

Package leaflet: Information for the patient

CINQAERO 10 mg/mL concentrate for solution for infusion reslizumab

Read all of this leaflet carefully before you are given this medicine 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 4.

What is in this leaflet

1. What CINQAERO is and what it is used for
2. What you need to know before you are given CINQAERO
3. How CINQAERO is given
4. Possible side effects
5. How to store CINQAERO
6. Contents of the pack and other information

1. What CINQAERO is and what it is used for

What CINQAERO is

CINQAERO contains the active substance reslizumab, a monoclonal antibody, a type of protein that recognises and binds to a specific target substance in the body.

What CINQAERO is used for

CINQAERO is used to treat severe eosinophilic asthma in adult patients (18 years of age and over) when the condition is not well controlled despite treatment with high-dose inhaled corticosteroids together with another asthma medicine. Eosinophilic asthma is a type of asthma where patients have too many eosinophils in the blood or lungs. CINQAERO is used together with other medicines to treat asthma (inhaled corticosteroids plus other asthma medicines).

How CINQAERO works

CINQAERO blocks interleukin-5 activity and reduces the number of eosinophils in your blood and lungs. Eosinophils are white blood cells involved in asthma inflammation. Interleukin-5 is a protein your body makes that plays a key role in inflammation in asthma by activating eosinophils.

What are the benefits of using CINQAERO

CINQAERO reduces how often you have flare-ups of your asthma, helps you breathe better and decreases your asthma symptoms.

2. What you need to know before you are given CINQAERO

You must not receive CINQAERO:

- if you are allergic to reslizumab or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or nurse before you are given CINQAERO:

- if you have a parasitic infection or if you live in an area where parasitic infections are common or if you are travelling to such a region, as this medicine may weaken your body's ability to fight certain types of parasitic infections.

Also, talk to your doctor or nurse when you are given CINQAERO:

- if your asthma remains uncontrolled or worsens during treatment with this medicine;
- if you have any of the symptoms of an allergic reaction (e.g. itching, trouble breathing, wheezing, fever, shivering, dizziness, headache, nausea, vomiting, abdominal discomfort, skin rash, redness or swelling). Serious allergic reactions have occurred in patients receiving this medicine (see section “4. Possible side effects”).

Children and adolescents

This medicine is NOT intended for use in children and adolescents below the age of 18 years.

Other medicines and CINQAERO

Tell your doctor if you are using, have recently used or might use any other medicines.

This is particularly important:

- if you are receiving other medicines which affect your immune system;
- if you have recently received a vaccination or if you are likely to need a vaccination.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before you are given this medicine.

The active substance in this medicine may pass into breast milk but only during the first few days after birth.

Driving and using machines

It is unlikely that CINQAERO will affect your ability to drive and use machines.

CINQAERO contains sodium

This medicine contains 4.6 mg sodium (main component of cooking/table salt) in each vial of 10 mL, and 1.15 mg sodium in each vial of 2.5 mL. This is equivalent to 0.23% and 0.06%, respectively, of the recommended maximum daily dietary intake of sodium for an adult.

3. How CINQAERO is given

Always follow the instructions exactly as your doctor has told you. Check with your doctor if you are not sure.

The dose depends on your body weight. Your doctor will work out the right dose for you. The maximum dose is 3 mg per kg of body weight. CINQAERO will be given every 4 weeks. You will be given CINQAERO by a doctor or nurse as an infusion (drip) into a vein. The infusion will take about 20 to 50 minutes.

Your doctor or nurse will watch you closely during and after your infusion for signs of an allergic reaction.

If you miss your scheduled dose of CINQAERO

If you miss a scheduled dose of CINQAERO, ask your doctor when to schedule your next treatment.

If you stop using CINQAERO

Do NOT stop treatment with CINQAERO unless your doctor tells you to, even if you feel better. Interrupting or stopping treatment with this medicine may cause your asthma symptoms to come back.

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

4. Possible side effects

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

Serious side effects

- Serious allergic reactions
Serious allergic reactions can happen uncommonly (may affect up to 1 in 100 people) while receiving CINQAERO or afterwards. Your doctor or nurse will watch you closely for signs of a reaction. Tell your doctor or nurse **straight away** if you have any of the symptoms of an allergic reaction (e.g. itching, trouble breathing, wheezing, fever, shivering, dizziness, headache, nausea, vomiting, abdominal discomfort, skin rash, redness or swelling).

