

PHARMOBEDIENT

March 18, 2025

**Dockets Management Staff
Food and Drug Administration
Department of Health and Human Services
Room 1061, 1-23
5630 Fishers Lane
Rockville, MD 20852**

Petition for Reconsideration

[2024-P-4134]

Dear Sir/Madam,

The undersigned submits this petition for reconsideration of the decision of the Commissioner of the U.S. Food and Drug Administration (FDA) in Docket No. 2024-P-4134.

A. Decision Involved

Pharmobedient has submitted suitability petition to seek FDA's authorization to submit an ANDA for a drug product with a strength different from the Reference Listed Drug (RLD), Cataflam (Diclofenac Potassium) Tablets, 25 mg and 50 mg. The proposed strength is 37.5 mg.

The Agency denied the petition, citing safety and effectiveness concerns. The RLD recommends a dosage which ranges from 100 to 200 mg/day in divided doses, i.e., 50 mg two, three, or four times a day. The Agency claims that there is no indication in the RLD labeling for the proposed dose strength to be used and would change the frequency of dosing to achieve the recommended dosing ranges.

B. Action Requested:

Pharmobedient requests the reconsideration of the FDA's decision and approval of the petition.

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C. Statement of Grounds:

Dosing recommendations for Diclofenac Potassium Tablets differ depending on the specific indication. The general dosing recommendations are as follows:

Use the lowest effective dose for the shortest duration consistent with individual patient treatment goals (see WARNINGS; Gastrointestinal Bleeding, Ulceration, and Perforation).

After observing the response to initial therapy with diclofenac potassium tablets, the dose and frequency should be adjusted to suit an individual patient's needs.

Indication	Dosing Recommendation
Treatment of pain or primary dysmenorrhea	50 mg three times a day. With experience, physicians may find that in some patients an initial dose of 100 mg of diclofenac potassium tablets, followed by 50 mg doses, will provide better relief.
Relief of osteoarthritis	100 to 150 mg/day in divided doses, 50 mg twice a day or three times a day.
Relief of rheumatoid arthritis	150 to 200 mg/day in divided doses, 50 mg three times a day or four times a day.

Please note that dosing recommendations in the RLD labeling allow for the dosing flexibility and advise using the lowest effective dose for the shortest duration.

For osteoarthritis relief, it suggests a dose of 100 to 150 mg per day in divided doses. Administering 37.5 mg three times a day can help achieve the recommended dosing range without altering the dosing frequency.

For the relief of rheumatoid arthritis, the recommendation is to use 150 to 200 mg per day in divided doses. Administering 37.5 mg four times a day can achieve the recommended dosing range without altering the dosing frequency.

The availability of 37.5 mg provides a prescribing physician with the ability to use the lowest effective dosage to achieve the treatment goals without changing the dosing frequency.

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Pharmobedient respectfully requests the Commissioner to reconsider the decision and approve the petition after proposed drug product's labeling change.

Sincerely,



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