as prescribed by your doctor.

2. What you need to know before you take Clobazam Milpharm

Do not take Clobazam Milpharm if:
- You are allergic (hypersensitive) to clobazam, other benzodiazepine medicines or any of the other ingredients of Clobazam Milpharm Tablets (see section 6).

Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- You are pregnant or are planning to have a baby (see below under 'Pregnancy, breast-feeding and fertility' for more information).
- You are breast-feeding.
- You have ever had problems with drugs or alcohol dependence in the past.
- You suffer from an illness that causes muscle weakness (called 'myasthenia gravis').
- You have liver problems.
- You have breathing problems.
- You stop breathing for short periods during sleep (called 'sleep apnoea syndrome')
- The patient is under 6 years old.

Do not take if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Clobazam Milpharm.

Warnings and precautions
Talk to your prescriber before taking this medicine if:
- You have problems with controlling your movements (called 'spinal or cerebellar ataxia').
- You have depression, irrational fears and obsessions.
- You have delusions (believing things which are not true) or hallucinations (sensing things which are not there).
- You have kidney problems.
- You have ever become dependent upon another drug or alcohol. Alcohol should not be taken during treatment with Clobazam Milpharm as there is an increased risk of experiencing side effects.
- You are over 65. This is due to the increased sensitivity to adverse reactions in the elderly such as drowsiness, dizziness and muscle weakness. There is also an increased risk of fall that may result in serious injury.
- You have difficulty digesting medicines. Some patients' livers 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.
- You are taking any medicinal or non-medicinal products containing cannabidiol, as it may increase the side effects of clobazam.

Your prescriber will discuss with you how to gradually reduce your dose before stopping the medicine. It is important that you do not stop taking the medicine suddenly as you will be more likely to experience withdrawal symptoms. Your prescriber will ensure that your plan for stopping treatment is tailored to you and can be adapted according to your needs and experience of any withdrawal symptoms.

Benzodiazepines should only be used by those they are prescribed for. Do not give your medicine to anyone else. Taking higher doses or more frequent doses of benzodiazepines may increase the risk of addiction. Overuse and misuse can lead to overdose and/or death.

Drowsiness, difficulties breathing, coma and death may occur if Clobazam Milpharm is taken together with opioids. Clobazam Milpharm 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.

Some studies have shown an increased risk of suicidal ideation, suicide attempt and suicide in patients taking certain sedatives and hypnotics, including this medicine. However, it has not been established whether this is caused by the medicine or if there may be other reasons. If you have suicidal thoughts, contact your doctor as soon as possible for further medical advice (see section 4).

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Clobazam Milpharm.

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

In particular, tell your doctor if you are taking any of the following:
- Medicines for epilepsy (such as phenytoin, carbamazepine, stiripentol or valproic acid).
- Medicines for depression (such as Monoamine Oxidase Inhibitors (MAOIs) or tricyclic anti-depressants such as trazodone, or Selective Serotonin Re-uptake Inhibitors (SSRIs) such as fluvoxamine or paroxetine).
- Medicines for severe mental illness called 'antipsychotics' (such as chlorpromazine, haloperidol, clozapine and pimozide).
- 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).
- Antihistamines that make you sleepy (such as chlorphenamine, promethazine or diphenhydramine).
- Lithium – used for a mental illness called 'manic-depressive illness' (mood changes between a state of high excitability or exaggerated emotions and depression).
- Cimetidine – used to treat ulcers and heartburn.
- Omeprazole – used to treat stomach conditions.
- Ticlopidine – an antiplatelet medication used to prevent blood clots.
- Fluconazole – used in the treatment of fungal conditions.
- Dextromethorphan – used to relieve dry, irritating coughs.
- Nebivolol – used to treat high blood pressure.
- Cannabidiol-containing products (medicinal or non-medicinal products).

Concomitant use of clobazam 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.

