Package leaflet: Information for the user

Topiramate Milpharm 25 mg film-coated tablets
Topiramate Milpharm 50 mg film-coated tablets
Topiramate Milpharm 100 mg film-coated tablets
Topiramate Milpharm 200 mg film-coated tablets

topiramate

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

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

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

Topiramate belongs to a group of medicines called "anti-epileptic medicines". It is used:
- alone to treat seizures in adults and children over age 6.
- with other medicines to treat seizures in adults and children aged 2 years and above.
- to prevent migraine headaches in adults

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

Do not take Topiramate Milpharm
- if you are allergic to topiramate or any of the other ingredients of this medicine (listed in section 6).

For migraine prevention:
- You must not use Topiramate Milpharm if you are pregnant
- If you are a woman who is able to become pregnant, you must not take Topiramate Milpharm, unless you use highly effective contraception (birth control) during your treatment. See below under "Pregnancy, breast-feeding and fertility – Important advice for women".

Treatment of epilepsy :
- You must not use Topiramate Milpharm if you are pregnant, unless no other treatment gives sufficient seizure control for you.
- If you are a woman who is able to become pregnant, you must not take Topiramate Milpharm unless you use highly effective contraception (birth control) during your treatment. Do not stop taking Topiramate Milpharm or your contraception until you have discussed this with your doctor. Your doctor will advise you further and make sure you are aware of and understand all of the risks of taking Topiramate Milpharm during pregnancy and the risks of seizures during pregnancy See below under "Pregnancy, breast-feeding and fertility – Important advice for women".

Make sure you read the patient guide that you will receive from your doctor.
A patient card is provided with the Topiramate Milpharm package to remind you of the risks in pregnancy.

If you are not sure if the above applies to you, talk to your doctor or pharmacist before using Topiramate.

Warnings and precautions
Talk to your doctor or pharmacist before taking Topiramate Milpharm if you:
- have kidney problems, especially kidney stones, or are getting kidney dialysis
- have a history of blood and body fluid abnormality (metabolic acidosis).
- have liver problems
- have eye problems, especially glaucoma
- have a growth problem
- are on a high fat diet (ketogenic diet)
- are a woman who is able to become pregnant. Topiramate Milpharm can harm an unborn child when taken during pregnancy. Highly effective contraception (birth control) must be used during your treatment and for at least 4 weeks after the last Topiramate Milpharm dose. See section 'pregnancy and breastfeeding' for further information.
- are pregnant. Topiramate Milpharm can harm an unborn child when taken during pregnancy.

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

If you have epilepsy, it is important that you do not stop taking your medicine without first consulting your doctor.

You should also talk to your doctor before taking any medicine containing topiramate that is given to you as an alternative to Topiramate Milpharm.

You may lose weight if you use Topiramate Milpharm so your weight should be checked regularly when using this medicine. If you are losing too much weight or a child using this medicine is not gaining enough weight, you should consult your doctor.

A small number of people being treated with anti-epileptic medicines such as Topiramate Milpharm have had thoughts of harming or killing themselves. If at any time you have these thoughts, immediately contact your doctor.

Topiramate can cause serious skin reactions, tell your doctor immediately if you develop a skin rash and/or blisters (see also section 4 'Possible side effects').

Topiramate Milpharm may in rare cases cause high levels of ammonia in the blood (seen in blood tests) which can lead to a change in brain function, especially if you are also taking a medicine called valproic acid or sodium valproate. Since this may be a severe condition, tell your doctor immediately if the following symptoms occur (see also section 4 'Possible side effects'):
- difficulty thinking, remembering information, or solving problems
- being less alert or aware
- feeling very sleepy with low energy

At higher doses of Topiramate Milpharm, the risk of developing these symptoms may increase.

Other medicines and Topiramate Milpharm

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Topiramate Milpharm and certain other medicines can affect each other. Sometimes the dose of some of your other medicines or Topiramate Milpharm will have to be adjusted.

Especially, tell your doctor or pharmacist if you are taking:
- other medicines that impair or decrease your thinking, concentration, or muscle coordination (e.g. central nervous system depressant medicines such as muscle relaxants and sedatives).
- hormonal contraceptives. Topiramate Milpharm can affect how well some hormonal contraceptive (birth control) methods work. An additional barrier method of contraception such as a condom or pessary/diaphragm should be used. You should talk to your doctor about the best kind of contraception to use while you are taking Topiramate Milpharm.

