EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Temozolomide Accord

temozolomide

Table of contents

AUTHORISED
This medicine is authorised for use in the European Union.

Overview

This is a summary of the European Public Assessment Report (EPAR) for Temozolomide Accord. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Temozolomide Accord.

What is Temozolomide Accord?

Temozolomide Accord is a cancer medicine that contains the active substance temozolomide. It is available as capsules (5 mg; 20 mg; 100 mg; 140 mg; 180 mg; 250 mg).

Temozolomide Accord is a 'generic medicine'. This means that Temozolomide Accord is similar to a 'reference medicine' already authorised in the European Union (EU) called Temodal.

What is Temozolomide Accord used for?

Temozolomide Accord is used to treat malignant glioma (brain tumours) in the following groups of patients:

- adults with newly diagnosed glioblastoma multiforme (an aggressive type of brain tumour). Temozolomide Accord is used first with radiotherapy and then on its own;
- adults and children three years of age and over with malignant glioma such as glioblastoma multiforme or anaplastic astrocytoma, when the tumour has returned or got worse after standard treatment. Temozolomide Accord is used on its own in these patients.

The medicine can only be obtained with a prescription.

How is Temozolomide Accord used?

Treatment with Temozolomide Accord should be prescribed by a doctor with experience in the treatment of brain tumours.

The dose of Temozolomide Accord depends on body surface area (calculated using the patient's height and weight) and ranges from 75 to 200 mg per square metre, once a day. The dose and the number of doses depend on the type of tumour being treated, whether the patient has been treated before, whether Temozolomide Accord is being used alone or with other treatments, and how the patient responds to treatment. Temozolomide Accord should be taken without food. Patients may also need to take medicines to prevent vomiting before taking Temozolomide Accord.

For full details, see the summary of product characteristics (also part of the EPAR).

How does Temozolomide Accord work?

The active substance in Temozolomide Accord, temozolomide, belongs to a group of cancer medicines called alkylating agents. In the body, temozolomide is converted to another compound called MTIC. MTIC binds to the DNA of cells while they are reproducing, which stops cell division. As a result, the cancer cells cannot divide, slowing down the growth of tumours.

How has Temozolomide Accord been studied?

Because Temozolomide Accord is a generic medicine, studies in people have been limited to tests to determine that it is bioequivalent to the reference medicine, Temodal. Two medicines are bioequivalent when they

produce the same levels of the active substance in the body.

What are the benefit and risk of Temozolomide Accord?

Because Temozolomide Accord is a generic medicine and is bioequivalent to the reference medicine, its benefits and risks are taken as being the same as the reference medicine's.

Why has Temozolomide Accord been approved?

The CHMP concluded that, in accordance with EU requirements, Temozolomide Accord has been shown to have comparable quality and to be bioequivalent to Temodal. Therefore, the CHMP's view was that, as for Temodal, the benefit outweighs the identified risk. The Committee recommended that Temozolomide Accord be given marketing authorisation.

Other information about Temozolomide Accord

The European Commission granted a marketing authorisation valid throughout the EU for Temozolomide Accord on 15 March 2010. The name of the medicine was changed to Temozolomide Accord on 27 May 2015.

For more information about treatment with Temozolomide Accord, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

Temozolomide Accord: EPAR - Summary for the public (PDF/84.19 KB)

First published: 26/03/2010
Last updated: 01/07/2015

Available languages (22)

This EPAR was last updated on 27/06/2023

Authorisation details

Product details	
Name	Temozolomide Accord
Agency product number	EMEA/H/C/001125
Active substance	temozolomide
International non-proprietary name (INN) or common name	temozolomide
Therapeutic area (MeSH)	• Glioma • Glioblastoma
Anatomical therapeutic chemical (ATC) code	L01AX03
Generic Ⓖ	This is a generic medicine, which is developed to be the same as a medicine that has already been authorised, called the reference medicine. A generic medicine contains the same active substance(s) as the reference medicine, and is used at the same dose(s) to treat the same disease(s). For more information, see Generic and hybrid medicines.

Publication details	
Marketing-authorisation holder	Accord Healthcare S.L.U.
Revision	23
Date of issue of marketing authorisation valid throughout the European Union	15/03/2010
Contact address	Accord Healthcare S.L.U. Edificio Este Planta 6a World Trade Center

Publication details

Moll De Barcelona S/n
08039 Barcelona
SPAIN

Product information

26/06/2023 Temozolomide Accord - EMEA/H/C/001125 - IB/0063/G

Temozolomide Accord : EPAR - Product Information (PDF/644.61 KB) (updated)

First published: 26/03/2010
Last updated: 27/06/2023

Available languages (24)

This medicine's product information is available in all **official EU languages**.

Select 'available languages' to access the language you need.

Product information documents contain:

- summary of product characteristics (annex I);
- manufacturing authorisation holder responsible for batch release (annex IIA);
- conditions of the marketing authorisation (annex IIB);
- labelling (annex IIIA);
- package leaflet (annex IIIB).

You can find product information documents for centrally authorised human medicines on this website. For centrally authorised veterinary medicines authorised or updated from February 2022, see the Veterinary Medicines Information website .

Temozolomide Accord : EPAR - All Authorised presentations (PDF/17.32 KB)

First published: 26/03/2010
Last updated: 08/07/2015

Available languages (24)

Pharmacotherapeutic group

Antineoplastic agents

Therapeutic indication

For the treatment of adult patients with newly diagnosed glioblastoma multiforme concomitantly with radiotherapy (RT) and subsequently as monotherapy treatment.

For the treatment of 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.

Assessment history

Changes since initial authorisation of medicine

Temozolomide Accord : EPAR - Procedural steps taken and scientific information after authorisation (PDF/208.26 KB) (updated)

First published: 08/07/2011
Last updated: 27/06/2023

Initial marketing-authorisation documents

Temozolomide Hospira : EPAR - Public assessment report (PDF/310.93 KB)

First published: 26/03/2010

Last updated: 26/03/2010

CHMP summary of positive opinion for Temozolomide Hospira (PDF/32.14 KB)

Adopted

First published: 17/12/2009
Last updated: 17/12/2009
EMA/CHMP/810712/2009

More information on Temozolomide Hospira

Questions and answers on generic medicines (PDF/66.45 KB)

First published: 09/07/2007
Last updated: 07/12/2012
EMA/393905/2006 Rev. 2

Available languages (22)

European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

Tel: +31 (0)88 781 6000

How to find us

Postal address and deliveries

Business hours and holidays

European Union agencies network

An agency of the European Union