CDSCO

Pregabalin to join Schedule H1 of the Drugs Rules, 1945

G.S.R. 377(E), the Drugs (Second Amendment) Rules, 2026, adds "51. Pregabalin" to Schedule H1 of the Drugs Rules, 1945, in force 180 days after Gazette publication.

THE MINISTRY OF HEALTH and Family Welfare (Department of Health and Family Welfare) issued notification G.S.R. 377(E), dated May 13, 2026, making the Drugs (Second Amendment) Rules, 2026. It was published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), No. 342, dated May 20, 2026. The Central Government made the rules under sections 12 and 33 of the Drugs and Cosmetics Act, 1940, after consultation with the Drugs Technical Advisory Board. CDSCO hosts the same file under the name "Notification for amendment in Schedule H1 for inclusion of Pregabalin and its drug formulations". The notification is signed by Harsh Mangla, Joint Secretary, under F. No. X.11014/14/2025-DR.

KEY FACTS

AUTHORITY
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Ministry of Health and Family Welfare (Department of Health and Family Welfare)

DOCUMENT
Notification G.S.R. 377(E), the Drugs (Second Amendment) Rules, 2026



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The rules make one change to the Drugs Rules, 1945. In Schedule H1, after serial number 50 and the entries relating to it, they insert a new serial number and entry: "51. Pregabalin". The entry names the drug only. It does not mention formulations, strengths, dosage forms or pack sizes, and the notification does not restate what Schedule H1 requires for a drug listed in it. It makes no provision for stock made, labeled or sold before the rules take effect.

The English text says the rules "shall come into force after one eighty days from the date of publication of these rules in the Official Gazette"; the Hindi text says one hundred and eighty days. The Gazette issue is dated May 20, 2026, though its Gazette ID and digital signature carry May 21. The rules give no calendar date. Counted from May 20, 2026, 180 days run to November 16, 2026.

The rules finalize draft rules published as G.S.R. 54(E), dated January 21, 2026, in the Gazette of January 27, 2026. The draft invited objections and suggestions within thirty days from the date copies of the Gazette were made available to the public, which was January 27, 2026. The notification records that the Central Government considered the objections and suggestions received from the public. It does not say what they were or how the final rules differ from the draft. Its note records that the Drugs Rules, 1945 were last amended before this by G.S.R. 135(E), dated February 16, 2026.

A later amendment builds on the new entry. The Drugs (Tenth Amendment) Rules, 2026, G.S.R. 607(E) of July 8, 2026, insert entry 52 in Schedule H1 "after the entry '51. Pregabalin'", for oral formulations containing more than 12% alcohol v/v in packs over 30 milliliters.

Issued by	Ministry of Health and Family Welfare (Department of Health and Family Welfare)
Document	Notification G.S.R. 377(E), the Drugs (Second Amendment) Rules, 2026
Dated	May 13, 2026

Published	Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), No. 342, May 20, 2026
Gazette ID	CG-DL-E-21052026-272775
Amends	Drugs Rules, 1945: Schedule H1, new serial number 51 after serial number 50
New entry	"51. Pregabalin"
Applies to	Pregabalin; the entry names the drug only
Takes effect	"after one eighty days from the date of publication of these rules in the Official Gazette" (Hindi text: one hundred and eighty days); the Gazette issue is dated May 20, 2026
Draft	G.S.R. 54(E), January 21, 2026, published in the Gazette of January 27, 2026; objections and suggestions from the public considered
Legal basis	Sections 12 and 33, Drugs and Cosmetics Act, 1940; after consultation with the Drugs Technical Advisory Board
Related	G.S.R. 607(E), July 8, 2026, the Drugs (Tenth Amendment) Rules, 2026: entry 52 inserted after "51. Pregabalin"
Signed by	Harsh Mangla, Joint Secretary
File number	F. No. X.11014/14/2025-DR

The notification (PDF, 540 KB)

Source: Gazette of India, CG-DL-E-21052026-272775.

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IndusDesk

hello@indusdesk.com · +91 11 4141 3939

9th Floor, Hemkunt House, Rajendra Place, New Delhi, Delhi 110008, India

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