Tell your doctor if your menstrual bleeding changes while you are taking hormonal contraceptives and Topiramate Milpharm. Irregular bleeding may occur. In this case, continue taking the hormonal contraceptives and inform your doctor.

Keep a list of all the medicines you take. Show this list to your doctor and pharmacist before you start a new medicine.

Other medicines you should discuss with your doctor or pharmacist include other anti-epileptic medicines, digoxin, risperidone, lithium, hydrochlorothiazide, metformin, pioglitazone, glibenclamide, amitriptyline, haloperidol, propranolol, diltiazem, venlafaxine, flunarazine, St. John's wort (Hypericum perforatum) (a herbal preparation used to treat depression) warfarin used to thin the blood.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before using Topiramate Milpharm.

Topiramate Milpharm with food, drink and alcohol
You can take Topiramate Milpharm with or without food. Drink plenty of fluids during the day to prevent kidney stones while taking Topiramate Milpharm. You should avoid drinking alcohol when taking Topiramate Milpharm.

Pregnancy and breast-feeding and fertility
Important advice for women who are able to become pregnant

Topiramate Milpharm can harm an unborn child. If you are a woman who is able to become pregnant, talk to your doctor about other possible treatments. Visit your doctor to review your treatment and discuss the risks at least once a year.

Migraine prevention:
- For migraine, you must not use Topiramate Milpharm if you are pregnant.
- For migraine, you must not use Topiramate Milpharm if you are a woman who is able to become pregnant unless you are using highly effective contraception (birth control).
- Before the start of treatment with Topiramate Milpharm a pregnancy test should be performed in a woman who is able to become pregnant.

Treatment of epilepsy:
- For epilepsy, you must not use Topiramate Milpharm if you are pregnant, unless you and your doctor have agreed that no other treatment gives sufficient seizure control for you.
- For epilepsy, you must not use Topiramate Milpharm if you are a woman who is able to become pregnant unless you are using highly effective contraception. Do not stop taking Topiramate Milpharm or your contraception (birth control) until you have discussed this with your doctor. Your doctor will make sure you have received information about the risks of taking Topiramate Milpharm during pregnancy and about the risks of seizures during pregnancy, which may put you or your unborn child at risk.
- Before the start of treatment with Topiramate Milpharm a pregnancy test should be performed in a woman who is able to become pregnant.

The risks of topiramate when taken during pregnancy. The risks apply whether topiramate is taken for migraine prevention or treatment of epilepsy.

There is a risk of harm to the unborn child if Topiramate Milpharm is used during pregnancy.
- If you take Topiramate Milpharm during pregnancy, your child has a higher risk for birth defects. In women who take topiramate, around 4 - 9 children in every 100 will have birth defects. This compares to 1-3 children in every 100 born to women who do not have epilepsy and do not take an antiepileptic treatment. Particularly, cleft lip (split in the top lip) and cleft palate (split in the roof of the mouth) have been observed. Newborn boys may also have a malformation of the penis (hypospadia). These defects can develop early in pregnancy, even before you know you are pregnant.
- If you take Topiramate Milpharm during pregnancy, your child may have a 2- to 3-fold higher risk for autism spectrum disorders, intellectual disabilities, or attention deficit hyperactivity disorder (ADHD) compared with children born to women with epilepsy not taking antiepileptic medication.
- If you take Topiramate Milpharm during pregnancy, your child may be smaller and weigh less than expected at birth. In one study, around 18 in every 100 children of mothers taking topiramate during pregnancy were smaller and weighed less than expected at birth, while around 5 in every 100 children born to women without epilepsy and not taking antiepileptic medication were smaller and weighed less than expected at birth.
- Talk to your doctor if you have questions about this risk during pregnancy.
- There may be other medicines to treat your condition that have a lower risk of birth defects.

Need for contraception (birth control) *in women who are able to become pregnant:*
- If you are a woman who is able to become pregnant, talk to your doctor about other possible treatments instead of Topiramate Milpharm. If the decision is made to use Topiramate Milpharm, you must use highly effective contraception during your treatment and for at least 4 weeks after the last Topiramate Milpharm dose.
- One highly effective contraception (such as an intrauterine device) or two complementary contraceptives such as birth control pill together with a barrier method of birth control (such as a condom or pessary/diaphragm) must be used. Talk to your doctor about what contraception is most appropriate for you.
- Topiramate Milpharm can affect how well some hormonal contraceptive (birth control) methods work. If you are taking hormonal contraceptives an additional barrier contraceptive method (such as a condom or pessary/diaphragm) should be used.
- Tell your doctor if you experience irregular menstrual bleeding.

