

## **HEXAL launches Dimethyl fumarate HEXAL® a generic drug for Tecfidera®, in Germany, offering an economically efficient treatment option for the care of adult patients with multiple sclerosis\* " >**

Jun 10, 2022

- Dimethyl fumarate HEXAL® is bioequivalent to the originator product<sup>1,2,3</sup>
- Additional 196 pack size reduces co-payment burden for patients

**Basel, June 10, 2022** – Sandoz expands its portfolio and today announces the **launch** of the generic drug **Dimethyl fumarate HEXAL®**, which is approved for the treatment of adults with **relapsing remitting multiple sclerosis** (RRMS)<sup>1</sup>, in Germany.

"We are proud to introduce **a generic drug for German patients for the treatment of multiple sclerosis\***. Sandoz is committed to developing and delivering generic therapies to help patients access high-quality and affordable medicines. In the future, Hexal will no longer only make this available in symptomatic therapy, but also for the first time with **dimethyl fumarate** for the course-modifying treatment of multiple sclerosis\* in adults," said Peter Stenico, Head of Sandoz Germany and CEO of Hexal AG.

In Germany, about 250,000 people have MS<sup>4</sup> **and dimethyl fumarate** is **one of the most important active ingredients for its treatment**. The costs for course-modifying therapies are high, and the affordability and access to new treatments for MS patients represent a major challenge.<sup>5</sup>

Dimethyl fumarate HEXAL® enteric-coated hard capsules are a **cost-effective alternative in the treatment of adult patients with multiple sclerosis\* compared to the reference medicine Tecfidera®**. Hexal's medicine is available in the additional pack size of 196 pieces (N3), which reduces the co-payment burden for patients. Dimethyl fumarate HEXAL® is bioequivalent to the originator preperate.<sup>1,2,3</sup> However, unlike Tecfidera®, Dimethyl fumarate HEXAL® is only approved for the treatment **of adult** patients with relapsing remitting multiple sclerosis.<sup>1,2</sup>

Sandoz aims to improve the lives of patients with MS, free up health resources and provide access to high-quality medicines. In addition to drug therapy, Hexal focuses on patients and offers **patients FeelinX service**. Social isolation, movement restrictions or psychological stress as a possible consequence of MS can strongly influence the everyday life of patients. It is therefore important to give patients back quality of life. FeelinX takes up these topics and is available by phone or digitally.

### **About Dimethyl Fumarate HEXAL®**

Dimethyl fumarate is an oral medicine used to treat adult patients with relapsed remitting multiple sclerosis. The starting dose is 120 mg twice a day. After 7 days, the dose should be increased to the recommended maintenance dose of 240 mg twice a day.

### **About Sandoz in Germany**

Sandoz, a division of Novartis, is a global leader in generics and biosimilars. Our goal is to improve patients' access to healthcare services by developing and marketing novel, cost-effective approaches that address previously unmet medical needs. It is our ambition to be the world's leading and most valued generics company. With our broad portfolio of high-quality medicines covering all major therapeutic areas, we generated

sales of USD 9.6 billion in 2021. The headquarters of Sandoz Germany is located in Holzkirchen, in the greater Munich area.

As part of the Sandoz Group in Germany, the HEXAL® brand stands for the supply of patients with modern medicines and complex, innovative pharmaceuticals in Germany. With HEXAL®, we are making an important contribution to ensuring that patients continue to receive the medicines they need in the future. The range ranges from well-known OTC brands such as ACCU akut, Lorano akut and Gingium to highly complex, biotechnologically produced drugs.

Information and further media information can be found under [www.sandoz.de](http://www.sandoz.de)

## References

\*Treatment of adult patients with relapsing remitting multiple sclerosis.

1. SmPC Dimethyl fumarate HEXAL®, Status: May 2022
2. Technical information Tecfidera®. As of May 2022.
3. Data taken from the bioequivalence study in the context of approval and published in par.
4. <https://www.dmsg.de/multiple-sklerose/ms-erforschen/grafiken-des-quartals/monats>
5. Müller, S., T. Heidler, A. Fuchs, et al. 2020. 'Real-World Treatment of Patients with Multiple Sclerosis per MS Subtype and Associated Healthcare Resource Use: An Analysis Based on 13,333 Patients in Germany', *Neurology and Therapy*, 9: 67-83

## Dimethylfumarate HEXAL® 120/- 240 mg enteric-coated hard capsules

**Active ingredient:** dimethyl fumarate.

**Composition:** Each enteric-coated hard capsule contains 120/- 240 mg dimethyl fumarate. Excipients: croscarmellose sodium, highly dispersed silicon dioxide, sodium stearyl fumarate (Ph.Eur.), methacrylic acid methyl methacrylate copolymer (1:1) (Ph.Eur.) (relative mass: approximately 135000), methacrylic acid ethyl acrylate copolymer (1:1) dispersion 30 % ( Ph.Eur.), talc, triethyl citrate, glyceroyl monostearate 40-55, polysorbate 80, gelatin, titanium dioxide (E171), iron(III) hydroxide oxide x H<sub>2</sub>O (E172), brilliant blue FCF (E133), Schellack 45 % (20 % esterified), iron (II, III) oxide (E172), Propylene glycol (E1520), ammonia solution 28%.

**Applicationgeb.:** Adult with relapsing remitting multiple sclerosis.

**Counter-indication:** Überempfindlichkeit gegen die Inhaltsstoffe, Vermutung einer bestätigten progressiven multifokalen Leukoencephalopathie (PML).

**Side effect.** Gastroenteritis, progressive multifokale Leukoencephalopathie (PML), Herpes zoster, Lymphopenie, Leukopenie, Thrombocytopenie, Hypersensitivität, Anaphylaxie, Dyspnoe, Hypoxie, Hypotension, Angioödem, Brennen, Hitzegefühl, Hitzeblitz, Rhinorrhoe, Diarrhoe, Übelkeit, Schmerzen im oberen Abdomen, Bauchschmerzen, Erbrechen, Dyspepsie, Gastritis, Gastrointestinaler Infekt, erhöhte AST, erhöhte ALT, medikamentenbedingte Lebererkrankung, Pruritus, Ausschlag, Alopezie, Proteinurie, Wärmegewinn, Ketonkörper. In Urin nachweisbar, Albumin nachweisbar in Urin, Leukozytose.

Farbe: Einzelh. u. Hinw. siehe Fach- u. Usage info. Prescription.

**Mat.-No.:** 3/51014581 **Status:** May 2022

Hexal AG, 83607 Holzkirchen, [www.hexal.de](http://www.hexal.de)

**Contact person for further information:**

Joanna Justyna Konczalska  
Head Communications & Ext. Engagement Germany  
Industriestraße 25  
D-83607 Holzkirchen  
[info.presse@sandoz.com](mailto:info.presse@sandoz.com)

---

**Source URL:** <https://www.sandoz.com/news/media-releases/hexal-launches-dimethyl-fumarate-hexal-generic-drug-tecfigidera-germany-offering-economically-efficient-treatment-option-care-adult-patients-multiple-sclerosis>

**List of links present in page**

- <https://www.sandoz.com/news/media-releases/hexal-launches-dimethyl-fumarate-hexal-generic-drug-tecfigidera-germany-offering-economically-efficient-treatment-option-care-adult-patients-multiple-sclerosis>
- <https://www.sandoz.de/>
- <http://www.dmsg.de/multiple-sklerose/ms-erforschen/grafiken-des-quartals/monats>
- <http://www.hexal.de/>
- <mailto:info.presse@sandoz.com>