EYBELIS®-S OPHTHALMIC SOLUTION 0.002%

Omidenepag Isopropyl (20 micrograms/mL)

What is in this leaflet

What EYBELIS-S is used for

Eybelis-S comes in the form of eye drops and belongs to a group of medicines called anti-glaucoma/ocular hypertension drugs. Eybelis-S is used in patients (20 years of age and older) with open angle glaucoma and ocular hypertension.

How EYBELIS-S works

This medicine reduces the pressure in the eye by promoting the fluid drainage which controls the eye's fluid pressure.

Before you use EYBELIS-S

- *When you must not use it*
  - If you are hypersensitive to ingredients contained in Eybelis-S.
  - If you are now using Tafluprost (Tafluprost eye drops or any products containing Tafluprost).
  - If you have aphakic eyes (missing of lens in one or in both of your eyes) or have artificial lens implanted in the eyes.
  - The safety and efficacy of omidenepag isopropyl in children and adolescents have not yet been established. No data are available.

- *Before you start use it*

Before using this medicine, be sure to tell your doctor or pharmacist:

- If you have an ocular inflammatory disease such as iritis or uveitis.
- If you are pregnant or may possible be pregnant.
- If you are breastfeeding.

- *Taking other medicines*

You cannot concomitantly use Eybelis-S with a certain type of medicine such as Tafluprost (Tafluprost eye drops or any product containing Tafluprost).

Concomitant use of Eybelis-S with other glaucoma/ ocular hypertension medications should be done with caution.

Some medicines need special attention when concomitantly used. Be sure to consult your doctor or pharmacist if you are using other eye drops or intend to use new medicine(s).

How to use EYBELIS-S

- *How much to use*

Instill 1 drop a time, once a day. Strictly follow the instructions.
Open the affected eye and apply eye drops into the conjunctival sac. After pressing the lacrimal sac with the eyes closed for one to five minutes, open the eyes.

- *When to use it*

Once a day.

- *How long to use it*

Do not stop using this medicine unless your doctor instructs you to do so.

- *If you forget to use it*

If you realize you have forgotten to apply the medicine on the day, instill the missed dose as soon as possible.
If you realize you have forgotten to apply the medicine the next day, skip the missed dose and take your next dose at usual time. Do not take a double dose to make up for the dose you missed.

- *If you use too much (overdose)*

If you accidentally instill more than your prescribed dose, consult with your doctor or pharmacist.

While you are using it

- *Things you must do*
  - Keep this leaflet. You may need to read it again.
  - If you have any further questions, ask your doctor or your pharmacist.
  - If you experience any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

- *Things you must not do*

This medicine has been prescribed for you only. Do not share it with others. It may harm them, even if their symptoms are the same as yours.

- *Things to be careful of*

After applying this medicine, your vision may be temporarily blurred, or you get sensitive to light. Do not drive or operate machinery until your vision becomes clear.

Wash your hands well. Be careful not to let the tip of the eyedropper touch your eye when applying eye drops.

If you use more than one types of eye drops, wait at least 5 minutes between each drop.

If you are a contact lens wearer, remove the lenses before applying eye drops (if not, contact lenses may discolour). Wait at least 5-10 minutes before putting the contact lenses back into the eyes.

Side effects

Like all medicines, Eybelis-S can cause side effects, although not everybody gets them.

The very common adverse reaction is eye redness. The common adverse reactions are macular edema (symptoms is blurred vision), eye pain, inflammation of iris, sensitive to bright light and eye irritation. If any of these symptoms occur, consult with your doctor or pharmacist.

If you have macular edema including cystoid macular edema (symptoms such as reduced vision, difficulty seeing and blurred vision), you must stop taking this medicine and consult your doctor or pharmacist immediately.

If any of the side effects become serious, or if you notice any side effects that have not been listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers ➔

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Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Eybelis-S

- *Storage*

Protected from light. Store unopened pouches under refrigeration at 2-8°C.

After opening the pouch, store it at below 30°C and use within a month.

Keep medicine out of reach of children.

- *Disposal*

Do not use this medicine after the expiry date which is stated on the outer carton after "EXP". The expiry date refers to the last day of that month.

Do not throw away any medicines via waste water or household waste. Ask your doctor or pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Product Description

- *What it looks like*

It is a clear, colourless, sterile aqueous ophthalmic solution.

- *Ingredients*
  - Active ingredient

Each mL contains 20 micrograms of omidenepag isopropyl.

  - Inactive ingredients

Polyoxyl 35 castor oil, concentrated glycerin, disodium edetate hydrate, citric acid hydrate, sodium citrate hydrate, pH adjuster (sodium hydroxide and dilute hydrochloric acid) and purified water.

- *MAL number(s):*

MAL24096008ARZ

Manufacturer:
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