

Patient information leaflet: Information for the user

Conheal 0.15 mg/ml eye drops solution

sodium hyaluronate

Read all of this leaflet carefully before you start using this medicine, because it contains important information for you.

Always take this medicine exactly as it is prescribed in this patient information leaflet or as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- If any side effect develops with you, tell your doctor or pharmacist. This also relates to any other possible side effects not listed in this leaflet. See section 4.
- Tell your doctor if your symptoms are not mitigated or gets serious.

What is in this leaflet:

1. What Conheal 0.15 mg/ml eye drops solution (hereinafter Conheal eye drops) is and what it is used for?
2. What you need to know before you use Conheal 0.15 eye drops?
3. How to use Conheal eye drops?
4. Possible side effects
5. How to store Conheal eye drops?
6. Other information

1 What Conheal eye drops is and what it is used for?

The Conheal eye drops is an artificial tear containing sodium hyaluronate, which is useful for the treatment of dry eye syndrome developed for whatever reason, consequential chronic external corneal inflammations, corneal epithelial damages, ophthalmological symptoms of Sjögren syndrome and the treatment of wavy conjunctiva (so called conjunctivochalasis) as well as for the prevention of severe complications on the cornea.

2 What you need to know before you use Conheal 0.15 eye drops?

Do not use the Conheal eye drops

- if you are allergic (hypersensitive) to sodium hyaluronate or any other ingredients of this medicinal product (listed in section 6).

Special warnings and special precautions for use

When used with other eye drops, an interval of at least 5 minutes should be allowed between the instillation of the given eye drops and the Conheal eye drops. In all cases, the Conheal eye drops should be administered as the last one.

Before instillation, the contact lenses should be removed and should be reinserted 30 minutes after instillation at the earliest.

If irritation in the surrounding area of the eyes and of the conjunctiva appear, or these get more serious, respectively, or headache, ocular pains, visual disturbances develop, the treatment should be immediately discontinued.

Use of Conheal eye drops concurrently with other medicines

Please tell your doctor or pharmacist all other medicines you are taking or have recently taken, as well as the medicines you plan to take, including the medicines obtained without prescription.

The Conheal eye drops may increase the effect of other medicines administered to the eyes.

In case of concurrent application of any other ophthalmological preparations it is recommended to be cautious and it is recommended to have your doctor's preliminary approval.

Pregnancy and breast-feeding

If you are pregnant or breast-feeds, or if you plan to become pregnant or think that you may be pregnant, ask your doctor or pharmacist for advice before taking any medicine.

There are no adequate clinical data from the use of sodium hyaluronate in pregnant women. Nevertheless, as the sodium hyaluronate exerts local physical effect on the eyes, its use supposedly represent enhanced risk neither for the mother nor for the foetus, thus in case of necessity it can be used during pregnancy.

Driving and using machines

When using the product, after instillation, the vision may be transiently blurred. You must not drive or use any machines until your vision is clear.

3 How to use Conheal eye drops?

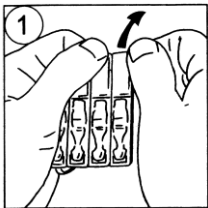
Always take this medicine exactly as it is prescribed in this patient information leaflet or as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

Instil 1 drop into each eye in general 4 times a day (during approx. 12 hours).

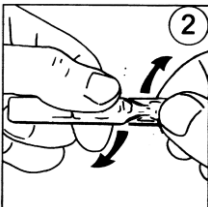
According to necessity, the daily dosage may change between 3 and 8 drops (during approx. 12 hours), depending on the severity of the symptoms.

The eye drops should be used up within 12 hours after the first opening the container.

After use, the container should be closed again. The container contains an eye drop amount sufficient for 1 day.



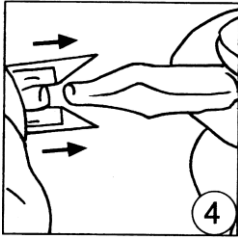
Detach one container



When opening, roll the cap until it gets torn off, then pull it.



Turn the container upside down, shake it and instil in your eye.



When closing, push back the cap onto the container and keep it for further use.

If you use more Conheal eye drops than you should

No data are available in humans regarding overdose. As the Conheal eye drops is an artificial tear preparation applied on the anterior surface of the eyeball, its overdose is not probable.

If you forget to use Conheal eye drops

The Conheal eye drops is a product used for the symptomatic treatment of the dry eye, according to the dosing given in section 3, depending on the severity of the symptoms. Therefore, differently from other medicinal products, its administration is not rigorously bound to points of time.

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

4 Possible side effects

Like all medicines, Conheal eye drops can cause side effects, although not everyone gets them.

Rarely, mild burning sensation in the eyes, blurred vision, itching, foreign body sensation may occur, or the eyelashes may become sticky, respectively.

The burning sensation, itching and the foreign body sensation, respectively, may be the symptom of the dry eye disease as well.

Reporting the side effects

If any side effect develops with you, tell your doctor or pharmacist. This also relates to any other side effects not listed in this leaflet.

You can report the side effects directly to the authorities through one of the contact points shown in the Annex V.

With reporting the side effects, you can also contribute that as much information as possible be available in connection with the safe use of this medicine.

5 How to store Conheal eye drops?

Keep out of the reach and sight of children.

Do not store above 25 °C.

Keep the container in the original outer carton in order to protect from light, moisture.

Keep the container of the eye drops tightly closed.

Do not use Conheal eye drops after the expiry date which is stated on the cardboard box after “Exp”. The expiry date refers to the last day of that month.

Do not throw any medicines into the waste water or the household waste. Ask your pharmacist what to do with your medicines not used any longer. These measures promote the protection of the environment.

6 Other information

What Conheal eye drops contains

- The active ingredient of the product is sodium hyaluronate.
1 ml of the solution contains 0.15 mg of sodium hyaluronate.
0.0975 mg of sodium hyaluronate by (0.65-ml) container
- Other ingredients: Carbomer 981 (in form of sodium salt), glycerine, purified water.

What Conheal eye drops looks like and contents of the pack

0.65 ml of eye drops solution in a low-density polyethylene container the closing cap of which can be broken down when opening and can be placed back as a closing element.

5 or 10 pieces of containers fixed together in an aluminium/paper pouch and a cardboard box.

5, 10, 20 or 30 pieces of containers in a cardboard box.

Marketing Authorisation Holder and Manufacturer

PannonPharma Gyógyszergyártó Kft.

H 7720 Pácsvárád, Pannonpharma út 1., Hungary

OGYI-T-21033/01	5x	0.65 ml
OGYI-T-21033/02	10x	0.65 ml
OGYI-T-21033/03	20x	0.65 ml
OGYI-T-21033/04	30x	0.65 ml

This leaflet was last approved in January 2019