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Kromeya (*adalimumab*)

An overview of Kromeya and why it is authorised in the EU

What is Kromeya and what is it used for?

Kromeya is a medicine that acts on the immune system (the body's natural defences) and is used to treat the following conditions:

- plaque psoriasis (a disease causing red, scaly patches on the skin);
- psoriatic arthritis (a disease causing red, scaly patches on the skin with inflammation of the joints);
- rheumatoid arthritis (a disease causing inflammation of the joints);
- axial spondyloarthritis (inflammation of the spine causing back pain), including ankylosing spondylitis and when there are clear signs of inflammation but X-ray does not show disease;
- polyarticular juvenile idiopathic arthritis and active enthesitis-related arthritis (both rare diseases causing inflammation in the joints);
- Crohn's disease (a disease causing inflammation of the gut);
- ulcerative colitis (a disease causing inflammation and ulcers in the lining of the gut);
- non-infectious uveitis (inflammation of the layer beneath the white of the eyeball).

Kromeya is mostly used in adults when their condition is severe, moderately severe or getting worse, or when patients cannot use other treatments. For more information on the use of Kromeya in all conditions, including when it can be used in children, see the package leaflet or contact your doctor or pharmacist.

Kromeya contains the active substance adalimumab and is a 'biosimilar medicine'. This means that Kromeya is highly similar to another biological medicine (the 'reference medicine') that is already authorised in the EU. The reference medicine for Kromeya is Humira. For more information on biosimilar medicines, see here.

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How is Kromeya used?

Kromeya is available as a solution for injection under the skin in a vial or pre-filled syringe or pen, and is usually given every 2 weeks. The dose and frequency of injection depend on the condition to be treated and the dose for a child is usually calculated according to the child's weight. After training, patients or their carers may inject Kromeya if their doctor considers it appropriate.

Kromeya can only be obtained with a prescription and treatment must be started and supervised by a doctor who has experience in the treatment of the diseases for which Kromeya is used. Eye specialists treating uveitis should also take advice from doctors who have experience of using adalimumab.

For more information about using Kromeya, see the package leaflet or contact your doctor or pharmacist.

How does Kromeya work?

The active substance in Kromeya, adalimumab, is a monoclonal antibody (a type of protein) that has been designed to recognise and attach to a substance in the body called tumour necrosis factor (TNF). TNF is involved in causing inflammation and is found at high levels in patients with the diseases that Kromeya is used to treat. By attaching to TNF, adalimumab blocks its activity, thereby reducing inflammation and other symptoms of the diseases.

What benefits of Kromeya have been shown in studies?

Laboratory studies comparing Kromeya with the reference medicine Humira have shown that the active substance in Kromeya is highly similar to that in Humira in terms of structure, purity and biological activity. Studies have also shown that giving Kromeya produces similar levels of the active substance in the body to giving Humira.

In addition, a study involving 443 patients with plaque psoriasis has shown that Kromeya is as effective as Humira in controlling the disease. The study compared injections of the two medicines given under the skin every 2 weeks: after 16 weeks, 90% of those treated with Kromeya and 92% of those treated with Humira had at least a 75% reduction in signs and symptoms of psoriasis.

Because Kromeya is a biosimilar medicine, the studies on effectiveness and safety of adalimumab carried out with Humira do not all need to be repeated for Kromeya.

What are the risks associated with Kromeya?

The safety of Kromeya has been evaluated, and on the basis of all the studies carried out the side effects of the medicine are considered to be comparable to those of the reference medicine Humira. The most common side effects with adalimumab (which may affect more than 1 in 10 people) are infections (including in the nose, throat and sinuses), injection site reactions (redness, itching, bleeding, pain or swelling), headache and muscle and bone pain.

Like other medicines of its class, Kromeya may affect the ability of the immune system to fight off infections and cancer, and there have been some cases of serious infections and blood cancers in patients using adalimumab.

Other rare serious side effects of adalimumab (which may affect up to 1 in 1,000 people) include failure of bone marrow to produce blood cells, disorder of the nerves, lupus and lupus-like conditions (where the immune system attacks the patient's own tissues, causing inflammation and organ

damage), and Stevens-Johnson syndrome (life-threatening reaction with flu-like symptoms and painful rash affecting the skin, mouth, eyes and genitals).

Kromeya must not be used in patients with active tuberculosis or other severe infections, or in patients with moderate to severe heart failure (an inability of the heart to pump enough blood around the body).

For the full list of side effects and restrictions with Kromeya, see the package leaflet.

Why is Kromeya authorised in the EU?

The European Medicines Agency decided that, in accordance with EU requirements for biosimilar medicines, Kromeya has a highly similar structure, purity and biological activity to Humira and is distributed in the body in the same way. In addition, studies in psoriasis have shown that the effectiveness of Kromeya is equivalent to that of Humira.

All these data were considered sufficient to conclude that Kromeya will behave in the same way as Humira in terms of effectiveness and safety in its authorised uses. Therefore, the Agency's view was that, as for Humira, the benefits of Kromeya outweigh the identified risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Kromeya?

Patients treated with Kromeya must be given a reminder card with information on the safety of the medicine.

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Kromeya have also been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Kromeya are continuously monitored. Side effects reported with Kromeya are carefully evaluated and any necessary action taken to protect patients.

Other information about Kromeya

Kromeya received a marketing authorisation valid throughout the EU on 2 April 2019.

Further information on Kromeya can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/Kromeya.

This overview was last updated in 11-2019.