Use of Topiramate Milpharm in girls
If you are a parent or a caregiver of a girl treated with Topiramate Milpharm, you must contact her doctor immediately once your child experiences her first period (menarche). The doctor will inform you about the risks to an unborn child due to topiramate exposure during pregnancy, and the need for using highly effective contraception.

If you wish to become pregnant while taking Topiramate Milpharm
- Schedule an appointment with your doctor.
- Do not stop using your contraception until you have discussed this with your doctor.
- If you take Topiramate Milpharm for epilepsy, do not stop taking it until you have discussed this with your doctor. Suddenly stopping Topiramate Milpharm can cause seizures to start again or happen more often or last longer than before. This may put you or your unborn child at risk.
- Your doctor will reassess your treatment as they may need to change or stop your medicine. The doctor will counsel you about the risks of Topiramate Milpharm during pregnancy. He/she may also refer you to another specialist.

If you have become pregnant or think you may be pregnant while taking Topiramate Milpharm:
- Schedule an urgent appointment with your doctor.
- If you are taking Topiramate Milpharm to prevent migraine, stop taking the medicine straight away, and contact your doctor. Your doctor will assess your condition and discuss your options with you.
- If you are taking Topiramate Milpharm for epilepsy, do not stop taking this medicine unless your doctor tells you to. Suddenly stopping Topiramate Milpharm can cause seizures to start again or happen more often or last longer than before. This may put you or your unborn child at risk.
- If you are taking Topiramate Milpharm for epilepsy, your doctor will assess your condition and discuss options with you. Your doctor will make sure you are aware of and understand all the risks of Topiramate Milpharm during pregnancy. They may advise that you need to switch to another medicine to treat your epilepsy. If so, they will explain how to make the change to this new medicine. He/she may also refer you to another specialist.
- If Topiramate Milpharm is used during pregnancy for epilepsy, you will be monitored closely to check how your unborn child is developing.

Make sure you read the patient guide that you will receive from your doctor.
A patient card is provided with the Topiramate Milpharm package to remind you the risks in pregnancy.

Breast-feeding
The active substance in Topiramate tablets (topiramate) passes into human milk. Effects have been seen in breastfed babies of treated mothers, including diarrhea, feeling sleepy, feeling irritable, and poor weight gain. Therefore, your doctor will discuss with you whether you abstain from breastfeeding or whether to abstain from treatment with Topiramate Milpharm. Your doctor will take into account the importance of the medicine to the mother and the risk for the baby.

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Mothers who breast-feed while taking Topiramate Milpharm must tell the doctor as soon as possible if the baby experiences anything unusual.

Driving and using machines
Dizziness, tiredness, and vision problems may occur during treatment with Topiramate Milpharm. Do not drive or use any tools or machines without talking to your doctor first.

Topiramate Milpharm contains 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.

Topiramate Milpharm contains Sodium
This medicine contains less than 1 mmol sodium (23 mg) per dosage unit, that is to say essentially 'sodium-free'.

3. How to take Topiramate Milpharm

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.
- Your doctor will usually start you on a low dose of Topiramate Milpharm and slowly increase your dose until the best dose is found for you.
- Topiramate Milpharm tablets are to be swallowed whole. Avoid chewing the tablets as they may leave a bitter taste.
- Topiramate Milpharm can be taken before, during, or after a meal. Drink plenty of fluids during the day to prevent kidney stones while taking Topiramate Milpharm.

If you take more Topiramate Milpharm than you should
- See a doctor right away. Take the medicine pack with you.
- You may feel sleepy, tired, or less alert; lack coordination; have difficulty speaking or concentrating; have double or blurred vision; feel dizzy due to low blood pressure; feel depressed or agitated; or have abdominal pain, or seizures (fits).

Overdose can happen if you are taking other medicines together with Topiramate Milpharm.

If you forget to take Topiramate Milpharm
- If you forget to take a dose, take it as soon as you remember it. However, if it is almost time for your next dose, skip the missed dose and continue as usual. If you miss two or more doses, contact your doctor.
- Do not take a double dose (two doses at the same time) to make up for a forgotten dose.

If you stop taking Topiramate Milpharm
Do not stop taking this medicine unless told to do so by your doctor. Your symptoms may return. If your doctor decides to stop this medication, your dose may be decreased gradually over a few days.

