

Tapclob

Clobazam 5mg/5mL and 10mg/5mL Oral Suspension

Consumer Medicine Information (CMI)

What is in this leaflet

This leaflet answers some common questions about Tapclob.

It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking this medicine against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Tapclob is used for

Tapclob is used to control certain types of epilepsy. Epilepsy is a neurological condition in which a person may experience repeated seizures (fits).

Tapclob belongs to a group of medicines called benzodiazepines. They are thought to work by their action on brain chemicals.

In general, benzodiazepines such as Tapclob should be taken for short periods only (up to one month). Continuous long term use is not recommended unless advised by your doctor. The prolonged use of benzodiazepines may lead to dependence on the medicine.

Your doctor, however, may prescribe Tapclob for another purpose.

Ask your doctor if you have any questions about why it has been prescribed for you.

This medicine is available only with a doctor's prescription.

Before you take Tapclob

When you must not take it

Do not take Tapclob if you have:

- severe or chronic lung disease
- a history of drug or alcohol abuse
- severe muscle weakness known as myasthenia gravis
- sleep apnoea syndrome where you snore heavily and stop breathing during the night
- severely reduced liver function.

Do not take Tapclob (clobazam) if you are allergic to it or any other medicine from the benzodiazepine group of medicines or any of the ingredients listed at the end of this leaflet.

Some symptoms of an allergic reaction include skin rash, itching, shortness of breath or swelling of the face, lips or tongue, which may cause difficulty in swallowing or breathing.

Do not take Tapclob if you are pregnant or if you intend to become pregnant.

Do not take it if you are breast-feeding or planning to breast-feed.

Tapclob passes into the breast milk and may cause drowsiness and/or feeding difficulties in the infant.

Do not use it after the expiry date (EXP) printed on the pack.

If you take it after the expiry date has passed, it may not work as well.

Do not use Tapclob if the packaging is torn or shows signs of tampering.

Before you start to take it

Tell your doctor or pharmacist if you have allergies to:

- any of the ingredients listed at the end of this leaflet
- any other medicines
- any other substances, such as foods, preservatives or dyes.

Tell your doctor if you are pregnant or plan to become pregnant.

Like most medicines of this kind, Tapclob is not recommended in pregnancy unless the expected benefits outweigh possible risks. Your doctor will discuss the risks and benefits of taking it if you are pregnant.

Tell your doctor if you are breast-feeding or planning to breast-feed.

Tapclob passes into breast milk and is not recommended for use while breast-feeding.

Tell your doctor if you have or have had any other medical

conditions, especially the following:

- liver, kidney or lung disease
- fits or convulsions (epilepsy)
- low blood pressure
- pre-existing muscle weakness
- unsteadiness when walking
- addiction to drugs or medicines
- glaucoma (high pressure in the eye)
- depression
- severe mental condition in which the person loses contact with reality and is unable to think and judge clearly
- mental illness with disturbances in thinking, emotional reactions and behaviour
- if you drink alcohol regularly
Your tolerance to alcohol will be reduced and it will increase the effect of Tapclob.

Alcohol should be avoided during Tapclob use.

If you have not told your doctor about any of the above, tell them before you take any Tapclob.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food store.

Some medicines may interfere with the absorption of Tapclob. These include:

- other sleeping tablets, sedatives or tranquillisers

- medicines used as sedatives or to treat anxiety
- medicines used to relieve stomach cramps or spasms, to prevent travel sickness and to treat Parkinson's disease
- alcohol, (ethanol), contained in some medicines eg cough syrups
- medicines used to treat reflux or upset stomach, such as omeprazole
- medicines for depression
- medicines for allergies, for example antihistamines or cold tablets
- pain relievers (such as opioids or narcotic analgesics)
- muscle relaxants
- dietary supplements and recreational products
- medicines to control fits (including marijuana)
- disulfiram, erythromycin or cimetidine
- lithium.

