

TAPCOM-S OPHTHALMIC SOLUTION 15MICROGRAMS/ML + 5MG/ML, SOLUTION IN SINGLE-DOSE CONTAINER

Tafluprost + Timolol (as maleate) (15mcg/mL + 5mg/mL)

What is in this leaflet

1. What Tapcom-S is used for
2. How Tapcom-S works
3. Before you use Tapcom-S
4. How to use Tapcom-S
5. While you are using it
6. Side effects
7. Storage and Disposal of Tapcom-S
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

What Tapcom-S is used for

Tapcom-S is used to treat a type of glaucoma called open angle glaucoma and also a condition known as ocular hypertension in adults. Both of these conditions are linked with an increase in the pressure within your eye and eventually they may affect your eyesight.

How Tapcom-S works

Tapcom-S ophthalmic solution contain tafluprost and timolol. Tafluprost belongs to a group of medicines called prostaglandin analogues and timolol belongs to a group of medicines called beta blockers. Tafluprost and timolol work together to lower the pressure in the eye. Tapcom-S is used when the pressure in the eye is too high.

Before you use Tapcom-S

- When you must not use it

Do not use Tapcom-S:

- if you are allergic to tafluprost, timolol, beta blockers or any of the other ingredients of this medicine (listed in section "Ingredients".)
- if you have now or have had in the past respiratory problems such as asthma, severe chronic obstructive bronchitis (severe lung disease which may cause wheeziness, difficulty in breathing and/or long-standing cough)
- if you have a slow heartbeat, heart failure or disorders of the heart rhythm (irregular heartbeats).
- If you are using an eye drop that containing omdenepag isopropyl.

- Before you start to use it

Before you use this medicine, tell your doctor if you have now or have had in the past:

- coronary heart disease (symptoms can include chest pain or tightness, breathlessness or choking), heart failure, low blood pressure
- disturbances of heart rate such as slow heart beat
- breathing problems, asthma or chronic obstructive pulmonary disease
- poor blood circulation disease (such as Raynaud's disease or Raynaud's syndrome)
- diabetes as timolol may mask signs and symptoms of low blood sugar
- overactivity of the thyroid gland as timolol may mask signs and symptoms of thyroid disease
- any allergies or anaphylactic reactions
- myasthenia gravis (a rare disease causing muscle weakness)
- other eye diseases; for example, disease of the cornea (the transparent tissue that covers the front of the eye) or a disease requiring eye surgery.

Tell your doctor if you have

- kidney problems
- liver problems.

- Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take other medicines.

Tapcom-S may affect or be affected by other medicines you are using.

In particular, tell your doctor if you are using or intend to use:

- other ophthalmic solution for the treatment of glaucoma
- medicines to lower blood pressure
- heart medicine
- medicines to treat diabetes
- quinidine (used to treat heart conditions and some types of malaria)
- antidepressants known as fluoxetine and paroxetine.

If you use other medicines in the eye, leave at least 5 minutes between putting in Tapcom-S and the other medication.

How to use Tapcom-S

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

- How much to use

The recommended dose is 1 drop of Tapcom-S in the eye or eyes, once daily. Do not instil more drops or use more often than as instructed by your doctor. This may make Tapcom-S less effective. Only use Tapcom-S in both eyes if your doctor told you to. Discard the opened container with any remaining contents immediately after use.

- When to use it

Once daily.

- How long to use it

Do not stop using Tapcom-S without asking your doctor. If you stop using Tapcom-S, the pressure in the eye will increase again. This may cause a permanent injury to your eye.

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

- If you forget to use it

If you forget to use Tapcom-S, use a single drop as soon as you remember, and then go back to your regular routine. However, if it is nearly time for the next dose, skip the missed dose. Do not use a double dose to make up for a forgotten dose.

- If you use too much (overdose)

If you use more Tapcom-S than you should, you may feel dizzy or have headache, heart symptoms or breathing problems. If necessary, contact a doctor for advice.