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.

Tell your doctor, or seek medical attention immediately if you have the following side effects:

Very common (may affect more than 1 in 10 people)
- Depression (new or worse)

Common (may affect up to 1 in 10 people)
- Seizures (fits)
- Anxiety, irritability, changes in mood, confusion, disorientation
- Problems with concentration, slowness of thinking, loss of memory, problems with memory (new onset, sudden change or increased severity)
- Kidney stone, frequent or painful urination

Uncommon (may affect up to 1 in 100 people)
- Increased acid level in the blood (may cause troubled breathing including shortness of breath, loss of appetite, nausea, vomiting, excessive tiredness, and fast or uneven heart beats)
- Decreased or loss of sweating (particularly in young children who are exposed to high temperatures)
- Having thoughts of serious self-harm, trying to cause serious self-harm
- Loss of part of the field of vision

Rare (may affect up to 1 in 1,000 people)
- Glaucoma – blockage of fluid in eye causing increased pressure in the eye, pain, or decreased vision
- Difficulty thinking, remembering information, or solving problems, being less alert or aware, feeling very sleepy with low energy – these symptoms may be a sign of a high level of ammonia in the blood (hyperammonemia), which can lead to a change in brain function (hyperammonemic encephalopathy).
- Serious skin reactions, such as Stevens-Johnson syndrome and toxic epidermal necrolysis - these may appear as rashes with or without blisters. Skin irritation, sores or swelling in the mouth, throat, nose, eyes and around the genitals. The skin rashes may develop into serious widespread skin damage (peeling of the epidermis and superficial mucous membranes) with life-threatening consequences.

Frequency not known (cannot be estimated from the available data):
- Inflammation of the eye (uveitis) with symptoms such as eye redness, pain, sensitivity to light, runny eyes, seeing small dots or getting blurred vision.

Other side effects include the following, if they get serious, please tell your doctor or pharmacist:

Very common (may affect more than 1 in 10 people)
- Stuffy, runny nose or sore throat
- Tingling, pain and/or numbness of various body parts
- Sleepiness, tiredness
- Dizziness
- Nausea, diarrhoea
- Weight loss

Common (may affect up to 1 in 10 people)
- Anaemia (low blood count)
- Allergic reaction (such as skin rash, redness, itching, facial swelling, hives)
- Loss of appetite, decreased appetite
- Aggression, agitation, anger, abnormal behaviour
- Difficulty falling or staying asleep
- Problems with speech or speech disorder, slurred speech
- Clumsiness or lack of coordination, feeling of unsteadiness when walking
- Decreased ability to complete routine tasks
- Decreased, loss of, or no sense of taste
- Involuntary trembling or shaking; rapid, uncontrollable movements of the eyes
- Visual disturbance, such as double vision, blurred vision, decreased vision, difficulty focusing
- Sensation of spinning (vertigo), ringing in the ears, ear pain
- Shortness of breath
- Cough
- Nose bleeds
- Fever, not feeling well, weakness
- Vomiting, constipation, abdominal pain or discomfort, indigestion, stomach or intestinal infection
- Dry mouth
- Hair loss
- Itching
- Joint pain or swelling, muscle spasms or twitching, muscle aches or weakness, chest pain
- Weight gain

Uncommon (may affect up to 1 in 100 people)
- Decrease in platelets (blood cells that help stop bleeding), decrease in white blood cells that help to protect you against infection, decrease in potassium level in the blood
- Increase in liver enzymes, increase in eosinophils (a type of white blood cell) in the blood
- Swollen glands in the neck, armpit, or groin
- Increased appetite
- Elevated mood
- Hearing, seeing, or feeling things that are not there, severe mental disorder (psychosis)
- Showing and/or feeling no emotion, unusual suspiciousness, panic attack
- Problems with reading, speech disorder, problems with handwriting
- Restlessness, hyperactivity
- Slowed thinking, decreased wakefulness or alertness
- Reduced or slow body movements, involuntary abnormal or repetitive muscle movements
- Fainting
- Abnormal sense of touch; impaired sense of touch
- Impaired, distorted, or no sense of smell
- Unusual feeling or sensation that may precede a migraine or a certain type of seizure
- Dry eye, sensitivity of the eyes to light, eyelid twitching, watery eyes
- Decreased or loss of hearing, loss of hearing in one ear
- Slow or irregular heartbeat, feeling your heart beating in your chest
- Low blood pressure, low blood pressure upon standing (consequently, some people taking topiramate may feel faint, dizzy, or may pass out when they stand up or sit up suddenly)
- Flushing, feeling warm
- Pancreatitis (inflammation of the pancreas)
- Excessive passing of gas or wind, heartburn, abdominal fullness or bloating
- Bleeding gums, increased saliva, drooling, breath odour
- Excessive intake of fluids, thirst
- Skin discolouration
- Muscle stiffness, pain in side
- Blood in urine, incontinence (lack of control) of urine, urgent desire to urinate, flank or kidney pain
- Difficulty getting or keeping an erection, sexual dysfunction
- Flu-like symptoms
- Cold fingers and toes
- Feeling drunk
- Learning disability

