



Diclofenac Colestyramine Granules / Powder (DICLOFENAC RESINATE)

P.J.Healthcare

Information Sheet:

 Diclofenac Colestyramine Resinate Granules / Powder is a new formulation of Diclofenac with faster speed of onset action, better efficacy than traditional Diclofenac preparations and <u>a dual quick slow action</u>.

Page | 2

• 145.6 mg Diclofenac Colestyramine (= Diclofenac resinate) corresponding to 75 mg Diclofenac Sodium.

Advantages

- Local GMP Good Manufacturing Practice Certifications
- Conformity to innovators Product Profile
- In-house Product Specifications & test method & document support
- Efficient delivery time
- Availability: In Granules / Powder
- Packing in HDPE container

Products Categories & Application:

- Diclofenac Possesses Analgesic, Anti- inflammatory and Antipyretic properties.
- Better tolerability for the resinate in comparison to traditional Diclofenac preparations, especially GI disturbances.
- The faster onset of action, the sustained-release effect, lower gastric side effects add on to the superior potency of Diclofenac to provide effective pain relief in arthritis and postoperative pain/outcomes.
- Nonsteroidal anti- inflammatory drugs (NSAIDs) are the most widely used of all analgesic agents.
- Better compliance with twice-daily dosing in chronic conditions like arthritis.
- Diclofenac-colestyramine was also found not to affect renal function when used for short-term therapy
- Diclofenac-colestyramine is an improved formulation of Diclofenac which utilizes the ion-exchange resin drug delivery technology.
- Diclofenac, like other NSAIDs, can injure the gastric mucosa by preventing the protective effect of prostaglandins. Colestyramine is an IER that forms a complex with Diclofenac, and thus helps to reduce mucosal damage by direct contact in the gastric lumen.

Office: Surya Niwas, Plot No. 51, Road No. 4, Pushpa Park, Near St. Joseph School, Malad - East, Mumbai - 400 097. INDIA. Phone: +91-22- 28893685; Tele Fax: +91-22-28893684; E-mail: info@pit2limited.com/ / info@pitalthcare.co.in



Diclofenac Colestyramine Granules / Powder (DICLOFENAC RESINATE)

PRODUCT SPECIFICATION

Page | 3

Product: Diclofenac Colestyramine Granules / Powder

SR.NO.	TEST	SPECIFICATION
1	Appearance	Off white to yellowish, granular free
		flowing powder
2	pH	Between 6.0 to 9.0
3	Water by KF	NMT 10%
4	Dissolution of Diclofenac calculated as Diclofenac sodium - After 1 hours - After 2 hours - After 4 hours - After 8 hours	Between 55 - 75% of effective content Between 60 - 80% of effective content Between 70 – 90% of effective content Not less than 75% of effective content
5	Assay of Diclofenac calculated as Diclofenac sodium (on anhydrous Basis)	Between 46.5% and 56.8%

Office: Surya Niwas, Plot No. 51, Road No. 4, Pushpa Park, Near St. Joseph School, Malad - East, Mumbai - 400 097. INDIA. Phone: +91-22- 28893685; Tele Fax: +91-22-28893684; E-mail: info@pihealthcare.co.in