These medicines may be affected by Tapclob, or they may affect how well it works. You may need to take different amounts of your medicine or take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or to avoid while taking Tapclob.

How to take Tapclob

How much to take

The dose of Tapclob may be different for each person. Your doctor will decide the right dose for you.

Ask your doctor if you are unsure of the correct dose for you.

He/she will tell you exactly how much to take.

Follow the instructions you are given.

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

If you take the wrong dose, Tapclob may not work as well and your problem may not improve.

The usual dose for adults is:

20 - 30 mg daily in divided doses or as a single dose at night.
Maximum dose 60 mg.

The usual dose for children and the elderly is:

Half the adult dose.

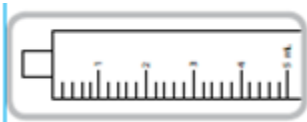
How to take it

Always take this medicine exactly as your doctor has told you.

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 Tapclob 5mg/5ml Oral Suspension and 2mg of Tapclob 10mg/5ml Oral Suspension. The smaller increments are 0.2ml or 0.2mg of Tapclob 5mg/5ml Oral Suspension and 0.4mg of Tapclob 10mg/5ml Oral Suspension.



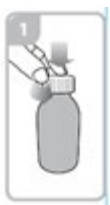
30ml dosing cup. Each numbered increment is 5ml - equivalent to 5mg of Tapclob 5mg/5ml Oral Suspension and 10mg of Tapclob 10mg/5ml Oral Suspension.



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):



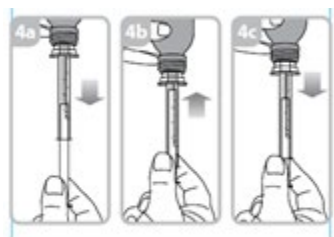
Holding the bottle, take the plastic syringe adaptor from the box and insert the adaptor into the bottle neck (figure 2). Ensure it is well fixed:



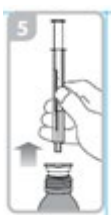
Take the syringe and put it in the adaptor opening (figure 3). Turn the bottle upside down:



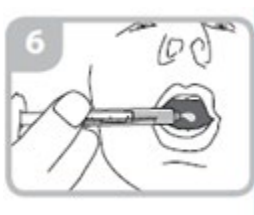
Fill the syringe with a small amount of suspension by pulling the piston down (figure 4a), then push the piston upward in order to remove any possible bubble (figure 4b). Pull the piston down to the graduation mark corresponding to the quantity in milliliters (ml) prescribed by your doctor (figure 4c).



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.

When to take it

If you are not sure when to take it, ask your doctor.

How long to take it

Do not use Tapclob for longer than your doctor has advised.

Ask your doctor if you are not sure how long to take the medicine for.

If you forget to take it

Do not try to make up for missed doses by taking more than one dose at a time.

This may increase the chance of getting an unwanted side effect.

If it is almost time for your next dose, skip the dose you missed and take the next dose when you are meant to.

Do not take a double dose to make up for the dose you have missed.

If there is still a long time to go before your next dose, take it as soon as you remember, and then go back to taking it as you would normally.

If you are not sure what to do, ask your doctor.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor, or Poisons Information Centre (telephone 0800 POISON, 0800 764 766), or go to Accident and Emergency at your nearest hospital, if you think you or anyone else may have taken too much Tapclob.

Do this even if there are no signs of discomfort or poisoning.

Also report any other medicine or alcohol which has been taken. You may need urgent medical attention.

If you take too much Tapclob you will probably feel drowsy, confused, tired, dizzy, have difficulty breathing, feel weak or become unconscious.

While you are taking it

Things you must do

Use Tapclob exactly as your doctor has prescribed.

Tell all doctors, dentists and pharmacists who are treating you that you are taking Tapclob.

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking Tapclob.

If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking this medicine.

If you become pregnant while you are taking this medicine, tell your doctor immediately.