Rare (may affect up to 1 in 1,000 people)
- Abnormally elevated mood
- Loss of consciousness
- Blindness in one eye, temporary blindness, night blindness
- Lazy eye
- Swelling in and around the eyes
- Numbness, tingling and colour change (white, blue then red) in fingers and toes when exposed to the cold
- Inflammation of the liver, liver failure
- Abnormal skin odour
- Discomfort in your arms or legs
- Kidney disorder

Not known (frequency cannot be estimated from the available data)
- Maculopathy is a disease of the macula, the small spot in the retina where vision is keenest. You should call your doctor if you notice a change or decrease in your vision.

Children
The side effects in children are generally similar to those seen in adults, but the following side effects may be more common in children than adults.
- Problems with concentration
- Increased acid level in the blood
- Having thoughts of serious self-harm
- Tiredness
- Decreased or increased appetite
- Aggression, abnormal behaviour
- Difficulty falling or staying asleep
- Feeling of unsteadiness when walking
- Not feeling well
- Decrease in potassium level in the blood
- Showing and/or feeling no emotion
- Watery eyes
- Slow or irregular heartbeat

Other side effects that may occur in children are:

Common (may affect up to 1 in 10 people)
- Sensation of spinning (vertigo)
- Vomiting
- Fever

Uncommon (may affect up to 1 in 100 people)
- Increase in eosinophils (a type of white blood cell) in the blood
- Hyperactivity
- Feeling warm
- Learning disability

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

Store below 25°C.

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 Topiramate Milpharm contains
- The active substance is topiramate. Each film-coated tablet contains 25 mg, 50 mg, 100 mg or 200 mg Topiramate.
- The other ingredients are:
  Tablet core: cellulose microcrystalline, lactose monohydrate, starch pregelatinised (maize), sodium starch glycolate (type A), magnesium stearate.
  Tablet coating: hypromellose, titanium dioxide (E171), macrogol 400, polysorbate 80, iron oxide yellow (E172) (only in Topiramate Milpharm 50 mg & /100 mg), iron oxide red (E172) (only in Topiramate Milpharm 200 mg).

What Topiramate Milpharm looks like and contents of the pack
Film-coated tablet.

Topiramate Milpharm 25 mg film-coated tablets:
White, circular, biconvex film-coated tablets debossed with 'E' on one side and '22' on the other side.

Topiramate Milpharm 50 mg film-coated tablets:
Light yellow coloured, circular, biconvex film-coated tablets debossed with 'E' on one side and '33' on the other side.

Topiramate Milpharm 100 mg film-coated tablets:
Dark yellow coloured, circular, biconvex bevelled edged film-coated tablets debossed with 'E' on one side and '23' on the other side.

Topiramate Milpharm 200 mg film-coated tablets:
Pink coloured, circular, biconvex, bevelled edged film-coated tablets debossed with 'E' on one side and '24' on the other side.

Topiramate Milpharm film-coated tablets are available in polyamide / aluminium / PVC blister packs and HDPE tablet container with polypropylene cap with dessicant (silica gel).

Presentations:

Blister pack:
For 25 mg, 50 mg, 100 mg and 200 mg: 60 film-coated tablets
For 50 mg, 100 mg and 200 mg only: 30 film-coated tablets.

Bottle pack:
60 film-coated tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Milpharm Limited
1 Roundwood Avenue
Stockley Park, Uxbridge
UB11 1AF
United Kingdom

Manufacturer
APL Swift Services (Malta) Limited
HF26, Hal Far Industrial Estate, Hal Far
Birzebbugia, BBG 3000
Malta

or

Milpharm Limited
1 Roundwood Avenue
Stockley Park, Uxbridge
UB11 1AF
United Kingdom

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