



National Agency for Food & Drug Administration & Control (NAFDAC)

NAFDAC Public Assessment Report (NAPAR)

Mydexron 0.5 mg tablets

Dexamethasone 0.5 mg

A4-102340

Myron Pharma Limited

This report reflects the scientific assessment for the approval of mydexron 0.5 mg tablets. The product was licenced in July 2026.

PART 1: ABSTRACT

Mydexron tablets containing dexamethasone, manufactured at Jash Pharma Private Limited, Surat, Gujarat, India, was granted marketing authorization by NAFDAC for the treatment of inflammatory and immune system disorders on 28 July 2026.

Mydexron is indicated for the treatment of various inflammatory and immune system disorders.

For details on the uses of this product and for side effects and warnings, see the summary of product characteristics (SmPC), which can be found in the NAFDAC Greenbook.

The marketing authorization of mydexron by NAFDAC is based on the review of the Common Technical Document (CTD) dossier submitted to ascertain the quality, safety, and efficacy.

All accepted presentations of mydexron have been shown in part 2 of this report. The summary of product characteristics (SmPC) and the approved labelling have been presented in part 3 and part 4 respectively.

Scientific discussion on the quality, non-clinical and clinical aspects of mydexron have been presented in part 5 of this report.

The detailed steps taken to approve mydexron by NAFDAC have been presented in part 6 of this report.

No action or steps have been taken following the marketing authorization of mydexron tablets.

PART 2: ACCEPTED PRESENTATIONS

Product name	Active ingredients	Pharmaceutical form/description	Packaging	Pack size
Mydexron 0.5 mg tablets	Dexamethasone 0.5 mg	Uncoated tablet White, oval-shaped, uncoated tablets. The tablets have 'DEXA' embossed on one side, and a score line on the other side	Clear colourless plastic (PVC) on aluminium foil blister cards, each containing 10 tablets. Available in cartons of 10 x 10 tablets	10 x 10 tablets

PART 3: SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

Refer to the NAFDAC Greenbook URL below for the SmPC

See: <https://greenbook.nafdac.gov.ng/>

PART 4: LABELLING

Primary label



Secondary label



PART 5: SCIENTIFIC DISCUSSION

5.1. About the Product

5.1.1 Name of the product

Mydexron 0.5 mg tablets

5.1.2 Therapeutic indication

Mydexron is indicated for the treatment of various inflammatory and immune system disorders.

5.1.3 Applicant

Myron Pharma Limited, Salma Plaza Suite 36, Along Lokoja-Kaduna Expressway, Gwagwalada, Abuja, Federal Capital Territory.

5.1.4 Pharmaceutical form

Uncoated tablet

White, oval-shaped, uncoated tablets. The tablets have 'DEXA' embossed on one side, and a score line on the other side.

5.1.5 Storage

Store below 30°C.

5.1.6 Shelf life

36 months

5.1.7 Product presentation

Clear colourless plastic (PVC) on aluminium foil blister cards, each containing 10 tablets. Available in cartons of 10 x 10 tablets

5.2 Drug Substance

5.2.1 Manufacturer

The active ingredient, dexamethasone, is manufactured by Prachem Laboratories, Plot Number 3109, Phase 3, Gujarat Industrial Development Corporation, Chhatral, Taluka Kalol, District Gandhinagar, Gujarat 382729, India.

The API specifications are pharmacopoeial based.

Stability testing was conducted according to the requirements of NAFDAC. The proposed re-test period is justified based on the stability results when the API is stored in line with the storage statement.

5.3 Other ingredients

Other ingredients used in the formulation of mydexron include di-calcium phosphate, maize starch, polyvinyl pyrrolidone, maize starch, sodium methyl paraben, sodium propyl paraben, purified water, talcum, magnesium stearate, and sodium starch glycolate, all being pharmacopoeial controlled.

None of the excipients are derived from human or animal origin.

5.4 Drug Product

5.4.1 Drug product manufacturer

Jash Pharma Private Limited Plot No. 143-144, Surat Special Economic Zone, Sachin-394230, Surat, Gujarat, India.

5.4.2 Pharmaceutical development

The objective of the pharmaceutical development is to manufacture a generic which is stable, delivers the intended performance, and is safe, in terms of efficacy to the reference product Decadron 0.5 mg tablets currently licensed by Merck & Company, Incorporated.

The manufacturing method used was granulation, sizing, and compression. Comparative dissolution profile was conducted in line with ICH M9 guidelines between the reference product, Decadron 0.5 mg tablets (Merck & Company, Incorporated) and Mydexron. The profiles in the three BCS media are similar.

5.4.3 Specification

The finished product specification is based on the BP monograph and in-house standards. The finished product specifications include description, identification, uniformity of weight, hardness, dissolution, uniformity of content, and assay. The test procedures have been adequately validated.

5.4.4 Stability

Stability studies have been conducted at 30°C/75%RH long-term storage conditions and for six months at accelerated conditions in the packaging intended for marketing the product. The product proved to be quite stable in these conditions, with no apparent negative trend. Based on the data submitted, the proposed shelf life of 36 months and 'Store below 30°C' have been accepted.

5.5 Conclusion

Based on the assessment of data submitted, the benefit–risk profile of mydextron was acceptable for the following indication: 'for the treatment of various inflammatory and immune system disorders' and is included in the list of approved medicinal products by NAFDAC.

PART 6: STEPS TAKEN FOR REGISTRATION

The applicant, Myron Pharma Limited, Salma Plaza Suite 36, Along Lokoja-Kaduna Expressway, Gwagwalada, Abuja, Federal Capital Territory, submitted an application to the National Agency for Food and Drug Administration and Control (NAFDAC), for the registration of mydextron tablets.

The following are the steps for registration

October 2024	Date of receipt of application
August 2024	Date of conclusion of assessment
July 2026	Date of inspection
28 July 2026	Date of issuance of Marketing Authorization

PART 7: STEPS TAKEN FOLLOWING REGISTRATION

No action or steps have been taken following marketing authorization of mydextron tablets.