Things you must not do

Do not take more than the recommended dose unless your doctor tells you to.

Do not give this medicine to anyone else, even if they have the same condition as you.

Do not use this medicine to treat any other complaints unless your doctor tells you to.

Do not stop taking Tapclob, or lower the dosage, because you are feeling better, unless advised by your doctor.

Do not take Tapclob for a longer time than your doctor has prescribed.

Do not stop taking Tapclob or change the dose, without first checking with your doctor.

Stopping this medicine suddenly may cause some unwanted effects. You and your doctor will slowly reduce your dose of Tapclob before you can stop taking it completely.

Do not suddenly stop taking Tapclob if you suffer from epilepsy.

Stopping this medicine suddenly may make your epilepsy worse.

Things to be careful of

Do not drive or operate machinery until you know how Tapclob affects you.

Tapclob may cause drowsiness or dizziness in some people and therefore may affect alertness.

Make sure you know how you react to Tapclob before you drive a car, operate machinery, or do anything else that could be dangerous if you are drowsy, dizzy or not alert.

Even if you take Tapclob at night, you may still be drowsy or dizzy the next day.

Side effects

All medicines have some unwanted side effects. Sometimes they are serious, but most of the time they are not. Your doctor has weighed the risks of using this medicine against the benefits he/she expect it will have for you.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Tapclob.

It helps most people but it may have unwanted side effects in a few people.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- drowsiness, tiredness
- dizziness, unsteadiness, tremor, sweating, muscle aches, spasms or weakness
- loss of memory, confusion, lack of concentration
- depression
- headache, hangover feeling in the morning
- nausea, vomiting, diarrhoea, constipation
- weight gain
- dry mouth or slurred speech
- blurred vision
- skin rash
- changes in sex drive.

These are mild side effects of this medicine.

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- Severe blisters and bleeding in the lips, eyes, mouth, nose and genitals
- sudden anxiety or excitation
- hallucinations or delusions
- severe sleep disturbances
- irritability, aggressiveness
- breathing difficulties.

These are very serious side effects of Tapclob. You may need

urgent medical attention. Serious side effects are rare.

Check with your doctor as soon as possible if you have any problems while taking Tapclob, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

Tell your doctor if you notice anything else that is making you feel unwell when you are taking, or soon after you have finished taking Tapclob.

Other side effects not listed above may occur in some consumers.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

After taking Tapclob

If you have any queries about any aspects of your medicine, or any questions regarding the information in this leaflet, discuss them with your doctor or pharmacist.

Storage

Keep the bottle in the outer carton.

Keep the medicine in a cool dry place where the temperature stays below 25°C.

Use within 28 days of opening.

Do not store it, or any other medicines, in a bathroom, near a sink or on a window sill.

Do not leave it in the car.

Heat and damp can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking Tapclob or the medicine has passed its expiry date, ask your pharmacist what to do with any that is left over.

Return any unused medicine to your pharmacist.

Product description

What it looks like

Tapclob 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 150ml and 250ml.

Ingredients

The active ingredient (the ingredient that makes the oral suspension work) is clobazam.

Each 5ml of Tapclob 5mg/5ml Oral Suspension contains 5mg of clobazam.

Each 5ml of Tapclob 10mg/5ml Oral Suspension contains 10mg of clobazam.

Inactive Ingredients:

Sorbitol (E420)
Xanthan gum (E415)
Acesulfame potassium (E950)
Raspberry flavour

Sodium propyl hydroxybenzoate (E217)
Sodium methyl hydroxybenzoate (E219)
Disodium hydrogen phosphate dihydrate
Sodium dihydrogen phosphate dihydrate
Purified water

Tapclob does not contain sucrose, tartrazine or any other azo dyes.

Manufacturer/Sponsor

Tapclob is supplied in New Zealand by:

Max Health Ltd
PO Box 44452 Pt Chevalier
Auckland 1246.

This leaflet was prepared in January 2022.