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

Clobazam Milpharm with alcohol
Do not drink alcohol while taking Clobazam Milpharm. This is because there is increased risk of sleepiness and other side effects.

Pregnancy, breast-feeding and fertility
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 reassess the need for treatment. Do not stop taking Clobazam Milpharm without talking to your doctor.

A large amount of data has not shown evidence for 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.

Talk to your prescriber before taking this medicine if you:
- are or have ever been addicted to opioids, alcohol, prescription medicines, or illegal drugs, or if you
- have ever had a history of struggling to control your alcohol or drug intake.
- have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs.
- feel you need to take more of Clobazam Milpharm to get the same level of symptom control, this may mean you are developing tolerance to the effects of this medicine or are becoming addicted to it. Speak to your prescriber who will discuss your treatment and may change your dose or switch you to an alternative medication.

Taking this medicine regularly, particularly for a long time, can lead to physical dependence and addiction. Your prescriber should have explained how long you will be taking it for and, when it is appropriate to stop, how to do this safely. When your treatment is stopped, it is usually done gradually over a period which is specific to you and may occur over a period of weeks to months.

Physical dependence and addiction can cause withdrawal symptoms when you stop taking this medicine. Withdrawal symptoms can include: headaches, muscle pain, anxiety, tension, depression, restlessness, sweating, confusion or irritability. Do not stop taking your tablets suddenly. This could lead to more serious symptoms such as loss of the sense of reality, feeling unreal or detached from life, and unable to feel emotion. Some patients have also experienced numbness or tingling of the arms or legs, tinnitus (ringing sounds in the ears), oversensitivity to light, sound and touch, uncontrolled or overactive movements, twitching, shaking, feeling sick, being sick, stomach upsets or stomach pain, loss of appetite, agitation, abnormally fast heartbeats, panic attacks, dizziness or feeling that you are about to fall, memory loss, hallucinations, feeling stiff and unable to move easily, feeling very warm, convulsions (sudden uncontrolled shaking or jerking of the body).

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

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

If Clobazam Milpharm 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.

Do not take Clobazam Milpharm if you are breast-feeding or are planning to breast-feed. This is because it may pass into the mothers' milk.

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 sleepy or dizzy.

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- 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:
  - o The medicine has been prescribed to treat a medical or dental problem and
  - o You have taken it according to the instructions given by the prescriber or in the information provided with the medicine and
  - o 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.

Clobazam Milpharm Tablets contain lactose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Clobazam Milpharm

Always take this medicine exactly as your doctor has told you. **You should not take Clobazam Milpharm for longer than 4 weeks.** You should check with your doctor or pharmacist if you are not sure.

Your prescriber should have discussed with you how long the course of tablets will last. They will arrange a plan for stopping treatment. This will outline how to gradually reduce the dose and stop taking the medicine. Your prescriber will ensure that your plan for stopping treatment is tailored to you and can be adapted according to your needs and experience of any withdrawal symptoms.

Taking this medicine
Swallow the tablets whole or crushed and mixed with apple sauce. The tablets can be divided into equal halves of 5mg. Clobazam Milpharm can be taken with or without food.

- If you feel the effect of your medicine is too weak or too strong, do not change the dose yourself, but ask your doctor.
- Keep taking Clobazam Milpharm until your doctor tells you to stop.
- Clobazam Milpharm is usually given for 2-4 weeks. After that, your doctor will decide whether you should keep taking this medicine.

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

Children (6 years and above)
- The usual dose is 5mg each day.

Elderly
- The usual dose for anxiety is 10-20mg each day.

If you take more Clobazam Milpharm than you should
If you take more Clobazam Milpharm than you should, tell your doctor or go to your nearest hospital casualty department straight away. Do not drive yourself, because you may start to feel sleepy. Remember to take with you any tablets that are left and the pack. This is so the doctor knows what you have taken.

