TRIFLO TABLET

Trifluoperazine hydrochloride 5mg

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What Triflo is used for

Triflo is used to treat mental illnesses with disturbances in thinking, feelings and behaviour.

It may also be used to treat nausea and vomiting.

How Triflo works

Triflo contains trifluoperazine hydrochloride as the active ingredient. It belongs to a group of medicines called phenothiazine neuroleptics.

It helps to correct chemical imbalances in the brain, which may cause mental illness. These chemicals may also affect the parts of the brain which control nausea and vomiting.

Before you use Triflo

- When you must not take it Triflo must not be given to anyone who is unconscious or in a coma.

Do not take Triflo if you have or have had any of the following medical conditions:

• liver disease

- blood or bone marrow disorder.
- phaeochromocytoma, a rare tumour of the adrenal gland, which sits near the kidneys
- heart and blood vessel disease.

Do not take Triflo if you are allergic to any medicine containing trifluoperazine, other phenothiazine neuroleptics or any of the ingredients listed at the end of this leaflet.

- Before you start to use it

Tell your doctor or pharmacist if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any medical conditions, especially the following:

- heart problems, such as angina
- liver problems
- history of jaundice
- parkinsonism

Tell your doctor if you are:

• pregnant or intend to become pregnant.

Like most medicines of this kind, Triflo is not recommended to be used during pregnancy unless advised by your doctor. Your doctor will discuss the risks and benefits of using it if you are pregnant, and advise you regarding the recommended dose and duration of treatment.

• breastfeeding or plan to breastfeed.

It is recommended that you do not breastfeed while taking Triflo, as it may pass into breast milk and may affect your baby.

Tell your doctor if you will be in a hot environment or do a lot of vigorous exercise.

Triflo may make you sweat less, causing your body to overheat.

Tell your doctor prior to the use of this medicine if anyone in your family ever had a heart disease.

- Taking other medicines

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

Tell any health professional who is prescribing a new medicine for you that you are taking Triflo.

You may need different amounts of your medicine, or take it at different times, or you may need to take different medicines.

How to use Triflo

- How much to use

Mental illnesses
Initial dose of 5mg twice daily, gradually increased to 15mg to 20mg daily in divided doses.

When to use it

Try to take your Triflo at the same time each day.

- How long to use it

Continue taking the medicine for as long as your doctor tells you to.

- <u>If you forget to use it</u>

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 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.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

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

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

- <u>If you use too much</u> (overdose)

Immediately telephone your doctor for advice or go to Accident and Emergency at your nearest hospital if you think that you or anyone else may have taken too much Triflo. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

If you take too much Triflo, you may feel sleepy, dizzy or agitated. You may also have a dry mouth, fit or seizure, or muscle spasms.

While you are using it

- Things you must do

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking Triflo. If you become pregnant while taking this medicine, tell your doctor.

Go to your doctor regularly for a check-up.

See your doctor if you feel that your condition is not improving or is getting worse.

- Things you must not do

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

This medicine is only intended for the use of the patient it has been prescribed for.

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

Do not stop taking Triflo without checking with your doctor, even if you are feeling better.

If you stop taking Triflo suddenly, your condition may worsen or your chance of getting an unwanted side effect may increase.

To prevent this, your doctor may gradually reduce the amount of Triflo you take each day before stopping completely. Do not take any medicines that cause drowsiness while you are taking Triflo, unless recommended by your doctor.

- <u>Things to be careful of</u> Be careful driving or operating

machinery until you know how Triflo affects you.

As with other phenothiazine medicines, Triflo may cause sleepiness, poor co-ordination and blurred vision in some people.

Make sure you know how you react to it before you drive a car, operate machinery, or do

anything else that could be dangerous if you are dizzy or light-headed. If this occurs do not drive. If you drink alcohol, sleepiness or poor coordination may be worse.

If Triflo makes you feel lightheaded, dizzy or faint, get up slowly when getting up from a sitting or lying position.

Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure.

Be careful when drinking alcohol while taking Triflo.

Combining Triflo and alcohol can make you more sleepy, dizzy or light-headed. Your doctor may suggest to avoid alcohol while you are being treated with Triflo.

If your skin appears to be burning, tell your doctor.

Triflo may cause your skin to be much more sensitive to sunlight than it is normally. This could cause a skin rash, itching, redness, or severe sunburn.

Make sure you keep cool in hot weather and keep warm in cool weather.

Triflo may affect the way your body reacts to temperature changes.

Side effects

Like all medicines, Triflo tablet can cause side effects, although not everyone gets them

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

- drowsiness
- dryness of the mouth
- nasal congestion

- postural hypotension (is a form of low blood pressure that happens when you stand up from sitting or lying down.
- lowering of body temperature
- tachycardia arrhythmias (fast heart beat)
- agitation
- insomnia (sleep disorder)
- depression
- miosis and mydriasis (constriction and excessive dilation of pupil)
- convulsions
- photosensitivity
- skin rashes
- inhibition of ejaculation

These side effects are usually mild.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell. Other side effects not listed above may also occur in some people.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers → Reporting).

Storage and Disposal of Triflo

- Storage

Keep your tablets in the pack until it is time to take them.

If you take them out of their packaging, they will not keep well.

Keep them in a cool, dry place where the temperature stays below 30°C. Protect from light. Keep your tablets where young children cannot reach them.

- Disposal

If your doctor tells you to stop taking Triflo, or the tablets have passed their expiry date, ask your pharmacist what to do with any left over.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

What it looks like

Triflo 5 Tablet is a 6.5mm diameter in core, round, convex, scored, film-coated dark blue tablet.

- <u>Ingredients</u> Active ingredient:
- Trifluoperazine hydrochloride
- Inactive ingredients:
- Sodium starch glycolate
- Corn starch
- Lactose monohydrate
- Magnesium stearate
- Indigo carmine
- Opadry white
- <u>MAL number</u> MAL19861381A

Manufacturer

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Product Registration Holder UPHA PHARMACEUTICAL MFG (M) SDN BHD (53667-M) Lot 2&4, Jalan P/7, Section 13, Bangi Industrial Estate, 43650 Bandar Baru Bangi, Selangor Darul Ehsan

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