Retaane®

Anecortave acetate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Retaane. It does not contain all the available information. It does not take the place of talking to your doctor.

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

If you have any concerns about this medicine ask your doctor.

Keep this leaflet.

You may need to read it again.

What Retaane is used for

Retaane is used to treat a condition where abnormal blood vessels grow in the back of your eye causing loss of central vision and impairment of your sight. This condition is known as exudative or "wet" age-related macular degeneration or AMD.

AMD causes damage to the macula, the central zone of the retina. The retina is the light sensitive layer at the back of the eye. The macula is a very specialised region of the retina responsible for our ability to see detail, perceive colors and perform other activities that require focused, straight-ahead vision.

The most common cause of irreversible vision loss in people over the age of 50 is degeneration of the macula (AMD) caused by abnormal blood vessel growth.

How it works

Retaane works by stopping or slowing down the growth of abnormal blood vessels in your eye.

Ask your doctor if you have any questions about why you will be receiving this medicine.

This medicine is not addictive.

Before you are given Retaane

When you must not be given it

You must not be given Retaane if you have an allergy to:

 Anecortave acetate or any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

AMD is not seen in children. The safety and effectiveness of Retaane in children have not been established.

If you are not sure whether you should be given Retaane, talk to your doctor.

Before you are given it

Tell your doctor if

- 1. You have allergies to any other medicines, foods, dyes or preservatives.
- 2. You are pregnant or intend to become pregnant.

Retaane is not recommended for use during pregnancy.

3. You are breastfeeding or intend to breastfeed.

Your doctor will discuss the possible risks and benefits of having Retaane during breastfeeding.

- 4. You have, or have had, any of the following medical conditions:
- degenerative myopia
- scleral buckle

If you have not told your doctor about any of the above, tell him or her before you are given Retaane.

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.

Some medicines and Retaane may interfere with each other.

How Retaane is given

Your doctor will prepare and administer Retaane to you.

Follow the directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions, ask your doctor for help.

Retaane is given as an injection under your eyelid using a specially designed needle to access the back of the eye.

How is it given

You will be lying down or reclined in a chair. Firstly the doctor will prepare your eye for the injection with a local anaesthetic to numb the pain.

The doctor will then place an instrument called a speculum on your eye to hold back your eyelids before making an incision and inserting the specially designed needle.

Retaane is then slowly injected behind the eye. *When it is given*

Retaane is given as a single dose. If necessary it can be repeated at least every 6 months.

How long to continue treatment

Continue treatment with Retaane for as long as your doctor tells you.

This medicine helps to control your eye disease, but does not cure it. It is important to keep having your vision checked by your doctor even if you feel it has improved.

If you forget a treatment

If you miss a Retaane treatment you need to contact your doctor to arrange another appointment as soon as possible.

If you are given too much (overdose)

Take advice from your doctor. Overdose of Retaane may cause temporary eye discomfort or pain.

After having Retaane

Things you must do

You must contact your doctor if you have significant eye pain or discharge.

After injection of Retaane you may have your eye covered with a patch. This may impair your ability to drive or use machines. If so, do not operate machinery or do anything else that could be dangerous until the patch has been removed and any temporary treatment-related vision changes have disappeared.

Keep follow-up appointments with your doctor or clinic. If your doctor recommends you have another injection, it is very important that you come back at the appointed time, which is usually no more than 6 months after the previous injection.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well after being given Retaane.

Retaane may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

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

Do not be alarmed by the following list of side effects. You may not experience any of them.

After being given Retaane you may experience some or all of the following reactions in your eye:

- decreased vision
- eye discomfort, pain and redness
- swelling of the eye
- cataract
- decreased pressure in the eye
- drooping of the upper eyelid
- unequal pupil sizes, abnormal pupil response to light
- redness or swelling of the eyelid
- retinal detachment (structural changes in the back of the eye)
- foreign body sensation in the eye

You may also experience reactions in other areas of your body, including:

- shivering
- tiredness
- headache
- back pain
- nausea
- nasal allergy

These are usually mild side effects of Retaane.

Tell your doctor immediately or go to Accident & Emergency at your nearest hospital if any of the following happen.

These are very serious side effects. You may need urgent medical attention or hospitalisation. (These side effects are very rare.)

- sudden signs of allergy such as shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.
- chest pain or change in heat beat
- dizziness and light-headedness
- swelling of the hands, feet, ankles or legs.

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

Storing Retaane

Retaane is usually stored in the doctor's surgery or clinic, or at the pharmacy. However, if you need to store Retaane:

- Keep it where children cannot reach it.
- Keep Retaane in the original pack until it is time for it to be given.
- Keep it below 25°C. Do not freeze Retaane.
- You must not be given Retaane after the expiry date printed on the pack.
- Do not have Retaane if the packaging is torn or shows signs of tampering.

Product description

What it looks like

Retaane is a white to off-white suspension.

Ingredients

Active ingredient:

• Anecortave acetate Each 0.5 mL of Retaane contains 15 mg of

anecortave acetate.

Other ingredients

- Sodium phosphate, monobasic
- Sodium phosphate, dibasic dodecahydrate
- Tyloxapol
- Sodium chloride
- Water for Injection.

Supplier

Retaane is supplied in Australia by: Alcon Laboratories (Australia) Pty Ltd

25 Frenchs Forest Road East FRENCHS FOREST NSW 2086

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