LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Dogrivio
(dolutegravir sodium)

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Summary Public Assessment Report

Dogrivio
dolutegravir, dolutegravir sodium

Film-coated tablet, 25 mg, 50 mg

This is a summary of the public assessment report (PAR) for Dogrivio. 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 Dogrivio 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 Tivicay.
Dogrivio contains the active ingredient dolutegravir. Dolutegravir belongs to a group of anti-retroviral medicines called integrase inhibitors (INIs).

Dogrivio is used to treat **HIV (human immunodeficiency virus) infection** in adults, adolescents and children of at least 6 years of age or older, and who weigh at least 14 kg.

How does Dogrivio work?
Dogrivio does not cure HIV infection; it reduces the amount of virus in your body, and keeps it at a low level. As a result of that, it also increases the CD4 cell count in your blood. CD4 cells are a type of white blood cells that are important in helping your body to fight infection.

Not everyone responds to treatment with Dogrivio in the same way. Your doctor will monitor the effectiveness of your treatment.

Dogrivio is always used in combination with other anti-retroviral medicines (combination therapy). To control your HIV infection, and to stop your illness from getting worse, you must keep taking all your medicines, unless your doctor tells you to stop taking any.

How is Dogrivio 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 Dogrivio 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, Trivicay. Based on the submitted bioequivalence study, Dolutegravir, 50 mg, film-coated tablets are considered bioequivalent with Tivicay, 50 mg, film-coated tablets.

What are the possible side effects from Dogrivio?
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 restrictions, see the package leaflet.

Why is Dogrivio approved?
It was concluded that, in accordance with EU requirements, the product has been shown to have comparable quality and is bioequivalent to the reference medicine. Therefore, the Swedish Medical Products Agency decided that, as for Trivicay, 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 Dogrivio?
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 Dogrivio on the following website: MRI - Home.

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

This summary was last updated in 2026-04.