

Part VI: Summary of the risk management plan

Summary of risk management plan for Temozolomide PGF 5 mg, 20 mg, 100 mg, 140 mg, 180 mg, 250 mg hard capsules (temozolomide)

This is a summary of the risk management plan (RMP) for Temozolomide PGF 5 mg, 20 mg, 100 mg, 140 mg, 180 mg, 250 mg hard capsules. The RMP details important risks of Temozolomide PGF 5 mg, 20 mg, 100 mg, 140 mg, 180 mg, 250 mg hard capsules, how these risks can be minimised, and how more information will be obtained about Temozolomide PGF 5 mg, 20 mg, 100 mg, 140 mg, 180 mg, 250 mg hard capsules' risks and uncertainties (missing information).

Temozolomide PGF 5 mg, 20 mg, 100 mg, 140 mg, 180 mg, 250 mg hard capsules' summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Temozolomide PGF 5 mg, 20 mg, 100 mg, 140 mg, 180 mg, 250 mg hard capsules should be used.

I. The medicine and what it is used for

Temozolomide PGF 5 mg, 20 mg, 100 mg, 140 mg, 180 mg, 250 mg hard capsules are authorised for the treatment of adult patients with newly-diagnosed glioblastoma multiforme concomitantly with radiotherapy and subsequently as monotherapy treatment, and children from the age of three years, adolescents and adult patients with malignant glioma, such as glioblastoma multiforme or anaplastic astrocytoma, showing recurrence or progression after standard therapy. It contains temozolomide as the active substance and it is given by mouth (orally).

II. Risks associated with the medicine and activities to minimise or further characterise the risks

Important risks of Temozolomide PGF 5 mg, 20 mg, 100 mg, 140 mg, 180 mg, 250 mg hard capsules, together with measures to minimise such risks and the proposed studies for learning more about Temozolomide PGF 5 mg, 20 mg, 100 mg, 140 mg, 180 mg, 250 mg hard capsules' risks, are outlined below.

Measures to minimise the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and SmPC addressed to patients and healthcare professionals;
- Important advice on the medicine's packaging;
- The authorised pack size — the amount of medicine in a pack is chosen so to ensure that the medicine is used correctly;
- The medicine's legal status — the way a medicine is supplied to the patient (e.g. with or without prescription) can help to minimise its risks.

Together, these measures constitute *routine risk minimisation* measures.

II.A List of important risks and missing information

Important risks of **Temozolomide PGF 5 mg, 20 mg, 100 mg, 140 mg, 180 mg, 250 mg hard capsules** are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely taken. Important risks can be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with the use of **Temozolomide PGF 5 mg, 20 mg, 100 mg, 140 mg, 180 mg, 250 mg hard capsules**. Potential risks are concerns for which an association with the use of this medicine is possible based on available data, but this association has not been established yet and needs further evaluation. Missing information refers to information on the safety of the medicinal product that is currently missing and needs to be collected (e.g. on the long-term use of the medicine);

List of important risks and missing information	
Important identified risks	None
Important potential risks	None
Missing information	None

II.B Summary of important risks

The safety information in the proposed Product Information is aligned to the reference medicinal product.

II.C Post-authorisation development plan**II.C.1 Studies which are conditions of the marketing authorisation**

There are no studies which are conditions of the marketing authorisation or specific obligation of **Temozolomide PGF 5 mg, 20 mg, 100 mg, 140 mg, 180 mg, 250 mg hard capsules**.

II.C.2 Other studies in post-authorisation development plan

There are no studies required for **Temozolomide PGF 5 mg, 20 mg, 100 mg, 140 mg, 180 mg, 250 mg hard capsules**.