If you forget to take Clobazam Milpharm
- If you forget a dose, take it as soon as you remember it.
- However, if it is nearly time for the next dose, skip the missed dose.
- **Do not** take a double dose to make up for a forgotten tablet.

If you stop taking Clobazam Milpharm

Do not suddenly stop taking this medicine. If you want to stop taking this medicine, discuss this with your prescriber first. They will tell you how to do this, usually by reducing the dose gradually so that any unpleasant withdrawal effects are kept to a minimum. This may occur over a period of weeks to months. Your prescriber will ensure that your plan for stopping treatment is tailored to you and can be adapted according to your needs and experience of any withdrawal symptoms.

Withdrawal symptoms such as: headaches, muscle pain, anxiety, tension, depression, restlessness, sweating, confusion or irritability. Do not stop taking your tablets suddenly. This could lead to more serious symptoms such as loss of the sense of reality, feeling unreal or detached from life, and unable to feel emotion. Some patients have also experienced numbness or tingling of the arms or legs, tinnitus (ringing sounds in the ears), oversensitivity to light, sound and touch, uncontrolled or overactive movements, twitching, shaking, feeling sick, being sick, stomach upsets or stomach pain, loss of appetite, agitation, abnormally fast heartbeats, panic attacks, dizziness or feeling that you are about to fall, memory loss, hallucinations, feeling stiff and unable to move easily, feeling very warm, convulsions (sudden uncontrolled shaking or jerking of the body).

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. You may feel ill after taking the tablets or notice unusual or unexpected symptoms. If this happens, tell your doctor.

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 Clobazam Milpharm (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'.

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
- Clobazam Milpharm 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):
- Dependence and addiction (see section "How do I know if I am tolerant or addicted?").
- 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

The following side effects are more likely to happen at the start of treatment. They usually last for a short time: feeling tired, dry mouth, constipation, loss of appetite, feeling sick, shaking fingers.

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.

Drug Withdrawal
When you stop taking Clobazam Milpharm, you may experience drug withdrawal symptoms, which include: headaches, muscle pain, anxiety, tension, depression, restlessness, sweating, confusion or irritability. Do not stop taking your tablets suddenly. This could lead to more serious symptoms such as loss of the sense of reality, feeling unreal or detached from life, and unable to feel emotion. Some patients have also experienced numbness or tingling of the arms or legs, tinnitus (ringing sounds in the ears), oversensitivity to light, sound and touch, uncontrolled or overactive movements, twitching, shaking, feeling sick, being sick, stomach upsets or stomach pain, loss of appetite, agitation, abnormally fast heartbeats, panic attacks, dizziness or feeling that you are about to fall, memory loss, hallucinations, feeling stiff and unable to move easily, feeling very warm, convulsions (sudden uncontrolled shaking or jerking of the body).

How do I know if I am tolerant or addicted?
If you notice any of the following signs whilst taking Clobazam Milpharm, it could be a sign that you have become addicted.
- You may feel the need to keep taking the medication for longer than your doctor recommended
- You feel you need to use more than the recommended dose
- You are using the medicine for reasons other than prescribed
- When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again

If you notice any of these signs, it is important you talk to your prescriber.

Reporting of side effects
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

5. How to store Clobazam Milpharm

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

This medicine does not require any special storage conditions.

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 Clobazam Milpharm Tablets contain:
- The active substance is clobazam. Each tablet contains 10 mg of clobazam.
- The other ingredients are lactose monohydrate, starch, pregelatinised (maize starch), talc, silica colloidal anhydrous, and magnesium stearate

What Clobazam Milpharm Tablets look like and contents of the pack

Clobazam Milpharm 10 mg Tablets are white to off-white, round, approximately 6mm, biconvex uncoated tablet debossed with "CL and 10" separated with scoreline on one side and plain on the other side.

The tablet can be divided into equal doses.

The tablets are provided in clear PVC - Aluminium foil blister pack.
Pack size of 30 tablets.

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