swissmedic

Summary report on authorisation dated 30 December 2024

Fruzaqla® (active substance: fruquintinib)

Authorisation in Switzerland: 27 August 2024

Hard capsules for the treatment of metastatic colorectal cancer (mCRC) in adults who have previously received available standard treatments and in whom the disease has progressed

About the medicinal product

The medicinal product Fruzaqla contains the active substance fruquintinib.

Fruzaqla is used as monotherapy (the only treatment) in adults with metastatic colorectal cancer (cancer of the large intestine and rectum that has spread to other parts of the body).

Fruzaqla is specifically used in patients who have previously received various standard treatments, including fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy and, if their cancer is RAS wild type[1], anti-EGFR agents[2]. Treatment with Fruzaqla is initiated if the disease has continued to progress following treatment with trifluridine/tipiracil or regorafenib, or if patients have not tolerated these treatments.

Fruzaqla was authorised as part of the joint initiative of the Access Consortium. This joint initiative is a collaborative project between the drug regulatory authorities in Australia (Therapeutic Goods Administration, TGA), Canada (Health Canada, HC), Singapore (Health Sciences Authority, HSA), the United Kingdom (Medicines & Healthcare products Regulatory Agency, MHRA), and Swissmedic and the pharmaceutical industry. The joint initiative coordinates the assessment of authorisation applications for new active substances that have been submitted in at least 2 of the 5 countries. The authorisation application for Fruzaqla was submitted for assessment to the regulatory authorities in Australia, Canada, Singapore, the United Kingdom, and Switzerland. Each country assessed a part of the application and then shared and discussed the results. At the end of the process, each authority decided on the application independently.

Swissmedic considered the assessments by the foreign reference authorities in its decision on the authorisation.

[1] RAS wild type: RAS wild type means that the RAS gene is not mutated. This is important information for the treatment of metastatic colorectal cancer because patients with RAS wild type tumours generally respond better to certain treatments, such as anti-EGFR agents.

[2] Anti-EGFR agents: anti-EGFR agents are medicines that inhibit the epidermal growth factor receptor (EGFR). EGFR is a protein found on the surface of cells and is involved in cell growth and division. It is often over-active in many types of cancer, including colorectal cancer and this leads to uncontrolled cell growth and the development of tumours.

Further details of the Access joint initiative are published on the Swissmedic website: Access Consortium (swissmedic.ch).

Mode of action

The medicinal product Fruzaqla contains the active substance fruquintinib. Fruquintinib is a tyrosine kinase inhibitor, a group of medicinal products that inhibit tumour growth by reducing the blood supply to tumour cells. This restricts the supply of nutrients and oxygen to the tumour, which can slow down or halt tumour growth.

Use

Fruzaqla is a prescription-only medicine. It is available as hard capsules for oral administration (swallowing) containing a 1 mg or 5 mg dose of the active substance fruquintinib.

The recommended dosage for adults is 5 mg once daily at approximately the same time each day for 21 days, followed by a 7-day break in treatment, giving a treatment cycle of 28 days.

Efficacy

The efficacy of Fruzaqla was evaluated in the global FRESCO-2 study in 691 patients who had previously received standard treatments.

Study participants received either Fruzaqla or placebo (dummy drug) for 21 days followed by a 7-day pause in a 28-day treatment cycle.

The study found a significant improvement in overall survival (OS)[3] in patients treated with Fruzaqla, with median[4] OS of 7.4 months compared with 4.8 months for the placebo group.

Progression-free survival (PFS)[5] also improved significantly to a median of 3.7 months compared with 1.8 months in the placebo group.

[3] Overall survival (OS): overall survival refers to the period between the start of treatment and the death of the patient.

[4] Median: the value that lies exactly in the middle of a distribution of data is called the median or central value. Half of the data values are always less than the median, the other half are always greater.

[5] Progression-free survival (PFS): period between the start of a treatment or a clinical trial and the onset of disease progression or the death of the patient.

Precautions, undesirable effects, & risks

Fruzaqla must not be used in those who are hypersensitive to the active substance or any of the excipients.

The most common undesirable effects (affecting more than 20 % of patients) include high blood pressure (49.3 %), anorexia (appetite loss) (35.6 %), proteinuria (excessive excretion of proteins in the urine) (35.5 %), palmar-plantar erythrodysaesthesia syndrome[6] (34.6 %), hypothyroidism (reduced thyroid gland activity) (32.4 %), dysphonia (voice changes) (28.6 %), diarrhoea (26.3 %), and asthenia (weakness or lack of strength) (24.5 %).

All precautions, risks, and other possible undesirable effects are listed in the Information for patients (package leaflet) and the Information for healthcare professionals.

Why the medicinal product has been authorised

The treatment options available to patients with metastatic colorectal cancer (mCRC) who do not respond to or tolerate standard treatments are currently limited. Fruzaqla offers these patients a new treatment option capable of extending their overall survival. Studies have shown that Fruzaqla significantly improves the overall survival and progression-free survival of mCRC patients who have previously received standard treatments, including fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy and, if their cancer is RAS wild type, anti-EGFR agents.

Despite a number of clinically relevant side effects, the benefits outweigh the risks. In view of these findings, Swissmedic has authorised the medicinal product Fruzaqla, containing the active substance fruquintinib, in Switzerland for the treatment of adults with metastatic colorectal cancer who have previously received 1 or more standard treatment(s).

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Fruzaqla®

Information for patients (package leaflet): Information for patients Fruzaqla®

Healthcare professionals can answer any further questions.

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Summary report on authorisation.

Swissmedic monitors medicinal products authorised in Switzerland. Swissmedic initiates the necessary action in the event of newly discovered adverse drug reactions or other safety-relevant signals. New findings that could impair the quality, efficacy, or safety of this medicinal product are recorded and published by Swissmedic. If necessary, the medicinal product information is adapted.

[6] Palmar-plantar erythrodysaesthesia syndrome: painful redness and swelling of the palms of the hands and soles of the feet