LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Qulventra
(ivacaftor)

SE/H/2756/001-002/DC

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Summary Public Assessment Report

Qulventra
Ivacaftor

Film-coated tablet, 75 mg, 150 mg

This is a summary of the public assessment report (PAR) for Qulventra. It explains how the assessment was made and why the authorisation was recommended as well as the conditions of use. It is not intended to provide practical advice on how to use the product.

For practical information about the use of the product, patients should read the package leaflet or contact their doctor or pharmacist.

What is Qulventra and what is it used for?

The product is a ‘generic medicine’. This means that it is similar to a ‘reference medicine’ already authorised in the European Union (EU) called Kalydeco

Qulventra tablets are indicated:

• as monotherapy for patients aged 6 years and older and weighing 25 kg or more with cystic fibrosis (CF) who have an R117H CFTR mutation or one of the following gating mutations in the CFTR gene: G551D, G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N or S549R.

• In combination with tezacaftor/ivacaftor tablets for patients aged 6 years and older with CF who have two F508del mutations in the CFTR gene (homozygous for the F508del mutation) or who have an F508del mutation and certain other second mutations that result in reduced amount and/or function of the CFTR protein (heterozygous for the F508del mutation with a residual function (RF) mutation). If you have been prescribed <Product name> to be taken with tezacaftor/ivacaftor, read the package leaflet of the latter. It contains important information about how to take these two medicines.

• In combination with ivacaftor/tezacaftor/elexacaftor tablets for patients aged 6 years and over who have CF, with at least one mutation in the CFTR gene that is responsive to Qulventra in combination with ivacaftor/tezacaftor/elexacaftor. If you have been prescribed Qulventra to be taken with ivacaftor/tezacaftor/elexacaftor, read the package leaflet of the latter. It contains important information about how to take these two medicines.

How does Qulventra work?

Qulventra contains the active substance ivacaftor. Ivacaftor acts at the level of the cystic fibrosis transmembrane conductance regulator (CFTR), a protein that forms a channel at the cell surface that allows the movement of particles such as chloride in and out of the cell. Due to mutations in the CFTR gene (see below), chloride movement is reduced in those with cystic fibrosis (CF). Ivacaftor helps certain abnormal CFTR proteins open more often to improve chloride movement in and out of the cell.

How is Qulventra used?

The pharmaceutical form is film-coated tablet for oral use.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription in Sweden.

What benefits of Qulventra have been shown in studies?

Because the product is a generic medicine, studies have been limited to tests to determine that it is bioequivalent to the reference medicine, Kalydeco. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects from Qulventra?

Because the product is a generic medicine, its benefits and possible side effects are taken as being the same as the reference medicine.

For the full list of side effects, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

Why is Qulventra approved?

It was concluded that, in accordance with EU requirements, the product has been shown to have comparable quality and bioequivalent to the reference medicine. Therefore, the Swedish Medical Products Agency decided that, as for Kalydeco, the benefits are greater than its risks and recommended that it can be approved for use.

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

A risk management plan has been developed to ensure that the product is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore, new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

For more details, please see the full PAR for Qulventra on the following website: MRI - Home.

Other information about Qulventra

The full PAR for Qulventra can be found on the following website: MRI - Home. For more information about treatment with Qulventra please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2026-07.