Other side effects

Common (may affect up to 1 in 10 people)

- Increase of an enzyme in your blood (blood creatine phosphokinase).

Uncommon (may affect up to 1 in 100 people)

- Muscle pain (myalgia).

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below).

United Kingdom

The Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

Ireland

HPRa Pharmacovigilance Website: www.hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store CINQAERO

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

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

Store in a refrigerator (2°C - 8°C). Do not freeze.

Keep the vial in the outer carton in order to protect from light.

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

6. Contents of the pack and other information

What CINQAERO contains

- The active substance is reslizumab.
Each mL of concentrate contains 10 mg of reslizumab (10 mg/mL). Each vial of 2.5 mL contains 25 mg of reslizumab and each vial of 10 mL contains 100 mg of reslizumab.
- The other excipients are sodium acetate trihydrate, acetic acid glacial, sucrose and water for

injections.

What CINQAERO looks like and contents of the pack

CINQAERO is a clear to slightly hazy opalescent, colourless to slightly yellow concentrate for solution for infusion (sterile concentrate). Particles might be present. CINQAERO is supplied in glass vials containing 2.5 mL or 10 mL.

CINQAERO is available in packs containing 1 or 2 vials with 2.5 mL and in packs containing 1 or 2 vials with 10 mL.

Not all pack sizes may be marketed.

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Detailed information on this medicine is available on the European Medicines Agency web site:
<http://www.ema.europa.eu>.

The following information is intended for healthcare professionals only:

CINQAERO is provided as a concentrate for solution for infusion in a single-use vial. The solution for infusion is intended only for intravenous use after dilution and should be prepared using aseptic technique as follows:

Traceability

In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

Preparation of solution for infusion

1. Remove CINQAERO from the refrigerator. Do not shake the vial.
2. The medicinal product should be inspected visually before use. The concentrate is clear to slightly hazy opalescent, colourless to slightly yellow. Proteinaceous particles may be present in the concentrate that appear as translucent to white, amorphous particles, some of which may look fibrous. This is not unusual for proteinaceous solutions. The concentrate must not be used if coloured (except slightly yellow) or if foreign particles are present.
3. A suitable injection syringe should be used to withdraw the needed amount of concentrate from the vial(s) (see section 4.2 of Summary of Product Characteristics).
4. Slowly dispense the contents of the syringe(s) into an infusion bag containing 50 mL of sodium chloride 9 mg/mL (0.9%) solution for infusion. Gently invert the bag to mix the solution. This medicinal product must not be mixed with other medicinal products except sodium chloride 9 mg/mL (0.9%) solution for infusion.
5. Any concentrate remaining in the vial must be discarded.
6. It is recommended that the solution for infusion be administered immediately after preparation. Solutions of CINQAERO diluted in sodium chloride 9 mg/mL (0.9%) solution for infusion may be stored refrigerated at 2 °C-8 °C (or not above 25 °C if dilution has taken place in controlled and validated aseptic conditions), protected from light for up to 16 hours.
7. CINQAERO is compatible with polyvinylchloride (PVC) or polyolefin (PO) infusion bags.

Instructions for administration

1. CINQAERO should be administered by a healthcare professional prepared to manage hypersensitivity reactions including anaphylaxis (see section 4.4 of Summary of Product Characteristics). The patient has to be observed over the duration of the infusion and for an appropriate period afterwards. Patients should be instructed on how to recognise symptoms of serious allergic reactions.
2. If the solution for infusion has been stored in a refrigerator, allow it to reach room temperature (15 °C-25 °C).
3. The solution for infusion should be infused intravenously over 20 – 50 minutes. Infusion time may vary depending on the total volume to be infused.
4. The solution for infusion should not be infused concomitantly in the same intravenous line with other medicinal products. No physical or biochemical compatibility studies have been conducted to evaluate the co-administration of reslizumab with other medicinal products.
5. An infusion set with an in-line, sterile, non-pyrogenic, single-use, low-protein-binding filter (pore size of 0.2 µm) should be used for infusion. CINQAERO is compatible with polyethersulfone (PES), polyvinylidene fluoride (PVDF), nylon, cellulose acetate (CA) low protein binding in-line infusion filters.
6. Upon completion of the infusion, flush the infusion set with sterile sodium chloride 9 mg/mL (0.9%) solution for infusion to ensure that all of the CINQAERO solution for infusion has been administered.

For dosing instructions see section 4.2 of Summary of Product Characteristics.