While you are using it

- Things you must do

- Read all of this leaflet carefully before you start using this medicine

TAPCOM-S OPHTHALMIC SOLUTION 15MICROGRAMS/ML + 5MG/ML, SOLUTION IN SINGLE-DOSE CONTAINER

Tafluprost + Timolol (as maleate) (15mcg/mL+ 5mg/mL)

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.
- 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 "Side effects".

- Things you must not do

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.

- Things to be careful of

Children and adolescents

Tapcom-S is not recommended for children and adolescents below 18 years due to a lack of data on safety and efficacy in this age group.

Contact lenses

Remove contact lenses before putting in the drops and wait at least 15 minutes before putting the lenses back.

Pregnancy, breast-feeding and fertility

If you may become pregnant, you must use an effective method of birth control during Tapcom-S therapy. Do not use Tapcom-S if you are pregnant. You should not use Tapcom-S if you are breast-feeding. Ask your doctor for advice.

Driving and using machines

There are side effects associated with Tapcom-S, such as blurred vision, which may affect your ability to drive and/or operate machinery. Do not drive or operate machinery until you feel well and your vision is clear.

Side effects

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

You can usually carry on using the drops, unless the effects are serious. If you are worried, talk to a doctor or pharmacist.

The following are known side effects of using Tapcom-S:

Common side effects

The following may affect up to 1 in 10 people:

Eye disorders

Itching of the eye. Irritation in the eye. Eye pain. Redness of the eye. Changes in the length, thickness and number of eyelashes. Foreign body sensation in the eye. Discolouration of eyelashes. Sensitivity to light. Blurred vision.

Uncommon side effects

The following may affect up to 1 in 100 people:

Nervous system disorders

Headache.

Eye disorders

Dry eye. Redness of the eyelids. Small spotlike areas of inflammation on the surface of the eye. Watery eyes. Puffy eyelids. Tired eyes. Inflammation of the eyelids. Inflammation inside the eye. Discomfort in the eye. Eye allergy. Inflammation of the eye. Abnormal sensation in the eye.

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

Storage and Disposal of Tapcom-S

- Storage

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

Store the unopened foil pouches in a refrigerator (2°C - 8°C). Do not open the pouch until you are about to start using the ophthalmic solution as unused containers in an open pouch must be discarded 28 days after first opening the pouch.

After opening the foil pouch:

- Do not store above 25°C and protect from light.
- Use within 28 days..
- Discard an opened single-dose container with any remaining solution immediately after use.

- Disposal

Do not use this medicine after the expiry date which is stated on the single-dose container, pouch and the carton after 'Exp'. The expiry date refers to the last day of that month.

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.

Product Description

- What it looks like

Tapcom-S is a clear, colorless liquid (solution) supplied in single-dose plastic containers.

- Ingredients

- Active ingredient

The active substances are tafluprost and timolol. 1 ml of solution contains 15 mcg of tafluprost and 5 mg of timolol.

- Inactive ingredients

The other ingredients are glycerol, disodium phosphate dodecahydrate, disodium edetate, polysorbate 80, hydrochloric acid, concentrated and/or sodium hydroxide (to adjust pH), and water for injections.

- MAL number(s):

MAL17035023ACZ

Manufacturer

Laboratoire Unither
1 Rue De L Arquerie,
Coutances, 50200
France

TAPCOM-S OPHTHALMIC SOLUTION 15MICROGRAMS/ML + 5MG/ML, SOLUTION IN SINGLE-DOSE CONTAINER

Tafluprost + Timolol (as maleate) (15mcg/mL+ 5mg/mL)

Product Registration Holder

Santen Pharma Malaysia Sdn. Bhd.
Unit #23A-10, Q Sentral,
No. 2A, Jalan Stesen Sentral 2,
Kuala Lumpur Sentral,
50470 Kuala Lumpur, Malaysia.

Date of revision

Aug 2022

Serial Number

NPRA (R1/3) 11082022/240